Development of Hazard Analysis Critical Control Point (HACCP) Plan for the process of Homogenized Pasteurized Milk at Cargills Quality Dairies.

By

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02/AS/032

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DECLARATION

The work described in this thesis was carried out by me at the Department of Food Science & Technology, Faculty of Applied Sciences, Sabaragamuwa University of Sri Lanka, under the supervision of Mrs. R.S. Sabaragamuwa, Lecturer, Department of Food Science & Technology, Faculty of Applied Sciences, Sabaragamuwa University of Sri Lanka & Mrs. K. A. C. J. Gunathilake, Quality Assurance executive, Cargills Quality Dairies, Baduragoda, Meerigama. A report on this has not been submitted to any other university for another degree.

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Affectionately
Dedicated

To

My Parents, Teachers

&

My Alma mater

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ABSTRACT

HACCP is a systematic approach to the identification and assessment of the hazards and risks associated with a food operation in defining the means of their control. It reduces the hazards such as biological, chemical and physical to an acceptable level to ensure a safe product to the consumer.

Cargills Quality Dairies (pvt) Ltd being a confineable food establishment under the umbrella of Cargills Ceylon Limited, which is one of the largest food sector retailer in Sri Lanka. The study was aimed at development of an HACCP manual for Fresh milk and Low fat fresh milk that can be established with necessary modifications. HACCP manual was developed to establish an effective hazard controlling system through identifying critical control points with broader identification of manufacturing of liquid milk process.

As the first step all the potential hazards associated with each processing step, beginning from raw material reception to transportation of the product were identified. Then Critical Control Points (CCPs) were identified. CCP monitoring, Corrective action and verification procedures were established. A Good Manufacturing Practices (GMP) manual was developed and documented as a pre requisite program as well as a one of important factor on successful development of HACCP manual.

Milk reception chill bath, pasteurizer-holding tube, milk storage tank (MST) after the pasteurizer, filter at temporary storage tank, finish product storage chill room and transportation are identified as the points that are needed to be critically monitored.

Milk reception chill bath temperature need to maintain below 4^0C to avoid the rapid proliferation of bacterial count. HTST (72^0C for 20 second) is the minimum temperature is to monitor with the pasteurizer. Filter enclosed to temporary tank needs to monitor to prevent of occurrence of physical mater in the final product. Mesh size 100 is taken as suitable for the filter and naked inspections need to be done at the beginning of the filling process. Operational limits of the pasteurizer was 82^0C-90^0C, is far above the required heat treatment for HTST. It inactivates the natural bacterial inhibiters in milk. Hence shelf life of the product may shorten than normal pasteurized milk. It felt temperature controlling is critical in following steps after the pasteurization. The temperature 4^0C is taken as the control limit for those after pasteurization process such as MST, Finish product storage chill room and transportation to ensure a safe product to customer. Below 0^0C is taken as minimum temperature to prevent destruction of organoleptic qualities given that those changes may occur at -0.53^0C, the freezing point of milk.

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LIST OF ABBREVIATIONS

CCPs	Critical Control Points
CIP	Cleaning in Place
CLs	Critical Limits
Codex	Codex Alimentarius Commission, an FAO/WHO Organization
CQD	Cargills Quality Dairies
FAO	Food and Agriculture Organization
FDA	Food and Drug Administration
GAPs	Good Agricultural Practices
GDPs	Good Distribution Practices
GLPs	Good Laboratory Practices
GMPs	Good Manufacturing Practices
HACCP	Hazard Analysis Critical Control Points
HTST	High Temperature Short Time
IAMFES	International Association of Milk, Food and Environmental Sanitarians
ICMSF	International Commission for Microbiological Specifications for Foods
IDF	International Dairy Federation
ISO	International Organization for Standardization
MST	Milk Storage Tank
NACMCF	National Advisory Committee for Microbiological Criteria for Foods
NASA	National Aeronautics and Space Administration (USA)
TPC	Total Plate Count
SLS	Sri Lankan Standards
SQA	Supplier Quality Assurance
US	United States
USDA	United State Department of Agriculture
WHO	World Health Organization
EDB	Export Development Board

CHAPTER 01

Introduction

1.1 Introduction

As a result of globalization, food organizations in competitive market context need the product quality as one of the important factor to be considered at strategic decision-making process. Further development of Socio-economical, Educational and changes in consumer habits force the food companies to produce safe products that give minimum harmful effect to its consumers. Now global food companies are at a position where consumers seeks high quality safe product for reasonable price. To fulfill that requirement companies not only reduce the price, but also to ensure the quality of product available in the market. Globalization effect is more powerful than any time of the history. Companies are now go beyond territories for searching customers. Since the industry develops the quality standards become an essential tool to reach the consumers as they more aware of those standards and may tend to choose them more. Online Purchasing and use of information technology leads, companies and consumer are closer then ever before. To survive in a highly competitive market companies need to demonstrate that the products are safe to consume (than competitor).Further stake holders such as government departments(EDB, Ministry of Consumer affairs. etc(in Sri Lanka) research agencies, pressure groups would influence companies to have some quality assurance program.

Hazard analysis critical control point (HACCP) tool has become a buzzword among the food-based companies in recent decade. It has been recognized as an effective food safety management tool that can specially applied to food-based companies. HACCP system is comparable in-line with some other quality management standards such as ISO9000: 2001,Total Quality Management (TQM), ISO14000 etc. Further HACCP can be identifying as the core fundamental background of ISO22000, which is the latest ISO food safety management system (Peason, 1996).

Hazard analysis critical control point is a systematic approach and a scientific method for identification of all potential hazards and risks associated with a food operation and implementation of activities to control them to an acceptable level. HACCP was developed originally as a microbiological safety system in the early days of the US space

program. as it was vital to ensure the safety of food for the astronauts. In 1960, Pillsbury Company was engaged with the US spaced programme in food production. The project required to produce foods for space use with as close to 100% assurance that food not contain any pathogens (virus, bacteria, etc), chemical compounds and physical compounds that could cause an illness or injury. Since that HACCP has been a proven system, which if properly applied, will give confidence that food safety is been managing effectively.

Milk is a nutritionally complete food and the value of milk to the diet is unarguable. That characteristic of milk or its products fall themselves as a high sensitive material for microbial contamination and growth of bacteria, viruses and parasites etc. Further milk can be contaminated by physical and chemical factors resulting unsafe products to consume. Because of that, providing of safe milk based product is a somewhat challenging effort. To face this challenge it is needed to take special activities from farm to end users hand.

Hygiene requirements in milk products need to ensure that the product will not be a hazard to the consumer and will not spoil within the set of shelf life under the intended distribution and retail conditions. To achieve this objective whole production, distribution and even after the product has been sold, until consumption the relevant parameters need to be governed. In Europe council directive 92/46/EEC lays down the health rules for the production and prolong on market of milk and milk based products advocating hygiene standards, a HACCP based approach to monitoring and setting microbiological criteria for regulatory use. Internationally the Codex Alimentarius Commission is the regulatory body of governing these standard (Mortimore and Wallace).

Cargills Quality Dairies, a subsidiary of Cargills Ceylon company which is a giant player in food based products in Sri Lanka dealing with a super market chain, Fruit and vegetable based production house, Meat based product production house, leading franchising of international fast food outlets and liquor. Cargills Quality Dairies factory formerly managed by Unilever Ceylon Company which manufactured internationally recognized ice cream brand – Walls. Later the factory was overtaken by the Cargills Ceylon Limited. The plant has been equipped with modern advanced technology with

state of art working environment. The company take all its effect to provide a safe products to its customers.

Consumption of Liquid milk is recently increasing among Sri Lankan consumers in around last 2 to 3 years of time. Consumer understanding has increased on advantages of consumption of liquid milk over milk powder consumption. Several companies are playing in the liquid milk market at the moment and seem to have good potential in the future. Once company successfully implement the system an authorized certification body will recommends the company to CODEX International to issue the Certification (Early, 1998). It needs to renew in each one year period. Such certification gives competitive advantage in many fields, with a clear edge in the marketing the product over the competition

Cargills Quality Dairies has introduced two liquid milk forms, one is fresh homogenized pasteurized milk can and other is low fat homogenized pasteurized milk can.

This project work attempted to identification of all possible hazards that are associated with the two forms of milk can manufacturing processes. This would be a useful document for the company to implement the HACCP to the process with relevant modification with the process changes at the time of implementation.

1.2 Overall Objective

Identification of hazards in association with the Pasteurized homogenized fresh milk can and Pasteurized homogenized low fat milk can product lines and development of HACCP plan for the production processes.

1.3 Specific Objective

1. Development of Good Manufacturing Practices (GMP) manual for the company.
2. Identification of all potential Hazards Associated with the Homogenized pasteurized milk bottle process at Cargills Quality Daires.
3. Determination of critical control points (CCP) for identified Hazards within the processes.
4. Development of HACCP plan for the Homogenized pasteurized milk (full cream & low fat) product processes for the Company.

CHAPTER 2

Literature Review

2.1 General Overview

2.1.1. Development of HACCP concept

Hazard Analysis Critical Control Point (HACCP) is a systematic approach to the identification, evaluation, and control of food safety hazard.

HACCP concept was originated in 1960 as result of US space program's need to manufacture hazard free food for astronauts.(Peason and Dutson, 1996) The system was developed by Pillsbury Company who worked with NASA and US Army laboratories. Once it has been accepted among the food industry, it has been advocated by the Codex Alimentrarius Committee on Food Hygiene (1993,1997) and the National Advisory Committee on Microbiological Criteria for Foods (NACMCF.1992,1997) in the United State of America (Mortimore and Wallace., 1998).

HACCP has been proven that, if properly applied it will give confidence that food safety is being managed. Further it will give confidence to customer that product is safe for consumption.

Since that food companies understood the practicable implementation of the system it began to implement in other food companies in United State of America and countries among European Union.

Meeting food safety objectives.

- Producing a safe product every time.
- Providing evidence of safety production and handing of food products; this is particularly useful during regulatory inspection or prosecution.
- Having confidence in the product and ensuring that customers have confidence in your ability.
- Satisfying the customer request for HACCP to an international standard.
- Compliance with regulatory requirements.

(Mortimore and Wallace, 1998)

2.1.1.1. The Stages of HACCP concept

There are four stages to be considered when any company is ready to implement HACCP concept to the factory. There is a logical procedure that can be applied to any of the HACCP development.

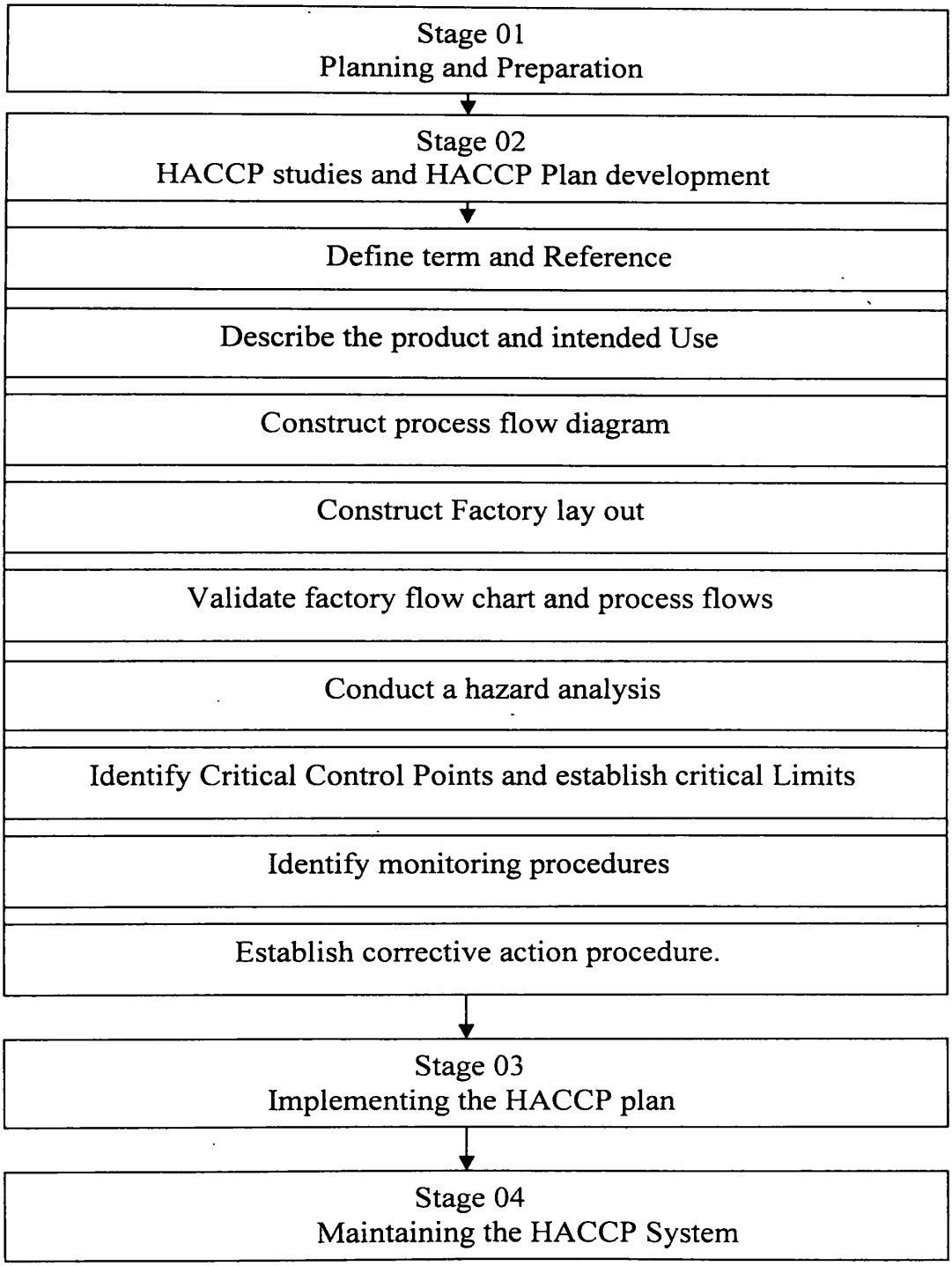


Fig.2.1 HACCP Plan Development Procedure

2.1.2.General benefits of implementing HACCP

- HACCP is a systematic approach relevant to all stages of food processing covers agricultural and horticultural practices harvesting, processing, product distribution and customer practices.
- HACCP has the potential to identify all to all hazards in a food process. That can be established to assure food safety or food Quality.
- HACCP is a total risk management tool in total quality management
- HACCP facilitates the more from retrospective and product testing to a preventative quality assurance approach enabling the manufacture to get it right the first time and reduce reject waste.
- HACCP focus technical resources on critical parts of the process and provides a cost-effective control of food-borne hazards.
- HACCP is recognized and promoted by international bodies (such as Codex Alimentarius Commission) as the system of choice for ensuring food safety and is becoming enshrined in national legislation. Proactive application in the food industry will facilitate compliance with developing legislation and demonstrates a diligent approach to food safety (Donald and Corlett, 1998).

2.1.3. Role of senior management in HACCP

Senior management commitment is a key factor of successful implementation of HACCP in any organization. Senior management need to identify the importance of the having such in its food based establishment. The first step is to plan the project and determine the time frame. The senior management can gain information from using various sources such as Books, journals, Internet, etc. But more effective way to gain fundamentals in a correct. it is advisable to attend a HACCP briefing session, which is done by various consultants or such firms. This understanding enables senior management to actively involving in the process and allocates appropriate strategy with considering respective organizational culture.

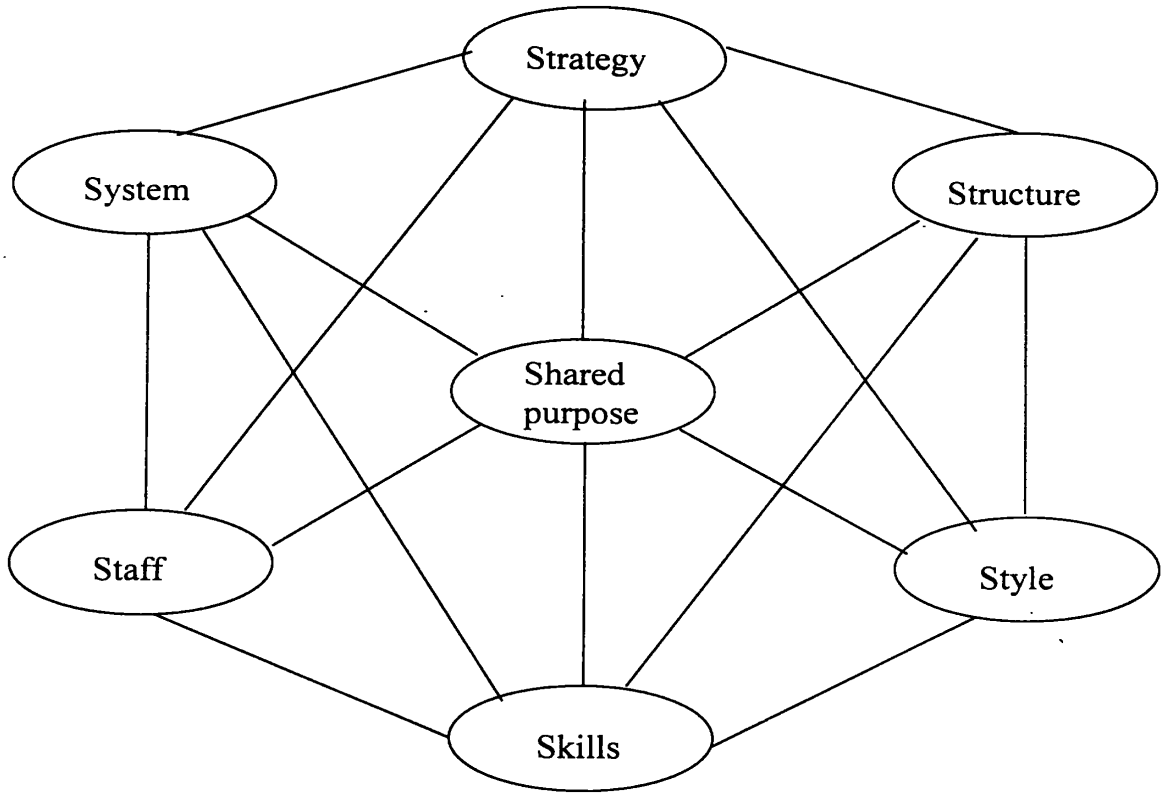


Fig. 2.2 Machasey's 7S Model

As given above, senior management can use Machasey's 7S model to implement of the strategy. In the model structure means defining roles. responsibilities and relationships of the team. Style refers to culture and formality that is required. Special skills and competencies that are required to implement the strategy effectively. Staff is about human factor that is needed to a successful implementation. Systems are other processes and infrastructure.

By adapting suitable implementation company can successful obtain the certification that would a value for money investment to the company.

2.1.4. Limitations and drawbacks of implementing HACCP

Improper application of HACCP would not result a hazard free product. Improper development of manual may be result due to improper trained of the team. Some time one person develops the plan to implement. So he may miss many of the points.

Some may say this is only to use with microbiological hazards and not addressing the other two and avoid to implement completely.

In some organization only need to obtain the certification of HACCP than to ensure the hazard free product. On such situations the maintain of the system may not properly done. It does not result the expected outcome of the plan.

In some condition implementation of HACCP is not effective due to lack of information and legal procedures in some countries.

Product quality is depend on raw martial quality and handing operations of raw material is very poor in some countries. So even thought the company has the HACCP certification would unable to produce hazard free product due to use of poor raw material.

2.2 The product description

Complete description of the product, raw material and ingredients that is used for the product is n need to be specified and clearly identified. Some of the product description that needs to identify may include as follows;

- Generic name/Product name
- The manner that the product is use
- The product packaging type and martial
- Product's intended shelf life information
- Storage conditions
- Product labeling, instruction
- Any special instruction that has been needed
- Any other mandatory required information

2.3 Pre-requisite programs

Pre-requisite programs are the basic foundation of the HACCP plan that is implementation at any food establishment. These program must be implement adequate and effectively in the process. By application of those able to control the number of CCPs occur in the process unnecessarily (Mortimore and Wallace, 1998).

2.3.1 GMP implementation

Good Manufacturing Practices are a key tool that a food establishment prevent from occurring of hazards. Before application of HACCP it is most important of implement GMP to the establishment.

2.3.1.1 Good Manufacturing Practices

GMP is one of the most important factors to be considered in any food-based establishment. If a company follows good manufacturing practices correctly, most of the CCPs can be controlled. So only few CCPs need to be monitored. A key issue for product safety is the risk of cross-contamination occurring during the process from the internal factory environment. Cross-contamination could arise from a wide range of sources and the inherent risks in a particular processing area must be understood. Most of these issues are managed through adherence to Good Manufacturing Practice (GMP). Some of the main factors that are consider in GMP manual can be identify as follows.

- **Factory Layout**

Factory building and layout need maintain to minimize the cross-contamination risks. This should include adequate segregation of raw materials and finished products. Full separation between raw and cooked product may be required and raw materials and finished products will need to be kept separate from the main processing area. Plant need to be availability of potable water, and adequate cleaning facilities. equipment and environment, with the connection of all other facilities. e.g. steam heating and cooling facilities. If there is any holding stage involved, adequate space for holding the required and cross-contamination should be minimized. Appropriate temperature-control facilities, humidity control facilities, lighting facilities need to be are available (Donald and Corlett, 1998).
The patterns of movement of staff and equipment should also be considered.
Staff needs to be facilitate with adequate hygiene facilities, such as changing and rest rooms and hand wash stations, along with canteen and recreational facilities.

- **People and personal hygiene**

Factory workers and other personnel who are enter in to food processing area could cause cross-contaminate the product with microbiological, chemical or physical hazards. The process layout and movement patterns should be considered in order to minimize this risk, along with the appropriate training programmes.
Employees need to be provided with all types of protective clothing that is required, along with frequencies of changing and laundering procedures. Facilities that you have given such rest rooms, hand wash stations, canteen, recreational facilities need to be

crosscheck whether are properly installed and working. All personnel in a food plant should be trained in Good Hygiene Practice. Company executives or specific person need to be monitor whether, employees are follow the good practice.

- **Buildings**

Design of building itself could pose a hazard or safety risk to the product, through harborage of pests and other contamination, or through physical contamination duo to poor design and maintenance. Surfaces should be non-porous and easy to keep clean, with all cracks filled and sealed, and overhead services should be kept to a minimum. All buildings should be well maintained to prevent physical hazards falling into the product, and drains should be designed and serviced so that the flow is always away from production areas, with no chance of back flow or seepage.

- **Equipment**

Equipment should be designed to minimize any cross-contamination risk. This could arise through parts of the equipment breaking off and gaining entry to the product as physical hazards. Alternatively, if equipment has any dead-leg areas, is difficult to clean or is poorly cleaned, microbiological build-up could contaminate the product. Chemical contamination could arise through

Lubricants or cleaning residues remaining on the equipment food-contact surfaces. Remember also to ensure that you can clean around and under equipment. If it is too close to the floor to clean underneath, the equipment should be sealed around the base.

- **Cleaning**

There must be sufficient facilities for the cleaning of equipment, people, plant and buildings, and these should be situated to enable their convenient use. Cleaning areas should not cause a cross-contamination risk to the process. Cleaning schedules should be prepared for all areas and staff must be adequately trained to carry out cleaning activities effectively.

- **Chemicals**

Storage facilities must be provided for any chemicals that are required for use in the manufacturing area. These must prevent the risk of product contamination. All

chemicals must be properly labeled and must not be decanted into food containers. All personnel handling chemicals must be trained in their safe use.

- **Raw materials**

Raw materials can act as cross-contaminants if they gain access to the wrong product, or if they are added in excess quantities. Handling areas for raw materials must be carefully planned, and areas used for more than one type of ingredient may require thorough cleaning between use (Walstra *et al*, 1999).

- **Storage**

Storage areas must be properly planned to minimize damage and cross-contamination issues. Consider whether you have adequate segregation, temperature and humidity control, and ensure that all storage areas are properly pest proofed. All materials should be stored off the floor and in sealed bags or containers. Part-used containers must be resealed after each use, and strict stock rotation should be employed.

- **Products**

Residues of other products can also cause a serious hazard if allergenic material is present or if they affect the intrinsic nature of the product that is contaminated. Production lines should be spatially separated to prevent cross-contamination, and handling and cleaning procedures should be planned appropriately.

- **Packaging**

Packaging areas and handling practices should be managed and controlled to prevent any cross-contamination risk. The packaging itself could be a major hazard, e.g. glass fragments, or could introduce microorganisms to the product. Make- sure that your packaging is suitable for the job and won't be damaged during product storage and distribution, and consider whether you have the correct coding and usage instructions printed legibly.

2.3.2 Supplier quality Assurance (SQA)

Raw material quality is another fundamental tool in HACCP. Company need to understand the possible hazards that is associated with the raw material that received. Different elements of an effective SQA may include some factors such as, agreed product specification; have an audit to suppler, etc. One thing that the company need

to understand is that company can not produced hazard free product alone it self, if any raw material contain a hazard. So good channel partnerships and mutual understanding of each others objective is beneficial both parties in this king of situation.

2.4 Principles of HACCP

The HACCP principle have international acceptance and details of the approach have been published by the Codex Alimentarius Commotion (1993,1997 and the National Advisory Commotion on microbiology criteria for foods (NACMCF. 1993,1997).

A HACCP study has seven principles.

- Principle 1: Hazard identification and hazard analysis
- Principle 2. CCP determination
- Principle 3. Establish critical limits
- Principle 4. Establish monitoring procedure
- Principle 5. Establish corrective action
- Principle 6. Establish Verification procedures
- Principle 7. Record keeping and documentation

Once the study has been completed the implementation can be done.

2.4.1 Principle 1: Hazard identification and hazard analysis

Hazard

A biological, chemical or physical property, or condition of, food with the potential to cause an adverse health effect.

Chemical hazard

Chemical contamination of foodstuff can happen at any stage of their production. The effect of chemical contamination on the consumer can be long team (chronic) or short team (acute). Some of chemical hazards that can be occurring in food establishments can be identify as follows.

- Cleaning Chemicals- Cleaning chemical can be identify as most significant chemical hazard in any food based company. Cleaning residuals may remain on utensils, pipelines and machinery that can be transferred to the food products.

Problem can be reduced by application of non-toxic cleaning chemicals or food grade chemicals. Design and management of appropriate cleaning procedure can be reduce the hazard to a minimum level.

- Allergens- some persons are sensitive to some foods and cause food allergic food intolerance. Major allergens that are common can be list as follows;
    - Eggs
    - Milk products
    - Tree nuts
    - Peanuts
- Veterinary residues-Hormones, antibiotics, growth regulators used in animal feed, treatment can be passed to food. Carry-over of antibiotic can cause major problems due to the potential for serious allergic responses in sensitive persons.

Biological hazard

Almost every food company will be at risk from one or more biological hazards. Those can be from either raw material or presence in the processing flow. Biological can be either be microbiological or macro biological.

Macro biological may be living flies or insects on the food. Microbiological aspect is the most important one that can cause lethal effect to humane. Microbs can be identifed as follows;

- Pathogenic Gram-positive bacteria – *Clostridium botulinum*, *Clostridium perfringens, Bacillus cereus, staphylococcus aureus, Listeria monocytogenes.*
- Pathogenic Gram-negative bacteria – *Salmonella, Shigella, Escherichia coil.Campylobacter jejuni, Vibrio parahaemolyticus, Vibrio vulnificus, Yersina enterocolitica.*
- Viruses - Viruses are presencet in animals, man, faeces, polluted waters and shellfish. They are transmitted from animal to people and from person to person.
- Parasites and protozoa Parasites such as *Toxoplasma intestinalis(lamblia), Cyclospora cayetanensis* gondii, Giardia and *Crytosporidium parvum* produce encysted larvae that infect man on ingestion. Raw milk and drinking water are the sources of *Giardia*, *Cyclospora* and *Crytosporidium* (Mortimore and Wallace, 1998).
- Mycotoxins. -Results of secondary metabolites by certain moulds.

- Patulin – Mycotoxin associated with fruit and fruit-juice products. Produced by several *Penicillium* spp. Considered as carcinogen, high concentration results haemorrhages and oedema (Fox, 1998).
- Vomitoxin.
- Fumonisin.

Physical hazard

Physical hazards also can enter in to a food product at any stage of the process. Normally physical hazards can be minimized by application of GMPs, GAPs and safe handling procedures.

Some of commonly found physical compounds in milk in Sri Lanka could be identified as follows;

Glass, Metals, Stones, Wood, Plastic, pests, intrinsic material.

2.4.1.1 Control measures

Control measures may be already implemented in the processed use to fulfill the legal or product quality parameters. Control measures can be applied to all the hazards that are associated as bacterial, chemical and physical.

Definition of control measures

Action and activities that can be used to prevent or eliminate a food safety hazard or reduce it to an acceptable level.

Some of identified control measure for bacterial hazard may be cooling, heating, time and temperature controlling, fermenting, controlling of product PH, drying etc.

- Most of chemical and physical controls are apply as sources controlling, production controlling and labeling controlling (Mortimore and Wallace, 1998).

2.4.2 Principle

2.4.3 2: CCP determination

CCP is a point, step or procedure where a food safety hazard can be prevented, eliminated or reduced to acceptable levels. (Mortimore and Wallace). Further it can be describe as a step where control can be applied and is essential to prevent eliminate or reduce a food safety hazard to acceptable levels. The systematic approach of

identification of CCPs would be use of CCP Decision Tree. Raw material decision Tree and process Decision Tree can be used accordingly. Several versions of the CCP Decision Tree have been published with different wording(NACMCF, 1992,1997;Codex,1993,1997).

Different facilities preparing the same food can differ in the risk of hazards and points, steps or procedures that are CCPs. This cause due to differences in each facility such as layout, equipment, selection of ingredients, or operation conditions.

2.4.4 Principle 3: Establish critical limits

Critical limit is defined as " the maximum or minimum value to which a physical, biological or chemical parameter must be controlled at a critical point to prevent, eliminate or reducing a hazard to an acceptable level of the identified hazard.(Mortimore and Wallace)

Critical limits must be based on authoritative technical information that is demonstrating the effectiveness of the critical limits to prevent, eliminate or reducing a hazard to an acceptable level. While establishing the critical limits the team need to analyses the relevant data from various sources such as published data including research papers, trade manuals, trade association information, professional expertise advices and company operation standards

2.4.5 Principle 4: Establish monitoring procedure

The term monitoring is refers to as planned sequence of observations or measurements to access the identified CCP is under the given process controls. It is essential to that the chosen monitoring procedure must be able to detect loss of control at the given CCP.

Monitoring can be done in three ways;

- On-line Monitoring- This is where the critical factors are monitored during the process. These may be monitor as continuous or discontinues manner.
- Off-line Monitoring- This is where samples are taken to some other place where critical factors can be monitored. One important thing is to consider ids the sample should be represent the relevant whole batch.
- Observation Monitoring- In this method specific action is observed by a responsible person at the production process.

- Monitoring procedure need to include;
  - What to monitor- process or product characteristic, which identified as critical limits or operation limits are monitoring.
  - How to monitor- Measuring equipments, the correct way of taking measurement need to be trained to the relevant persons.
  - Frequency of monitoring- Frequency of monitoring may depend on the closeness of operation limits are critical limits of the given CCP.
  - Who will be monitoring- Responsible persons of monitoring of CCP shall be clearly defined. The relevant employees works both on day shift and night shift need to be allocate according to the point. Those who are responsible, need to given a proper adequate trainings and need to have an idea and importance of their work.

2.4.6 Principle 5: Establish corrective action

Corrective actions are defined as "any action, which adjust the process to maintain control and prevent a deviation at the CCP. In other wards deviation from critical limits. (Pierson, 1992). When the process drift towards or exceeds the target levels it is adjusted, bringing it back within the normal operating band.

The general corrective action procedure shall covers the following;

- Investigation to determine the cause of deviation.
- Effective measures to prevent re-occurrence of the deviation.
- Verification of the effectiveness of the corrective action.

The special actions are need to take on a such a deviation. They may include, adjust the process to bring back to normal, hold the product, conduct several tests, trials to evaluate the process, destroy the product if there is a hazard or a quality drawback, rework the product, etc.

2.4.7 Principle 6: Establish Verification procedures

Verification is the application of method, procedures, tools and tests in addition to those used in monitoring to determine compliance with the HACCP plan, and/or where the HACCP plan needs modifications.

There are some elements of verification can be seen. Those are, validation of the monitoring devices, calibrations and calibration records, sampling and testing methods, microbial and end product testing, etc.

Even though the team is capable of validation it is recommended that use of other expert to crosscheck to ensure that nothing has missed.

2.4.8 Principle 7: Record keeping and documentation

The HACCP plan must be on file at the food establishment and must be made available to official inspectors upon request. Forms of recording and documenting the system may be developed, or standard forms may be used with necessary modifications. Typically, these may be forms that are completed on a regular basis and filed away. The forms should provide, documentation for all ingredients. Processing steps, packaging, storage and distribution. Mainly there are four types of HACCP records.

- HACCP plan and support documentation used in developing the plan;
- Records of CCP monitoring
- Records on corrective actions.
- Records of verification activities.

2.5 Milk

2.5.1 Definition

Milk is the lacteal secretion, practically free from colostrums, obtained by the complete milking of one or more healthy cows, which contains not less than 8.25% of milk solids-non-fat and less than 3.25% of milk fat.

(United States Public Heath Service). Minimum standards in are varying from 8.0%-8.5% for MSNF and 3.0%-3.8% for milk fat.

2.5.2 Milk Quality

Quality of the milk results the quality of the final product. Milk quality influence by a number of factors associated with milk production in the farm level to reception of the processing plant. Some factors can be controlled through good herdsmen ship, animal heath, and good milking practices and effective hygiene and house keeping (Early et al., 1998).

Contaminants

There are some contaminants that are harmful to the consumer.

- Pathogenic microorganisms. Many already be in milk udder or incorporated during or after milking.
- Antibiotics, used to treat (the udder of) the cow.
- Radionuclides.
- Toxicants taken up by the cow.
- Disinfections used on the farm or in the plant.
- Other toxicants entering the milk by contamination during and after milking.
- Bacterial toxins formed during keeping of the milk
- Hydrogen peroxide suitable for food use contains the amount of H_2O_2 as specified by the vendor (usually between 30 and 50 percent.). Treatment of milk with 0.3 per cent. Hydrogen peroxide for 24 hours at 30°C or 30 minutes at 51°C had no detectable influences on the milk fat or the fat soluble vitamins A and D_3 and ß-carotene (FAO Nutrition meeting- No. 40A,B,C WHO/Food Add./67.29).

2.5.3 Raw milk handling

Milk collection, reception and storage

Milk that has been taken to the collection center need to be chilled immediately. When the move from churns to bulk transportation and the storage of raw milk at the law temperatures, the milk flora is predominantly psychotropic and mainly Gram-negative bacteria are found (Early, 1998).

- Raw milk, which has not been refrigerated, must be processed as soon as possible after acceptance at the processing establishment.
- Raw milk must be processing within 36 h from acceptance if the milk has been kept at not more than 6^0C.
- Raw milk must be processed within 48 h from acceptance if the milk has been kept at 4^0C or lower.

2.5.4 Skim milk-Non Fat Milk

Non-fat milk or skim milk is that portion of milk that remains after the cream has been removed, in whole or in part. Skim milk contains all the nutriments of the milk, exception of the fat and vitamins associated with the fat (Lampert,1970). Skim milk

can use by persons that desire a low caloric value in their diet. Various standards required a maximum fat content of 0.1% to 0.5% and a solid-non-fat content of not less than 8.0% to 8.5%. Some time the skim milk is fortified with vitamin A and D and a product with other added vitamins and minerals is also prepared (Davis, 2001).

Table.2.1 Composition of non-fat milk (Lampert, 1970)

	Plain skim milk
Water	90.42%
Protein	03.68%
Fat	00.10%
Lactose	05.00%
Ash	00.80%

2.5.5 Heat treatment

Heat treatment is mainly aimed at killing of microorganisms and inactivation of enzymes, or to achieving some other, mainly chemical changes (Walstra et al., 1999).

Objectives of heat treatment

- Increasing the keeping quality-This concerns killing of spoilage organisms and their spores. Inactivation of enzymes both native in milk and excreted by microorganisms. Auto oxidation of lipids can be limited and avoided rapid creaming.
- Warranting the safety of the consumer- It specially concerns killing of pathogens like *mycobacterium tuberculosis*, *Coxiella burnetii*, *Staphylococcus aureus*, *Salmonella* species, *Listeria monocytogenes* and *Campylobacter jejuni*. Fairly moderate heat treatment kills all of above organisms with other pathogens that is enter unintentionally in to the milk.
- Establishing specific product properties-Example such as heating the milk before its evaporation to increase the coagulation stability of the evaporated milk during its sterilization.

2.5.6 Pre-requisites for heating process

- Desirable time-temperature relationship, which could be practicable. It covers aspects such as controllability, reliability, uniformity and sterilization effect.

- The expense should be low. This may depends on price, life time, maintenance and operation cost, amount of energy needed for heating and cooling, ways which the company can use low energy by appropriate regeneration method and rate of flow though the process.
- No undesirable hazard/quality occur to the product. This would include absorption of extraneous matter such as Cu, Sn, plasticizers. disruption or coalescence of fat and some time excessive growth of thermophilic bacteria can occur in pasteurizer.
- The of working need to fit into the planning. For example, operation like centrifugation or humanization in the process line may be desirable and possibilities to adjust heating temperature, time and flow rate.
- Properties of liquid. Such as thermal conductivity and viscosity of the liquid. O_2 content affects the possibility of growth of several bacteria such as *Bacillus*. The O_2 content of long life milk product may affect the development of off flavour by fat autoxidation.

2.5.7 Heating Equipments

Liquid milk can be heated and cooled in a batch process, in a heats exchanger, or in a packed form. Holder pasteurizer or batch pasteurizer is the originally developed method and still in practice. Usually it's jacketed vats involved are fitted with an agitator. through the double jacket, steam or hot water circulate followed by cold water (Walstra et al., 1998).

In plate heat exchangers, a large heating surface is assembling in a confined space and or a small area. Heating agent and incoming liquid are present in thin layers and are separated by a thin wall, a plate. One advantage of this method is that the energy consumption (for heating and cooling) can be relatively small because heat can be regenerated. When milk comes in the heat exchanger, it is heated by milk that has already been heated and that is at the sane time being cooled by the milk coming in. The latter is subsequently being heated further by hot water (or Steam). It may then flow through a holder section, to achieve a sufficient heating time. After being cooled by the incoming milk, it is cooled further by means of cold water (or another cooling agent)(Walstra et al., 1998) Always liquids flows in counter flow to maintain constant temperature (Atherton and Newlander., 2003).

One drawback of plate heat exchangers is that the rubber gas cut can become leaky, they do not resist high pressures, and they automatically be changed. Cracks can be formed in the plates. As a result, small amounts of raw milk might leak in to the milk already pasteurized (Walstra et al.,1998).

2.5.8 Thermization

Thermization is a heat treatment, which can be used to extend the storage life of milk prior to pasteurization or more severe heat treatments.

- Milk shall receive a heat treatment of 57^0C-68^0C for 15 seconds.
- Milk that has been kept for more than 36^0C should not thermized.
- Heated milk should shoe appositive reaction to the phosphatase test.

2.5.9 Pasteurized Milk

International Dairy Federation defined pasteurization as;

A process applied to a product with the object of minimizing possible health hazard arising from pathogenic microorganisms associated with milk by heat treatment, which is consistent with minimal chemical, physical and organoleptic change in the product (SDF. 1983:p.99).

Pasteurization is applied to ensure microbiological safety and to extend shelf life during refrigerated (<6°C) distribution. Pasteurized to ensure their safety by minimizing numbers of vegetative pathogens. Low-temperature-holding (LTH) or Low-temperature Long time and high-temperature-short-time (HTST) treatments are commonly used. Treatments of 30 minutes or more at lower temperatures between 61-66°C applied in the past have been gradually replaced by high-temperature-short time treatments (HTST), temperate is normally 7I°C to 78°C for at least 15 seconds (often 30 seconds) or very brief heating for a few seconds at 85°C in some countries.

Time-temperature requirements vary from country to country and are frequently under regulatory control as are the construction and operation of heating equipment. The actual treatments applied to the milk are often more severe to ensure that heating requirements are met.

Minimal LTLT and HTST treatments may permit the survival of thermoduric and spore-forming organisms, in particular if present in high levels, making it difficult to meet norms for pasteurized product.

Psychotropic strains of both thermoduric and spore-forming organisms may grow slowly at temperatures as low as 5°C and can cause spoilage or may be hazardous to health.

Cooling milk after pasteurization

In order to prevent the growth of surviving bacteria in pasteurized milk, it is essential that the milk need to be cooled rapidly after the heating period.

- Plate-type Coolers.

  Plate-type coolers operate in the same manner as the plate-heat exchangers are operated. Instead of hot water, cold water, refrigerated brine or glycol is circulated between the plates in order to cool the milk.

2.5.10 Homogenization

Homogenization of milk causes disruption of milk fat globules in to smaller ones. (Alford and Johnson, 1987). The milk fat-interface is considerably increased by 5-10 times.

Homogenized milk

The milk that has been subjected to such temperature and processes, which will ensure break up of the fat globules in to main smaller particles that rise to form a fat layer.

2.5.11 Cream separation

Cream separator is use to separate fat component of the milk to produce Non-fat milk or Low-fat milk. Milk soluble vitamins are remove from the milk. Low fat milk need to contain fat of not less than 0.5% and not greater than 2%. So milk is standardize from fresh milk to rearrange the fat level of the low fat liquid milk (Atherton and Newlander,1987).

2.5.12 Packaging containers

High-density polyethylene (HDPE) containers are commonly used for milk canning and are an alternative form to carton packaging. Due its convenience of handing it has become most popular form of packaging for pasteurizes milk that is available at retail level. HDPE is used rather than low-density polyethylene (LDPE) for plastic

containers, because the material provides strength and rigidity (Ralph Early, 1998). The operations involved in plastic container filling can be managed to a high level of hygiene, thereby limiting the risk of post-pasteurization contamination.

2.5.13 Shelf life

Shelf life is the time during which the product can be kept under certain conditions. (E.g., at a a given temperature) with out apparent undesirable changes.

Changes in liquid milk during storage can be identified as follows.

- Decomposition by bacteria growth in milk. (Acid production, protein breakdown and fat hydrolysis.
- Chemical reactions causing oxidized.
- Decompositions by milk enzymes or by extracellular bacterial enzymes.
- Physicochemical changes like creaming, flocculation, and gel formation.

Decomposition of pasteurized milk is especially cause by growth of microorganisms. That can determine by

- Storage temperature.
- Extent of recontamination.
- Growth rate.
- Number of spores of B.careus in the original milk
- Activity of substances inhibiting bacterial growth

(Information sited on 24.6.2006 http://drinc.ucdavis.edu/dairyp/dairyp2.htm)

There is no real point in lowering the temperature to below 4-5°C because during transit and storage in the distribution network higher temperatures normally occur such as 7^0C (Walstra, 1999)

The growth rate of bacteria depends on the temperature and the bacterium species involved.

Table.2.2 Generation time (h) of some bacterial strains in pasteurized milk

Temp. (°C)	4	7	10	20
Bacillus cereus	00	10	4	1
Bacillus cimtlans	20	12	10	3
Enterobacter cloacae	8	5	3	1
Pseudomonas putida	6	4	3	1
Listeria monocytogenes		20		
L monocytogenes, in High-pasteurized milk	30	11	9	2

The shelf life of the milk at various temperatures may be predicted if the species of the bacteria involved as well as their initial count and generation time are known. The shelf life of the milk depends on the growth possibilities of the bacteria present, whereas the total count just after pasteurization does not give sufficient information. After pasteurization of the milk its count usually amounts to 500-1000 ml, unless many heat-resistant bacteria are present in the original milk. As a rule, the milk is spoiled by "sweet curdling." caused by *B. cereus* (10 h at 7°C). Unless it is recontaminated *B. cereus*, forming lecithinase, is also responsible for the "bitty cream" defect in nonhomogenized milk (Helen and Sharpe, 1981).

Average Number of Days That Pasteurized Milk can be Stored at Various Temperatures Before it Reaches the Criteria for the Guaranteed Day of Ultimate Sale (A) and of Guaranteed Shelf Life (B) is given below,

Table.2.3 Average days of ultimate sale and self-life

	Average number of days to obtain a count of					
	5*10-4 ml-1 (A)			5*10-6 ml-1 (B)		
Milk	4^0C	7^0C	10^0C	4^0C	7^0C	10^0C
Just after pasteurizer	>14	9.6	5.8	>14	13.6	9.8
Glass Bottle	12.8	6.0	4.7	13.5	8.7	7.3
Carton	>14	7.8	5.8	>14	10.9	7.0

Storage temperature below 6°C, *B.* cereus cannot grow; *B.circulanx* may then cause deterioration. High-pasteurized milk, made by heating at about 100°C. is mainly spoiled by *B. licheniformis*, or by *B. subtilis* if the keeping temperature is relatively high. Milk contains, say, 10 spores of *B. cereus* per 100 ml; its shelf life for normal storage conditions amounts to 12-14 days if it is not recontaminated. Shelf life can be extended by decreasing the count of *B. cereus* spores by means of bactofugation. Provisions should then be made against enzymic deterioration, while aseptic packing has to be applied.

If the pasteurized milk is *recontaminated*, deterioration is generally faster and of a different nature. The presence of coliforms detectable after keeping the milk at

20°C is a good indication of recontamination having occurred. The (recontaminated) milk, stored uncooled, turns sour by the growth of E.g. Mesophilic lactic acid bacteria: high-pasteurized milk deteriorates quickest. Below 10°C the milk deteriorates by the growth of *psychrotrophs*. The flavor becomes putrid and rancid due to protein degradation and hydrolysis of fat, respectively. Since these psychrotrophs are hardly affected by substances inhibiting bacterial growth, the deterioration rate below 7°C is similar for both high- and low-pasteurized (recontaminated) milk (Walstra,1999).

The rule is that the more *B. cereus* spores in non-recontaminated milk, or the heavier the recontamination, the faster the deterioration. Thorough cleaning and disinfections of the filling and lidding machine is needed to avoid recontamination (as far as possible) after flow-through pasteurization. In determining the day of ultimate sale, one usually assumes that some recontamination of the milk occurs.

Frequent and thorough inspections are needed during processing to limit recontamination and to meet the requirements at the day of ultimate sale. To that end, samples may be kept at various temperatures and tested at intervals. The drawback is that the user has already received the milk before the result of the shelf life test is known. Tests have therefore been developed that allow a fairly rapid detection of recontamination by gram-negative, non-spore-forming bacteria.

2.5.1.4. Vitamin A and D_3

Vitamin A is a colorless compound, having the formula $C_{20}H_{30}O$.It does not exist as such in plant but as the yellow colored pigment, carotene. The amount of Vitamin A in the milk appears to be associated directly with the carotene content of the feed. In general, it appears that a maximum about 2.5 grams of carotene per day is all that the cow may transfer to the milk. Practically the entire Vitamin A in milk is associated with the unsafonifiable portion of the milk fat. Both the carotene and the vitamin A are stable to heat, acids and alkalis. Large losses may occur through oxidation and exposure to the light.

Vitamin D_3 is formed when the cholesterol derivative, 7-dehydrocholesterol, is solar irradiated upon the skin of cows exposed to sunlight and then transmitted to the mammary gland. It is more expensive than Vitamin D_2 but is he only form of Vitamin D that can be assimilated by poultry. Since vitamin A and D are fat-soluble vitamins

they are removed in the cream separation process. Because of that fortification of vitamin A and D is done in processing of liquid milk and dairy products.

2.5.1.5.Micro Organisms in Milk

- *Mycobacterium tuberculosis* can originate from the cow and the milker. The bovine type of *M. tuberculosis* is also pathogenic to humans. Among the non-spore-forming pathogenic organisms. *M. tuberculosis* is the most heat-resistant: it is killed by low pasteurization of the milk, Eg. 15 s at 72°C. Incidentally, beverage milk should be pasteurized to inactivate 'alkaline phosphatase to the extent, that it is no longer detectable. This is mainly because inactivation of this enzyme ensures that *M. tuberculosis* has been killed. The related *M. para-tuberculosis* may also occur in milk, but it is very unlikely to be pathogenic to humans.
- *Staplniococcus aitreus* often occurs in the udder of a cow with mastitis. The bacterium is also abundant in humans. Some strains can form a heat-resistant toxin and cause inflammation (ulcers). Large numbers are required to form the toxin. Growth can be slowed down by low temperature (milk), low pH, and antagonistic components formed by lactic acid bacteria (Eg. in cheese). Low Pasteurization kills *S. aureus.* AH of these factors limit the frequency of food poisoning by *S. aureus* through milk and milk products, despite the fairly general presence of the organism in raw milk.
- *Salmonella* and *Shigella* spp. occur widely in nature, E.g., in dung and polluted water. They can cause intestinal disorders. Low pasteurization is adequate to kill them. Milk and milk products are hardly ever responsible for food poisoning by these bacteria (Helen and Sharp,1981).
- *Campylobacterjejuni* belongs to the family Spirillaceae and can occur in the intestinal tract of many animals. C *jejuni is* often responsible for enteritis. Diarrhea and abdominal cramps are the main features of the disease. Milk is usually contaminated by dung, possibly also through mastitis. The organism can continue growing for a few days in raw milk at low temperature. but it is very heat-sensitive and will not survive low pasteurization. It dies rapidly in cheese, partly because of the low pH. So far, a few outbreaks have been reported as due to raw milk.

- *Listeria monocytogenes* is often found in nature. It is pathogenic to humans and animals, and a severe infection can even be fatal. Some cases of contamination through milk are known. The organism is aerobic and can grow at a temperature as low as 5°C; it is killed by usual pasteurization.
- *Vibrio cholerae* can occur in polluted water. The milker. if suffering from cholera. can contaminate the milk.
- *Coxiella bitrnetii* belongs to the family Rickettsiae and causes Q fever in humans. It can occur in cows, goats, and sheep, and may be carried by ticks. The organism can cause mastitis but animals are often carriers without becoming ill. Low pasteurization, i.e., 15 s at 72°C. kills the bacteria but 30 min at 60°C does not. 1C holder pasteurization is applied the heating temperature should be adjusted to a few degrees over that required for inactivation of alkaline phosphatase.
- *Bacillus cerens* spores occur everywhere, e.g., in soil, dust, and feed. They survive pasteurization and, accordingly, are usually present in pasteurized milk. Psychrotrophic strains are occasionally found (some growth at 7°C). *B. cereus* can produce a toxin. However, large numbers are needed that obviously spoil the milk (awful flavor, sweet curdling), so that it will be neither consumed nor processed. Because of this, the health hazard is small. Some food products containing much starch pose a greater risk because spoilage is far more difficult to detect. If milk spoiled by *B. cereus* is used for preparation of foods, it may possibly cause food poisoning (intoxication). Heating to a temperature above 100°C kills the spores *of B. cereus.* Among the *Bacillus* spp., *B. cereus* belongs to the least heat-resistant.
- *Clostridium botulinum* is a dreaded spore-forming bacterium, sometimes occurring in soil and surface water. It causes botulism, which results from an exceedingly poisonous toxin, formed during growth in food products. Milk and dairy products are never the cause of botulism, though *C. botulinum* can occur*h* in milk. Milk is too aerobic to allow growth of the microorganism.
- *Clostridium perfringens* Spores occur in soil. dung, and consequentlare often present in raw milk. Milk and milk products are hardly ever the cause of food poisoning by this organism, though it produces a toxin during sporulation in the

digestive tract. This is because *C. perfringens* is outnumbered by other bacteria in raw milk, and large numbers of vegetative cells of the bacterium are required to cause illness. Sterilization as applied in the dairy factory kills *C. perfringens*. Babies are more susceptible to *C. perfringens* than adults. Because of this, milk intended for manufacture of baby formulas must be heated sufficiently, i.e., to about 100°C or higher, to kill the spores of *C. perfringens*. (Walstra,1999)

2.6 Process capability and process performances

- Process capability is the long-term performance level of the process after it has been brought under statistical control. In other words, process capability is the range over which the natural variation of the process occurs as determined by the system of common causes.
- Process capability is also the ability of the combination of people, machine, methods, material, and measurements to produce a product that will consistently meet the design requirements or customer expectation.

Measures of Process Capability - Process Capability Indices:

- Cp, Cpl, Cpu, and Cpk are the four most common and timed tested measures of process capability.
- Process capability indices measure the degree to which your process produces output that meets the customer's specification.
- Process capability indices can be used effectively to summarize process capability information in inconvenient unitless system.
- Cp and Cpk are quantitative expressions that personify the variability of the process (its natural limits) relative to its specification limits (customer requirements).
- Until a few years ago, most organizations used a goal of Ppk > 1.33, however, processes that must deliver Six Sigma performance require Pp > 2.0 and Ppk > 1.5.
- Cpk > 1.33 (A Highly Capable Process)
- Cpk = 1 to 1.33 (A Barely Capable Process).
- Cpk < 1 (The Process is not Capable) (Information sited on 3.5.2006 http://www.qualityamerica.com/knowledgecente/knowctrPpk_index.htm http://www.mmbstatistical.com/ContactMMBInc.html)

- Cp should always be greater than 2.0 for a good process which is under statistical control. For a good process under statistical control, Cpk should be greater than 1.5.
- Cp = Process Capability. A simple and straightforward indicator of process capability.
- Cpk = Process Capability Index. Adjustment of Cp for the effect of non-centered distribution.
- Pp = Process Performance. A simple and straightforward indicator of process performance.
- Ppk = Process Performance Index. Adjustment of Pp for the effect of non-centered distribution(Leavenworth and Grant, 2000).

Table. 2.4 Estimated equations and usages of process capability indexes

Index	Estimated Equation	Usage
Cp	(USL - LSL) / 6	Process Capability for two - sided specification limit, irrespective of process center.
Cpu	(USL - X-Bar) / 3s	Process Capability relative to upper specification limit.
Cpl	(X-Bar - LSL) / 3s	Process Capability relative to lower specification limit.
Cpk	Min. of (Cpu , Cpl) or Distance between mean of the process and the closest spec. limit / 0.5 of the	Process variability. Process Capability for two - sided specification limit Accounting for process centering.

2.7 Cleaner-Sanitizers

Cleaner-Sanitizer is made from combinations of ingredients already mentioned and involves no particularly new products. The value of these preparations is based on the ability for one product to act as a detergent and a sanitizer. The cleaner-sanitizer are combinations of compatible ingredients formulated to be effective under a wide range of conditions and against a wide variety of microorganisms (Atherton and Newlander. 2003).

CHAPTER 03

Methodology

3.1 Identification of the scope of HACCP study and company policy

Scope of the HACCP study was implemented as a entering to the HACCP study. Company policy ware recorded as to establish to identify the commitment of the company for its products.

3.2 Identification of HACCP team

By considering the key skills and responsibilities that each person was involved in the company, HACCP team was set up in a suitable manner. Team has been appointed a team leader who had good knowledge of the factory activities and experienced in development of HACCP plans. Selected team only contained appropriate number of persons else it's difficult to control and manage.

3.3 Product description and intended use of fresh milk and low fat milk

Product features and attributes ware understood as much as possible. Full description of the product such as composition, structure, processing, packaging, storage and distribution conditions, and expected shelf life were identified. Type of raw materials used, ingredients used, quantities of ingredients were recorded. Product's intended usages were identified as considering it's characteristics and observing catered target market.

3.4 Constructions of process flow diagrams

Process flow diagram of the two products has been identified and constructed. Further factory flow layout was identified with included the potential delay stages. Simultaneously all possible cross-contamination risks that would happen were identified. Then the process flow diagrams were confirmed with the discussion of the group.

3.5 Development of pre-requisite support system

3.5.1 Development of Good manufacturing Manual

GMP manual was developed to fulfillment of pre-requisite program. GMP manual was developed by considering several legal and industrial practices. (Appendix A)

3.5.2 Development of Suppler Quality Assurance Documentation

SQA questioner was developed for initial assessment of suppliers. (Appendix F)

3.6 Identification of Hazards and Hazard Analysis

All potential hazards such as biological hazards, chemical hazard and physical hazard were identified with regard to raw material and process steps of two milk forms of homogenized pasteurized fresh milk can and low fat fresh milk can. Raw material hazards and process flow hazards were separately identified, documented and discussed with other team members to identify any other hazard is to be considered. Possible sources or courses for each hazard also identified. Control measures are also documented to each identified hazard.

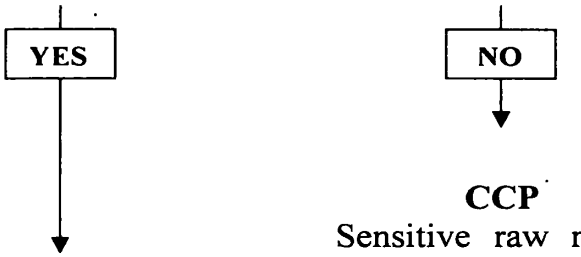
3.7 Determination of Critical Control Points

CCP decision tree approach was used to identify each CCP. Raw material control decision tree (Codex, 1997) was used to identify the CCPs in the raw material, which was used. Separate CCP decision tree (adapted from Codex, 1997) was used to identify CCPs in the process/process flow.

3.7.1 Critical Control Point identification for raw materials

Q1. Is there a hazard associated with this raw material?

Q2. Are you or the customer going to process this hazard out of the product?



Q3. Is there a cross-contamination risk to the facility or to other products which will Not be controlled?

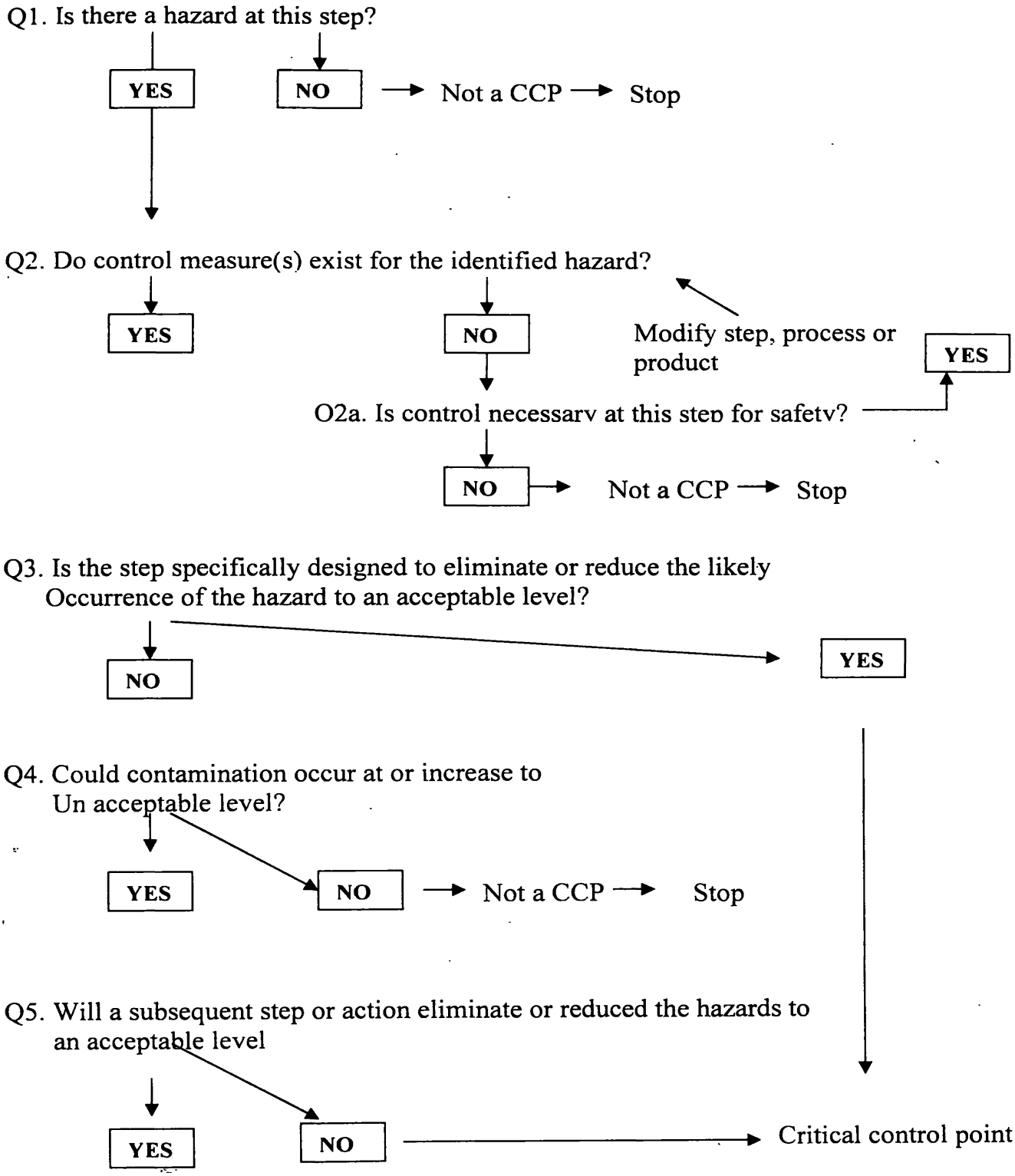
Key

* Proceed to your next raw material.

(Codex, 1997)

Fig.3.1 HACCP decision tree-Raw material

3.7.2 Critical Control Point identification for Process flow



Key

* Proceed to your next process step

(Codex, 1997)

Fig.3.2 A CCP decision tree- Process step

3.8 Preparation of the HACCP critical limits using control charts

Once CCPs were identified HACCP control charts were established. It documented as all the essential details about steps are clearly visualized.

Critical limits established using public sources as scientific publications, regulatory requirements and guild lines given by SLS. Then control charts were established by using identified CCPs.

The temperature of milk reception chill tanks (Appendix B), pasteurizer- holding tube (Appendix C). MST room temperature (Appendix D) and finished product storage chill room temperature (Appendix E) were recorded.

Then average temperatures was calculated and plotted on diagrams by using Minitab software.

3.9 Establishment of monitoring systems

Monitoring procedures for identified control points were established. Monitoring of relevant limits. responsible persons, how the monitoring done and monitoring frequency were established

3.10 Establishment corrective action procedure

Relevant corrective action for each identified CCP for any deviation that would indicate from the given critical limits. Established whom to be reported on such a deviation occasions and the relevant actions necessary to be take on such incident.

3.11 Establishment of verification procedure

Verification procedure and the responsible person of relevant verifications were established for each critical limits/critical points.

3.12 Established record keeping and documentation procedure

All hazards identification notes, process flow charts, factory flows, critical limits established records. log sheets. maintains records. CCP determination charts, GMP manual and SQA questioners were recorded.

CHAPTER 04

Result and discussion

4.1 Results

4.1.1 Scope of the HACCP plan

The HACCP manual for pasteurized homogenized fresh milk can and low fat can has been developed for implement that to ensure product safety throw out the milk reception to end consumer by analyzing and controlling all possible hazards.
In this plan Raw material reception to transport of finish product is addressed.

4.1.2 Identification of company safety policy

Cargills Quality Daries is dedicated to manufacture would –class products, using only the good manufacturing practices. The company will take every effort to maintain the highest standards of occupational health, hygiene, and ensure that all the employees will remain free from injury and preventing danger to property

The company will implement this policy on safety by

- Only producing and installing tested and proven start-of-the-machinery and technology.
- Continuously training our employees on safe manufacturing practices and vigorously implementing best practices in all areas.
- Controlling every aspect on factory operation asper the detailed HAZOP analysis.
- Continuously communicating with employees on the standards of safe work practices.
- Company practices all national legislation of heath and safety.

4.1.3 Identification of HACCP team

- Factory Engineer.
- Manufacturing Manager - Team Leader.
- Quality Executives.
- Microbiologist.
- Team Leaders
    - One worker from the production unit.
    - Mixing unit.

- Raw material stores.
- Cold stores and transport.

- Operation Assistant. (One)

4.1.4 Factory layout

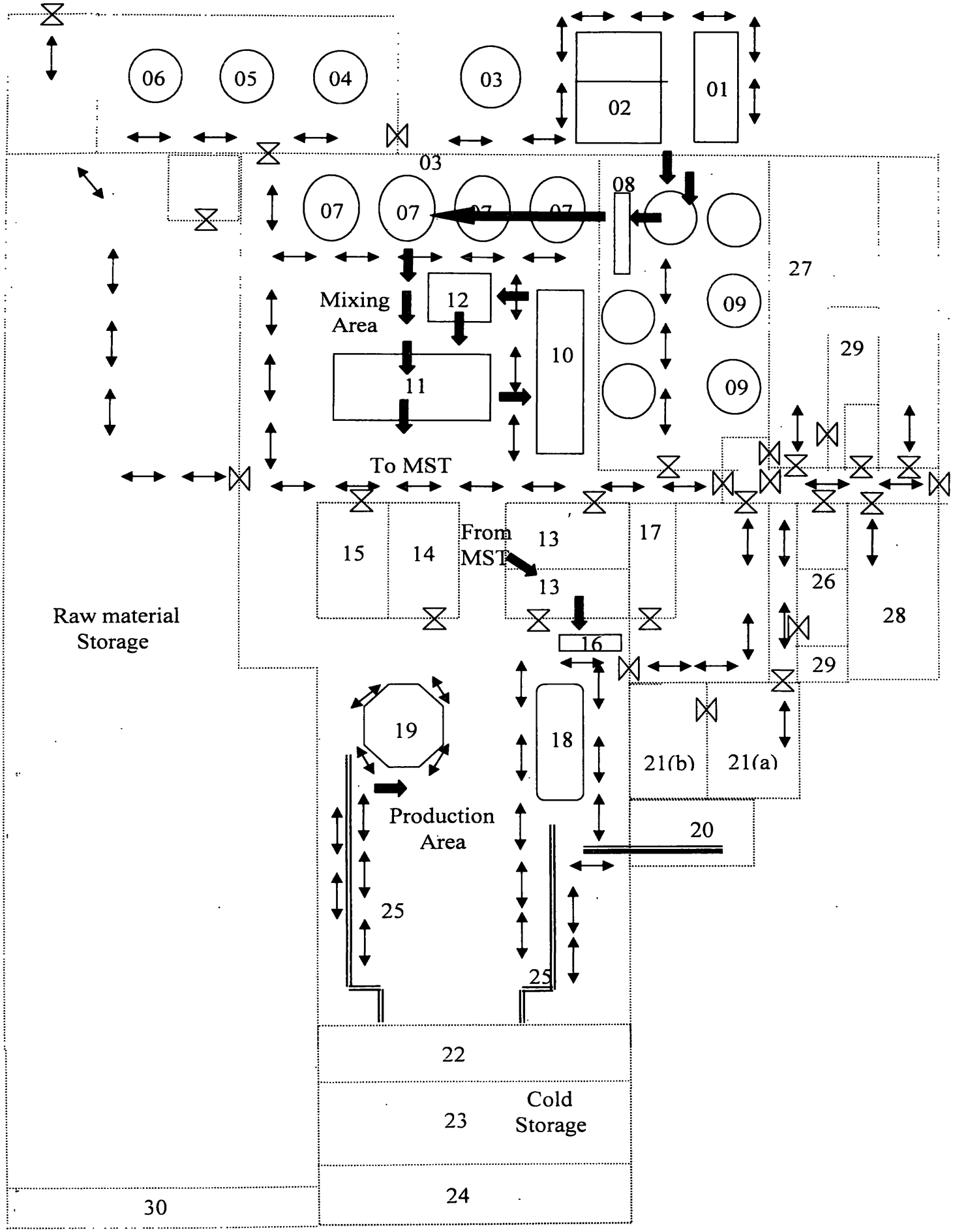


Fig. 4.1 Factory layout

Locations indicated by numbers:

01-Milk reception

02-Chill bath

03-Carbon filter

04-Detergent tank

05-Warm water tank

06-Cold water tank

07-Mixing tank

08-Heat exchanger

09-Chochelet tank

10-Homogenizer

11-Pasteurizer

12-Cream separator

13-Chill room

14-Production team leaders' room

15-Mixing control room

16-Milk bottle filling table

17-Production machinery store

18-In line filler

19-RIA

20-Hardning tunnel

21(a)-General laboratory

21(b)-Microbiological laboratory

22-Palatizing area

23-Cool storage

24-Dispatch area

25-Conveyer belt

26-Women's changing room

27-Men's changing room

28-Canteen

29-Lavatory

30-Cone baking area

4.1.5 Homogenized pasteurized fresh milk cans

4.1.5.1 Product description and intended use

The product is pasteurized homogenized liquid milk that will be consumed, with out further processing by the general population. (Including Children and elders). The product is packed in plastic cans of 1000ml, which is stored below 4 C^0.

4.1.5.1.1 Material and packaging used for the product

Raw materials

- Whole milk.
- Skimmed milk powder.
- Water. (De-chlorinated).

Packaging Material

- Plastic can- White in colure
- Bottle cap (with neck cap)- Dark blue in colure.

4.1.5.1.2 Product Specification

General Specification

- Fresh milk – Fat 4.22%
  - MSNF 8.44%
- SMP
- Water

Process Specification

- Pasteurized Temperature 81 for 25 sec
- Homogenization Pressure 160 Bar

Chemical Specification

- Total Solids (%) minimum - 12.0
- Fat content (%) minimum - 3.5
- Milk Solid Non Fat (MSNF) - 8.5

Microbial Specification

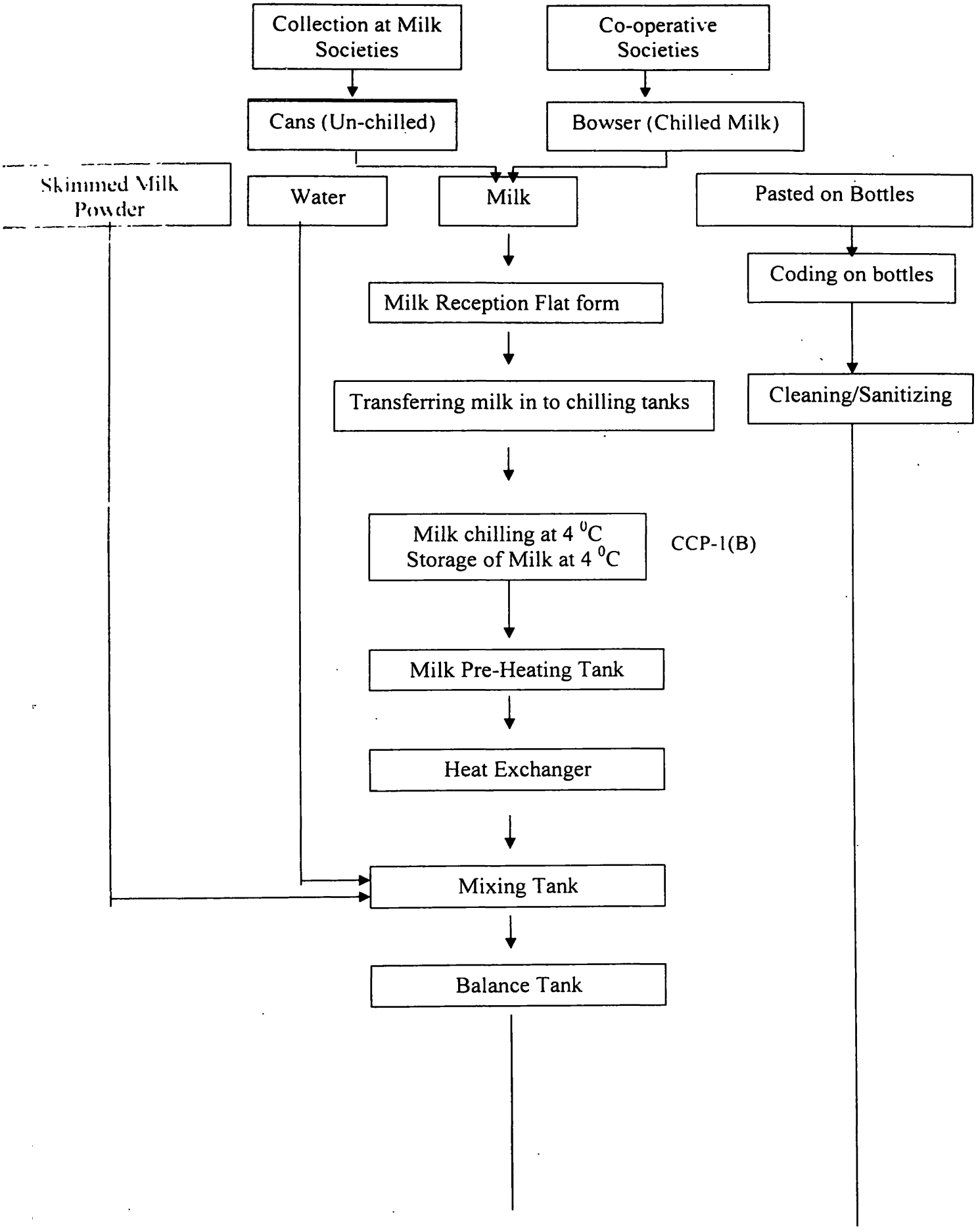
- Total Viable Count (TVC) < 30000/g
- Coliform Count - Absent in 1g

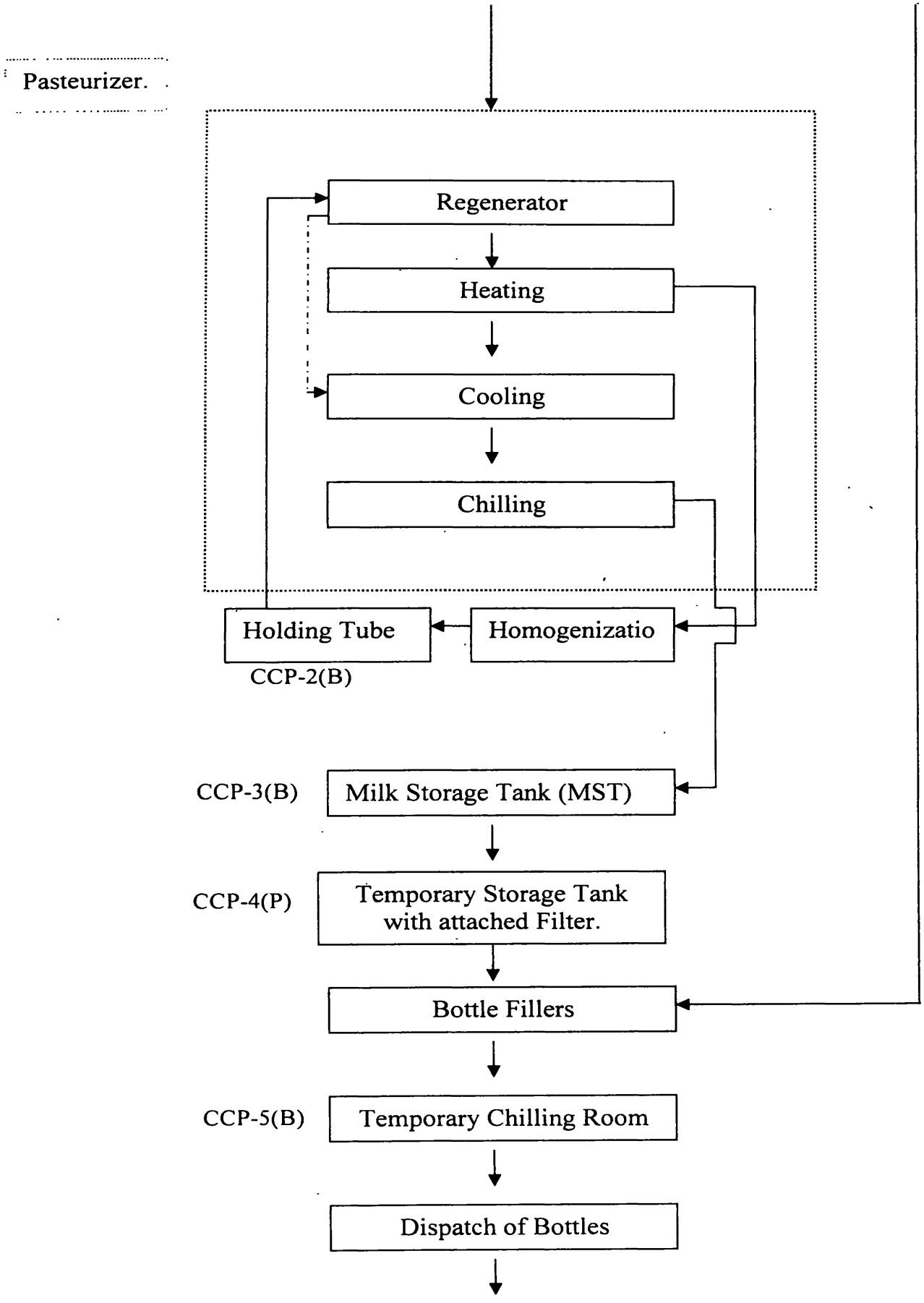
4.1.5.1.3 Packaging size/ Volume-1liter (1000ml).

4.1.5.1.4 Shelf life-7 days from manufacture date under storage of below 4^0 C temperature.

4.1.5.1.5 Label information-Product name, Brand name, Batch code, Date of manufacturing, Date of expiry, Retail price, Barcode, Storage condition, Contact address printed on the bottle.

4.1.5.2 Pasteurized homogenized fresh milk can manufacture Process




Pasteurizer.
Regenerator
Heating
Cooling
Chilling
Holding Tube
Homogenizatio
CCP-2(B)
CCP-3(B)
Milk Storage Tank (MST)
CCP-4(P)
Temporary Storage Tank with attached Filter.
Bottle Fillers
CCP-5(B)
Temporary Chilling Room
Dispatch of Bottles

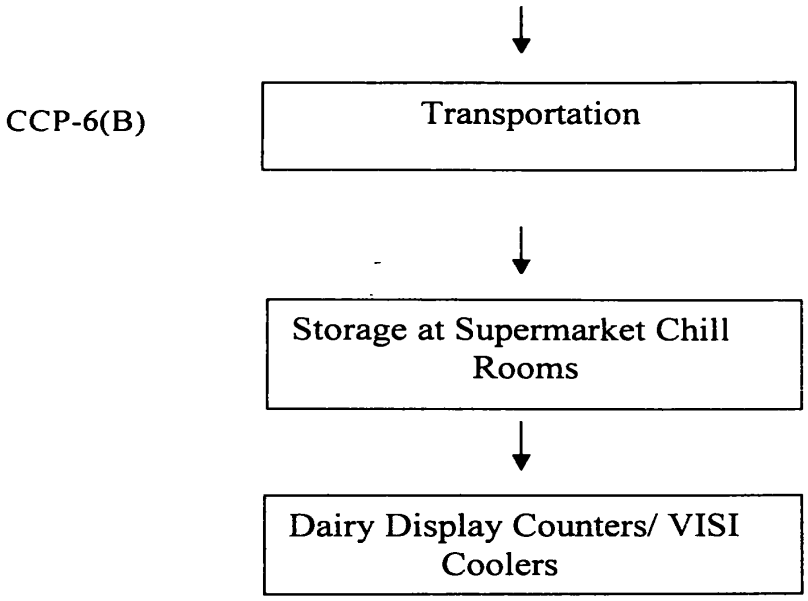


Fig. 4.2 Flow chart for Process of Pasteurized homogenized full cream milk can

4.1.5.2.1 Fresh milk can Process Flow Chart in Standard Icons

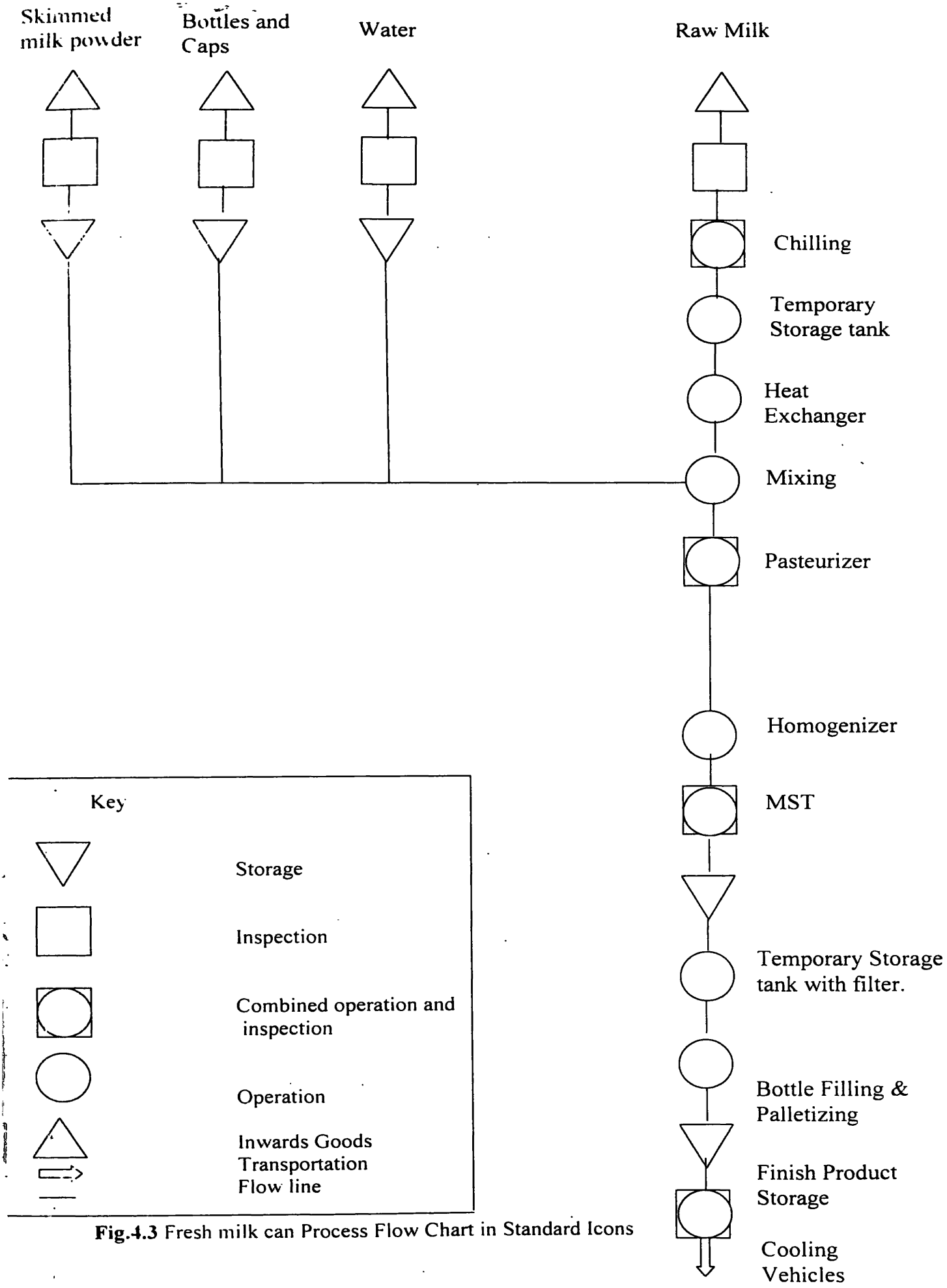


Fig.4.3 Fresh milk can Process Flow Chart in Standard Icons

4.1.5.3 Hazard analysis chart -Raw material- Fresh milk can

Table. 4.1 Hazard analysis chart for ingredients of the pasteurized homogenized fresh milk can

Ingredient	**Hazard**	**Control measure**
1.**Raw milk**		
Physical	Dust particles (Wood, glass)	GMP No(02-a,b,d),No(12-b)
	Dead bodies (Pests/Insects)	GMP No(02-a,b,d),No(12-b)
	Metal	GMP No(02-a,b,d)
Chemical	Cleaning chemicals	GMP No(15-b)
	Peroxides	GMP No(15-b)
	Pesticides	GMP No(15-b)
	Urea	GMP No(15-b)
	Antibiotics	GMP No(15-b),No(01-e)
	Radioactive elements	GMP No(15-b)
	Starch	GMP No(15-b)
	Sugar	GMP No(15-b)
Biological	Bacteria- *Bacillus cereus* *Listreia monocytogenes* *Yersinia enterocolitica* *Salmonella spp.* *Escherichia coli* O157:H7 *Canpylobacter jejuni* *Mycodacterium tuberculosis*	GMP No(01-d),No(03-c,d,e)
	Yeast	GMP No(01-d),No(03-c,d,e)
	Molds-*Aspergillus* *Fusarium* *Penicillium*	GMP No(01-d),No(03-c,d,e)
	Protozoa	GMP No(01-d),No(03-c,d,e)
2.**Skimmed Milk Power**		
Physical	Foreign matter	GMP No(01-a)
Chemical	Pesticides	GMP No(01-a)
	Radioactive elements	GMP No(01-a)
	Cleaning chemicals	GMP No(01-a)
	Antibiotics	GMP No(01-a)
	Biological:	
	Salmonella	GMP No(01-a),No(17)
	Escherichia coli	GMP No(01-a),No(17)
	Staphylococcus aureus	GMP No(01-a),No(17)

	Clostridium perferigenese	GMP No(01-a),No(17)
	Listeira monocytogense	GMP No(01-a),No(17)
	Bacillus serus	GMP No(01-a),No(17)
3.Water		
Physical	Foreign matter	GMP No(01-f)
Chemical	Cleaning chemicals	GMP No (01-b,c)
	Chlorine	GMP No(01-b,c)
	Pesticides	GMP No(20-d)
	Antibiotics	GMP No(20-d)
Biological	Vegetative pathogens	GMP No(17)
4. **Bottles and caps**		
Physical	Presence of foreign mater. Paper, plastics	GMP No(01-a)
Chemical	Presence of toxic chemicals	GMP No(01-a)
Biological	Contamination with Vegetative pathogens	GMP No(01-a)

4.1.5.4 Hazards analysis chart- Process step- Fresh milk can

All potential hazards were analysis according to the considering process chats, process flows. and activities associated with the production of pasteurized homogenized fresh milk process.

Table.4.2 Hazard analysis chart for process flow of the pasteurized homogenized fresh milk can

Process step	**Hazard**	**Control measures.**
1.Milk Reception flat form		
Physical	Wood, pests and insects. dust, leaves	GMP No (02-a,b). No.(02-a,b,c,d)
	Glass particles from uncovered lamps	Unmoved lamps should be covered

Chemical	Presence of cleaning residues.	GMP No (15-a,b,c,d)
	Mixing of laboratory chemicals in to the milk where analyzing milk at the reception	GMP No (20-b)
Biological	Vegetative pathogens due to wet Surface. *Listera monocytogense*	GMP No (01-d) GMP No (18-a,b)
2.Tranfering milk into chill tanks		
Physical	Intrinsic factors at outer surface of can contaminate.	GMP No (15-b), No (2-b) No (2-d,e)
	Contamination from maters due to uncovered area from filter cloth.	GMP No (03-b)
Chemical	-	-
Biological	-	-
3.Milk Chilling and storage		
Physical	Contamination with intrinsic factors.	GMP No (03-b,e)
Chemical	Cleaning chemical residuals	GMP No. (15-c,d,)
Biological	Proliferation of vegetative pathogens Bacteria- *Bacillus cereus* *Listreia monocytogenes* *Yersinia enterocolitica* *Salmonella spp.* *Escherichia coli* O157:H7	GMP No (03-c.d,e) No (18-b)
4.Pumping to pre-heating tank		
Physical	-	-

Chemical	Presence of cleaning residuals	GMP No (04), No.(15-c,d)
Biological	-	-
5. **Pre-heating (Heat Exchangers.)**		
Physical	Contamination with gasket materials. Chemical reactions	GMP No (15-a,b) Use of food grade gaskets.
Chemical	Remains of cleaning residuals.	No.(15-c,d)
Biological	-	-
6. **Mixing tank**		
Physical	Contamination of foreign material.	GMP No (09-b,c)
Chemical	Sudden drop of other mixture(ice cream)	GMP No (09-c)
Biological	Contamination by personal	GMP No (19)
7. **Balance tank**		
Physical	Sudden drop of a maintains tool	Balance tank lid should be property closed.
Chemical	-	-
Biological	Presence of Pathogenic bacteria- *Listera monocytogense*	GMP No (15)
8. **Pasteurizer**		
(a). **Regenerator**		
Physical	Contamination with gasket material	GMP No (18-a,b) Use of food grade gaskets.
Chemical	Chemical residuals	GMP No(06-a,d).No (a,c,d)

Biological	Contamination with raw milk. (Due to leakages from cracks in the plates and) Presence of gram negative rod-shaped bacteria at gaskets. *Enterobacteriaceae (Serratia, Enterbacter, Citrobacter, Hafnia)*	GMP No (06-d) GMP No (15-c,d), No-(18)
(b) **Heating & Holing tube**		
Physical	Contamination of gasket material	GMP No (18-b,a)
Chemical	Chemical residuals Chemical reactions	GMP No (06-a), No(18 - a,c,d)
Biological	Survival of vegetative pathogens due to improper time and temperature combination.	-
(c) **Cooling/ Cooling area**		
Physical	Contaminated with gasket martial.	GMP No (18-b,a)
Chemical	Chemical residuals	GMP No (06-a),No(15-a,c,d)
Biological	-	-
(d) **Chilling**		
Physical	Contamination of gasket material	GMP No (18-b,a)
Chemical	Contamination of Glycol	GMP No (18-b,a) No.(6-d)
	Cleaning chemical residues	GMP No (06-a), No(15-a,c,d)
Biological	-	-

9. **Homogenizer**		
Physical	Contamination with lubricant oil	GMP No (07-b) Use of food grade oils
Chemical	Chemical residuals	GMP No (06-a), No (15-a,c,d) No (07-a)
Biological	Vegetative pathogens due to bad Cleaning.	GMP No (15), No (19)
10.**MST**		
Physical	Contamination with plastic material and sample collecting equipments.	GMP No (09-b,d,f)
Chemical	Chemical residuals. Contamination with lubricant oil	GMP No (10- b,c,e), No (15-b,c,d) Use of food grade oil
Biological	Proliferation of vegetative pathogens.	
11.**Temporary storage tank with attached filter**		
Physical	Contamination of foreign mater	Chill room door should be closed every time. Proper closing of the tank GMP No (11-a,b,c)
Chemical	Chemical residuals	GMP No.(15-a,c,d)
Biological	Vegetative pathogens due to wet Surface. *Listeria monocytogenes*	GMP No.(15)
12. **Bottle filers/filling**		
Physical	Contamination of Metal particles.	GMP No (18-a,b)

	Contamination of foreign mater in to bottle.	Good visual inspection
Chemical	Remaining of chemical residuals	GMP N0(15-d)
Biological	Contaminations by filling persons. Presence of *Escherichia coli* O157:H7 at filling pipes	GMP No(12-a,b,c,d,e,g,h) No.(19) GMP N0(15-d)
13. **Temporary Chilling Room.**		
Physical	-	-
Chemical	-	-
Biological	Proliferation of vegetative pathogens.	GMP N0(13)
14.**Dispatch of bottles**		
Physical	Physical damagers to the bottle cause presence of material	Care full handling of bottles. Use of suitable crates
Chemical	-	-
Biological	Post contamination of *Listeria monocytogenes* due to bottle surface	Proper washing of bottle can surface.
15. **Transportation**		
Physical	Plastic particles may add if damages happened.	Proper stacking in carrier vehicles
Chemical	-	-
Biological	Proliferation of vegetative pathogens.	Proper cooling of vehicles before loading.
		Correct temperature maintenance.

16.**Storage at supermarket chill rooms**		
Physical	Damages of handling	Careful handling
Chemical	-	-
Biological	Proliferation of vegetative pathogens.	Correct temperature maintenance.
17. **Display counters/VISI coolers**		
Physical	-	-
Chemical	-	-
Biological	Proliferation of vegetative pathogens.	Maintenance correct temperature.

4.1.5.5 Hazard Justification

4.1.5.5.1 Hazard Justification-Raw material-Fresh milk

Hazards associated with Skim milk powder was taken as suppler certify that the product is free from hazard.

Hazards associated with raw milk such as antibiotics, radio active material, pesticides, etc ware not considered due to absence of such sources as large hospitals, dumping yards, chemical plants were not located in the area. Information or reported cases unable to found with regard to above

Adulterants such as sugar, starch, hydrogen peroxide, etc were tested and considered that milk shall not contain such material until recorded in future.

4.1.5.5.2 Hazard Justification-Process step-Fresh milk

Table. 4.3 Hazard Justification chart for process flow of the pasteurized homogenized fresh milk can

Process step	Hazard	Justification	Hazard is to be address in the plan(Y/N)	Control measures.
1.**Milk Reception flat form**				
Physical	Wood, dead bodies(insects), dust, leaves	CQD quality reports recorded the presence of these materials. But no out breaks were reported.	Y	GMP No (02-a,b), No.(02-a,b,c,d)
	Glass partials from uncovered lamps	No out breaks reported	Y	Unmoved lamps should be covered.
Chemical	Presence of cleaning residues.	No out breaks reported	Y	GMP No (15-a,b,c,d)
	Mixing of laboratory chemicals in to the milk where analyzing milk	No out breaks reported	Y	GMP No (20-b)

	at the reception			
Biological	Vegetative pathogens duc to wet Surface. *Listera monocytogense*	No out breaks reported	Y	GMP No (01-d) GMP No (18s-a,b)
2.**Tranfering milk into chill tanks**				
Physical	Intrinsic factors at outer surface of the cans can contaminate with milk	CQD quality reports and visual inspection reported the hazards. But no out breaks associated.	Y	GMP No (15-b), No (2-b) No (2-d,e)
	Contamination from foreign maters due to uncovered area from filter cloth.	Visual Observations. But no out breaks associated	Y	GMP No (03-b)
Chemical	-	-	N	-
Biological	-	-	N	-

3.**Milk Chilling and storage**				
Physical	Contamination with intrinsic factors.	CQD quality reports and visual inspection reported the hazards. But no out breaks associated.	Y	GMP No (03-b,e)
Chemical	Cleaning chemical residuals.	No out breaks reported	Y	GMP No. (15-c,d,)
Biological	Proliferation of vegetative pathogens Bacteria- *Bacillus cereus* *Listreie monocytogenes* *Yersinia enterocolitica* *Salmonella spp.* *Escherichia coli* O157:H7	CQD Micro biological records.	Y	GMP No (03-c,d,e) No (18-b)
4.Pumping to pre-heating tank				
Physical	-	-	N	-
Chemical	Presence of cleaning residuals	No out breaks reported	Y	GMP No (04), No.(15-c,d)
Biological	-	-	N	-

5.Pre-heating (Heat Exchangers.)				
Physical	Metal particle contamination	No out breaks reported. Contamination not reasonably likely to be occur.	Y	GMP No (18s-a,b)
	Contamination with gasket materials. Chemical reactions	Gasket contamination is not reasonably likely to be occur.	Y	GMP No (15-a,b) Use of food grade gaskets.
Chemical	Remains of cleaning residuals.	No out breaks reported	Y	No.(15-c,d)
Biological	-	-		-
6. **Mixing tank**				
Physical	Contamination of foreign material.	Out break occur due to malfunction of filter.	Y	GMP No (09-b,c)
Chemical	Sudden drop of other mixture (ice cream -ingredients)	Significant hazard would not occur due to addition of ice cream ingredients	Y	GMP No (09-c)
Biological	Contamination by personal	No out breaks reported	Y	GMP No (19)

7. **Balance tank**				
Physical	Sudden drop of a maintains tool	Such droppings are not reasonably likely to be occur.	Y	Balance tank lid should be property closed.
Chemical	-	-	-	-
Biological	Presence of Pathogenic bacteria- *Listera monocytogense*	No out breaks reported	Y	GMP No (15)
8. **Pasteurizer.**				
(a). **Regenerator**				
Physical	Contamination with gasket material	Contamination of gasket martial Is not reasonably likely to be occur.	Y	GMP No (18-a,b) Use of food grade gaskets.
Chemical	Presence of cleaning residues.	No out breaks reported	Y	GMP No (15-a,c,d)
Biological	Contamination with raw milk.(Due to leakages from craks in the plates.) *Salmonella spp.* Presence of gram-negative rod-shaped bacteria at gaskets.	Out break was reported. Largest out break of salmonellosis (250000) ever reported. (Romney,T.1988. Food Science and Technology Today,2, 268-71)	Y	GMP No (06-d) GMP No (15-c,d), No-(18)

	Enterobacteriaceae (Serratia, Enterbacter, Citrobacter, Hafnia)			
(b) **Heating & Holding tube**				
Physical	Contamination of gasket material	No out breaks reported	Y	GMP No (18-b,a)
Chemical	Chemical residuals Chemical reactions	No out breaks reported	Y	GMP No (06-a), No(18 -a,c,d)
Biological	Survival of vegetative pathogens due to improper time and temperature combination.	Salmonellosis (Moris, 1985) Yersiniosis (Walstra, 1999)	Y	-
(c) **Cooling/ Cooling area**				
Physical	Contaminated with gasket martial.	Contamination of gasket martial Is not reasonably likely to be occur.	Y	GMP No (18-b,a)
Chemical	Chemical residuals	No out breaks reported	Y	GMP No (06-a),No(15-a,c,d)

Biological	-	-	N	-
(d) **Chilling**				
Physical	Contamination of gasket material	No out breaks reported	Y	GMP No (18-b,a)
Chemical	Contamination of Glycol	Contamination of gasket martial Is not reasonably likely to be occur.	Y	GMP No (18-b,a) No.(6-d)
	Cleaning chemical residues	No out breaks reported	Y	GMP No (06-a), No(15-a,c,d)
Biological	-	-	N	-
9. **Homogenizer**				
Physical	Contamination with lubricant oil	Contamination of lubricant oil is not reasonably likely to be occur.	Y	GMP No (07-b) Use of food grade oils
Chemical	Chemical residuals	No out breaks reported		GMP No (06-a), No (15-a,c,d) No (07-a)
Biological	Vegetative pathogens due to bad Cleaning.	Information unable to found		GMP No (15), No (19)

10.**MST**				
Physical	Contamination with plastic material and sample collecting equipments.	Contamination is not reasonably likely to be occur.	Y	GMP No (09-b,d,f)
Chemical	Chemical residuals. Contamination with lubricant oil	No out breaks reported	Y	GMP No (10- b,c,e), No (15-b,c,d) Use of food grade oil
Biological	Proliferation of vegetative pathogens.	No out breaks reported	Y	
11. **Temporary storage tank with attached filter.**				
Physical	Contamination of foreign mater	Contamination of foreign mater is not reasonably likely to be occur	Y	Chill room door should be closed every time. Proper closing of the tank GMP No (11-a,b,c)
Chemical	Chemical residuals	No out breaks reported	Y	GMP No.(15-a,c,d)
Biological	Vegetative pathogens due to wet	Growth of pathogens is not	Y	GMP No.(15)

	Surface. *Listera monocytogense*	likely to be occur.		
12. **Bottle filers/filling**				
Physical	Contamination of Metal particles.	No out breaks reported	Y	GMP No (18-a,b)
	Contamination of foreign mater in to bottle.	No out breaks reported	Y	Good visual inspection
Chemical	Remaining of chemical residuals	No out breaks reported	Y	GMP N0(15-d)
Biological	Contaminations by filling persons. Presence of *Escherichia coli* O157:H7 at filling pipes	No out breaks reported	Y	GMP No(12-a,b,c,d,e,g,h) No.(19) GMP N0(15-d)
13.**Tempary Chilling Room**				
Physical	-	-	N	-
Chemical	-	-	N	-
Biological	Proliferation of vegetative	Information unable to found	Y	-

	pathogens.			
14.**Dispatch of bottles**				
Physical	Physical damagers to the bottle cause presence of material	No out breaks reported	Y	Careful handling of bottles. Use of suitable crates
Chemical	-	-	N	-
Biological	Post contamination of *Listera monocytogense* due to bottle surface	Contamination of pathogens is not likely to be occur.	Y	Proper washing of bottle can surface.
15. **Transportation**				
Physical	Plastic particles may add if damages happened.	No out breaks reported	N	Proper stacking in carrier vehicles
Chemical	-	-	N	-
Biological	Proliferation of vegetative pathogens.	No out breaks reported	N	Proper cooling of vehicles before loading. Correct temperature maintains throw out

				the transportation
16.**Storage at supermarket chill rooms**				
Physical	Damagers of handling	No out breaks reported	N	Careful handling
Chemical	-	-	N	-
Biological	Proliferation of vegetative pathogens.	CQD quality reports	N	Correct temperature maintenance.
17. **Display counters/ VISI coolers**				
Physical	-	-	N	-
Chemical	-	-	N	-
Biological	Proliferation of vegetative pathogens.	CQD quality reports	N	Maintenance correct temperature.

4.1.5.6 CCP Identification-Raw material- Fresh milk.

CODEX decision tree was used to identify the Critical Control Points that was associated with the raw material of fresh milk cans.

Table. 4.4 Decision tree analysis for raw material –Fresh milk

Ingredient	Hazard	Q1	Q2	Q3	CCP
1.Raw milk	Physical	Y	Y	N	Not a CCP
	Chemical	Y	N	-	Not a CCP
	Biological	Y	Y	N	Not a CCP
					Not a CCP
2.Skimmed milk powder	Physical	N	-	-	Not a CCP
	Chemical	N	-	-	Not a CCP
	Biological	N	-	-	Not a CCP
					Not a CCP
3.Water	Physical	Y	Y	N	Not a CCP
	Chemical	Y	N	-	Not a CCP
	Biological	Y	Y	N	Not a CCP

4.1.5.7 CCP Identification-Process Flow- Fresh milk.

CODEX decision tree was used to identify the Critical Control Points that was associated with the process flow of fresh milk cans.

Table. 4.5 Decision tree analysis for process flow –Fresh milk

Process step	Hazard	Q1	Q2	Q3	Q4	Q5	CCP
1.Milk reception plat form	Physical	Y	Y	N	Y	Y	Not a CCP
	Chemical	Y	Y	N	N	-	Not a CCP
	Biological	Y	Y	N	Y	Y	Not a CCP
2. Transferring milk in to chill tanks through muslin filter.							
	Physical	Y	Y	N	N	-	Not a CCP
	Chemical	-	-	-	-	-	-
	Biological	-	-	-	-	-	-
3.Milk Chilling and storage							
	Physical	Y	Y	N	N	-	Not a CCP
	Chemical	Y	Y	N	N	-	Not a CCP
	Biological	Y	Y	Y	-	-	CCP-1(B)

4. Pumping to pre-heating tank							
	Physical	-	-	-	-	-	-
	Chemical	Y	Y	N	N	-	Not a CCP
	Biological	-	-	-	-	-	-
5. Heat Exchangers.							
	Physical	Y	Y	N	Y	Y	Not a CCP
	Chemical	Y	Y	N	N	-	Not a CCP
	Biological	-	-	-	-	-	-
6. Mixing tank							
	Physical	Y	Y	N	Y	Y	Not a CCP
	Chemical	Y	Y	N	N	-	Not a CCP
	Biological	Y	Y	N	Y	Y	Not a CCP
7.Balance tank							
	Physical	Y	Y	N	N	-	Not a CCP
	Chemical	-	-	-	-	-	-
	Biological	Y	Y	N	N	-	Not a CCP
8.Pasteurizer							
(a). Regenerator							
	Physical	Y	Y	N	Y	Y	Not a CCP
	Chemical	Y	Y	N	N	-	Not a CCP
	Biological	Y	Y	N	N	-	Not a CCP
(b). Heating & Holding tube							
	Physical	Y	Y	N	Y	Y	Not a CCP
	Chemical	Y	Y	N	N		Not a CCP
	Biological	Y	Y	Y	-	-	CCP-2(B)
(c). Cooling/ Cooling area							
	Physical	Y	Y	N	Y	Y	Not a CCP
	Chemical	Y	Y	N	N	-	Not a CCP
	Biological	-	-	-	-	-	-
(d)Chilling							
	Physical	Y	Y	N	Y	Y	Not a CCP
	Chemical	Y	Y	N	N	-	Not a CCP
	Biological	-	-	-	-	-	-
9.Homogenizer							
	Physical	Y	Y	N	N	-	Not a CCP

	Chemical	Y	Y	N	N	-	Not a CCP
	Biological	Y	Y	N	Y	Y	Not a CCP
10.MST							
	Physical	Y	Y	N	Y	Y	Not a CCP
	Chemical	Y	Y	N	N	-	Not a CCP
	Biological	Y	Y	Y	Y	N	CCP-3 (B)
11. Temporary storage tank with attached filter.							
	Physical	Y	Y	Y	-	-	CCP-4 (P)
	Chemical	Y	Y	N	N	-	Not a CCP
	Biological	Y	Y	N	N	-	Not a CCP
12. Bottle filers/filling							
	Physical	Y	Y	N	N	-	Not a CCP
	Chemical	Y	Y	N	N	-	Not a CCP
	Biological	Y	Y	N	N	-	Not a CCP
13. Temporary Chilling Room							
	Physical	Y	Y	N	N	-	Not a CCP
	Chemical	Y	N	N	N	-	Not a CCP
	Biological	Y	Y	Y	-	-	CCP-5 (B)
14. Dispatch of bottles							
	Physical	Y	Y	N	N	-	Not a CCP
	Chemical	-	-	-	-	-	Not a CCP
	Biological	Y	Y	N	N	-	Not a CCP
15. Transportation	Physical	Y	Y	N	N	-	Not a CCP
	Chemical	Y	Y	N	N	-	Not a CCP
	Biological	Y	Y	N	Y	N	CCP-6 (B)

Note: Identified CCPs for pasteurized homogenized fresh milk can process were categorized in table.4.1.6.due to the similarity of the CCPs with pasteurized homogenized low fat milk.

4.1.6 Homogenized pasteurized Low fat milk cans

4.1.6.1 Product description and intended use

The product is pasteurized homogenized low fat liquid milk that will be consumed. with out further processing by the general population. Specially design for who are concern about low fat dietary. General population Including children and elders. The product is packed in plastic cans of 1000ml, which is stored below 4 C^0.

4.1.6.1.1 Material and packaging used for the product

Raw materials

- Whole milk.
- Skimmed milk powder.
- Water. (De-chlorinated).
- Vitamin A and D_3

Packaging Material

- Plastic can- White in colure
- Bottle cap (with neck cap)- Light blue in colure.

4.1.6.1.2 Product Specification

General Specification

- Fresh milk - Fat 1%
  -MSNF 8.45%
- SMP
- Water
- Vitamin A andD_3

Process Specification

- Pasteurized Temperature 81 for 25 sec
- Homogenization Pressure 160 Bar

Chemical Specification

- Total Solids (%) minimum - 11.0
- Fat content (%) minimum - 1.0
- Milk Solid Non Fat (MSNF) - 10.0

Microbial Specification

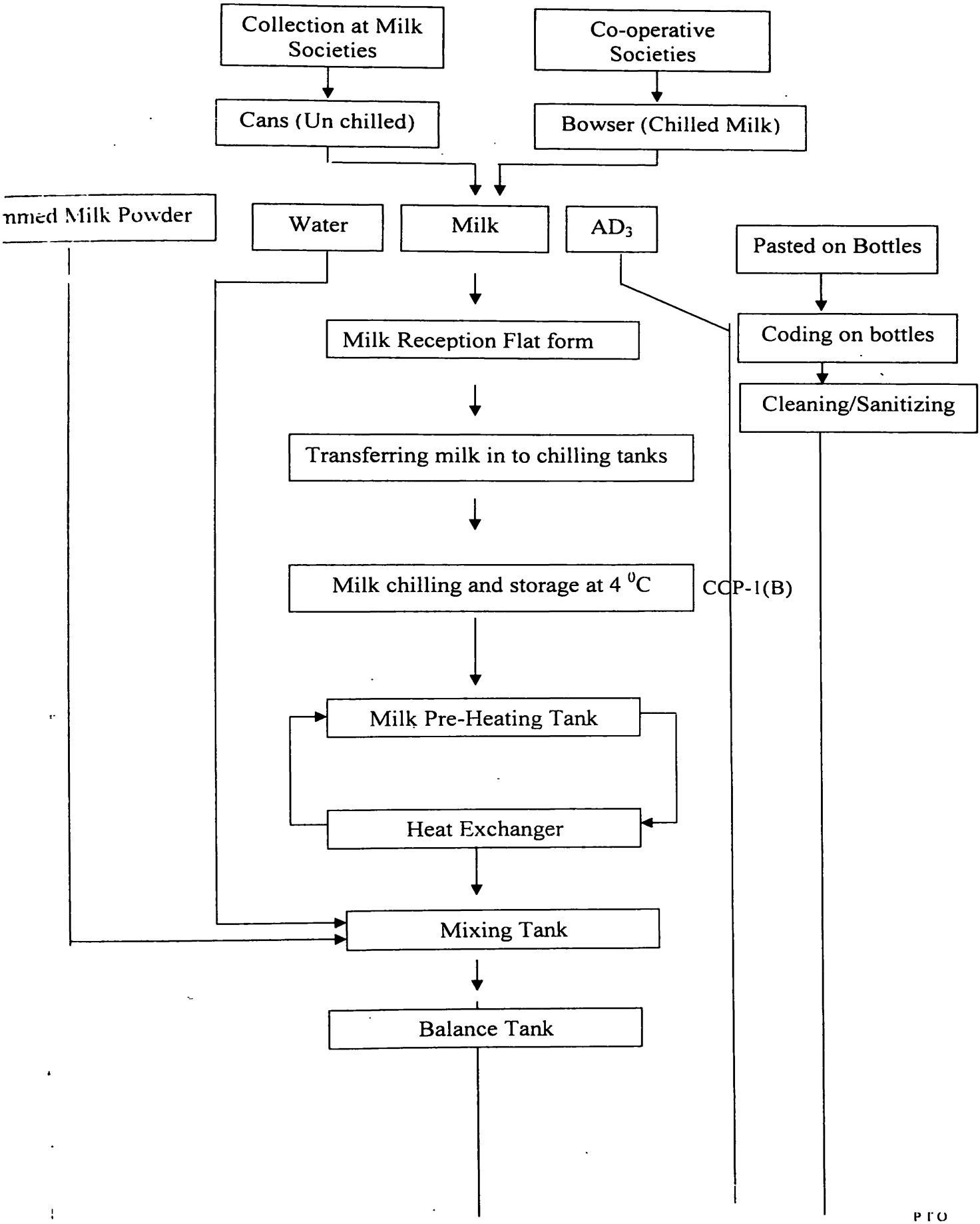
- Total Viable Count (TVC) < 30000/g
- Coliform Count - Absent in 1g

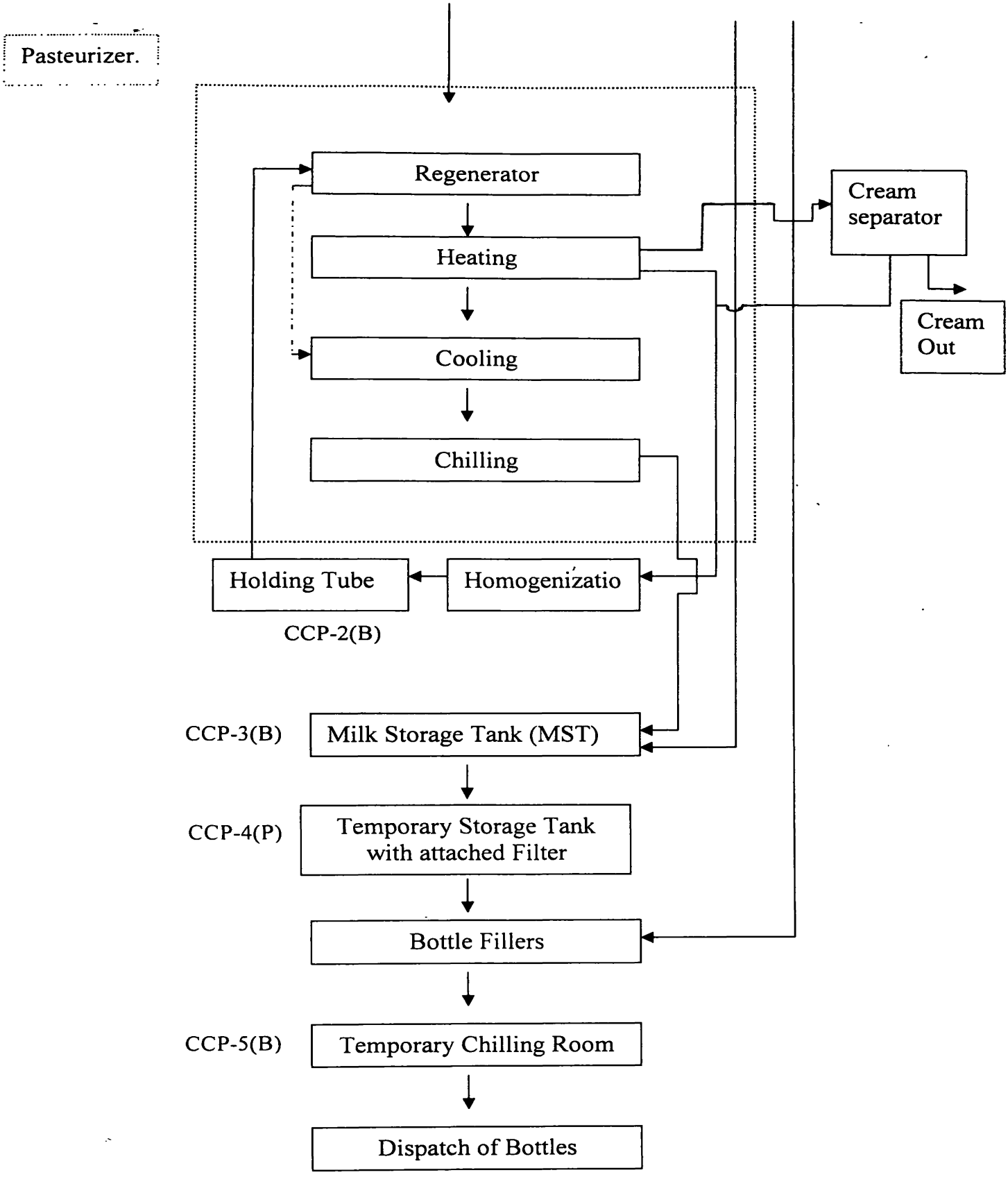
4.1.6.1.3. Packaging size/ Volume - 1liter (1000ml)

4.1.6.1.4. Shelf life - 7 days from manufacture date under storage of below 4 C^0 temperature

4.1.6.1.5 Label information-Product name, Brand name, Batch code, Date of manufacturing, Date of expiry, Retail price, Barcode, Storage condition, Contact address printed on the bottle.

4.1.6.2 Pasteurized homogenized low fat milk can manufacture Process




Pasteurizer.
Regenerator
Heating
Cooling
Chilling
Cream separator
Cream Out
Holding Tube
Homogenizatio
CCP-2(B)
CCP-3(B)
Milk Storage Tank (MST)
CCP-4(P)
Temporary Storage Tank with attached Filter
Bottle Fillers
CCP-5(B)
Temporary Chilling Room
Dispatch of Bottles

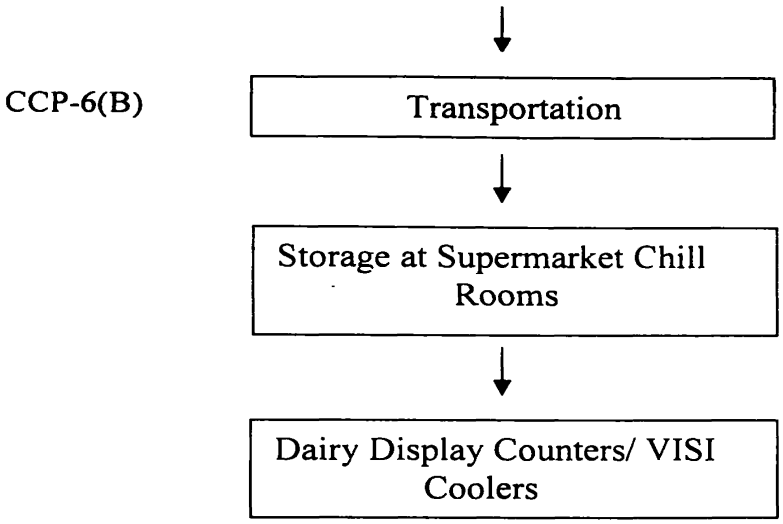
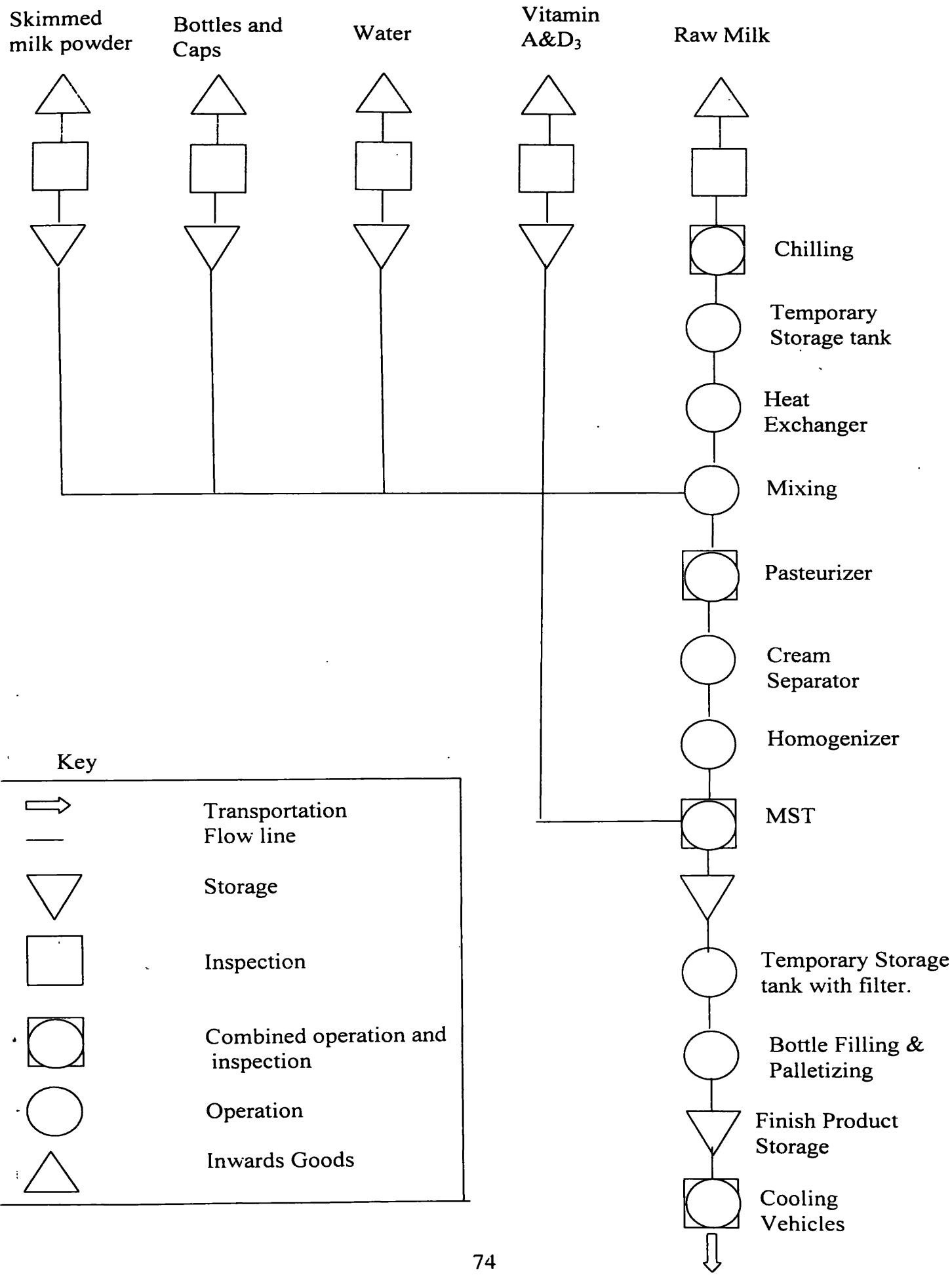


Fig. 4.4. Flow chart for Process of Pasteurized homogenized Low fat milk can

4.1.6.2.1 Low fat milk can Process Flow Chart in Standard Icons



4.1.6.3 Hazard analysis chart – Raw material - low fat milk can

Table. 4.6 Hazard analysis chart for ingredients of the pasteurized homogenized low fat milk can

Ingredient	Hazard	Control
1.**Raw milk**	**Physical:**	
	Dust particles (Wood. glass)	GMP No(02-a.b.d).No(12-b)
	Dead bodies (Pests/Insects)	GMP No(02-a,b,d),No(12-b)
	Metal	GMP No(02-a,b,d)
	Chemical:	
	Cleaning chemicals	GMP No(15-b)
	Peroxides	GMP No(15-b)
	Pesticides	GMP No(15-b)
	Urea	GMP No(15-b)
	Antibiotics	GMP No(15-b),No(01-e)
	Radioactive elements	GMP No(15-b)
	Starch	GMP No(15-b)
	Sugar	GMP No(15-b)
	Biological:	
	Bacteria- *Bacillus cereus* *Listreia monocytogenes* *Yersinia enterocolitica* *Salmonella spp.* *Escherichia coli* O157:H7 *Canpylobacter jejuni* *Mycodacterium tuberculosis* *Aerobacter aerogenes*	GMP No(01-d),No(03-c,d,e)
	Yeast	GMP No(01-d),No(03-c,d,e)
	Molds- *Aspergillus* *Fusarium* *Penicillium*	GMP No(01-d),No(03-c,d,e)
	Protozoa	GMP No(01-d),No(03-c,d,e)
2.**Skimmed Milk Power**	**Physical:**	
	Foreign matter	GMP No(01-a)
	Chemical:	
	Pesticides	GMP No(01-a)
	Radioactive elements	GMP No(01-a)
	Cleaning chemicals	GMP No(01-a)
	Antibiotics	GMP No(01-a)

	Biological:	
	Salmonella	GMP No(01-a),No(17)
	Escherichia coli	GMP No(01-a),No(17)
	Staphylococcus aureus	GMP No(01-a).No(17)
	Clostridium perferigenese	GMP No(01-a).No(17)
	Listera monocytogense	GMP No(01-a),No(17)
	Bacillus serus	GMP No(01-a).No(17)
3.**Water**	**Physical:**	
	Foreign matter	GMP No(01-f)
	Chemical:	
	Cleaning chemicals	GMP No(01-b,c)
	Chlorine	GMP No(01-b,c)
	Pesticides	GMP No(20-d)
	Antibiotics	GMP No(20-d)
	Biological:	
	Vegetative pathogens.	GMP No(17)
4. **Bottles and caps**	**Physical:**	
	Presence of foreign mater. Paper, plastics	GMP No(01-a)
	Chemical:	
	Presence of toxic chemicals	GMP No(01-a)
	Biological:	
	Contamination with Vegetative pathogens.	GMP No(01-a)
5.**Vitamin A&D_3**	**Physical:**	
	Foreign matter	GMP No(01-a)
	Chemical:	
	Toxic substances	GMP No(01-a)
	Biological:	
	No	GMP No(01-a)

4.1.6.4. Hazard analysis of pasteurized homogenized low fat milk can process.

All potential hazards were analysis according to the considering process charts. process flows. and activities associated with the production of pasteurized homogenized fat low can process.

Table. 4.7 Hazard analysis chart- process step- low fat milk can

Process step	**Hazard**	**Control measures.**
1. Milk Reception platform		
Physical	Wood, pests and insects, dust, leaves	GMP No (02-a,b), No.(02-a,b,c,d)
	Glass partials from uncovered lamps	Unmoved lamps should be covered
Chemical	Presence of cleaning residues.	GMP No (15-a,b,c,d)
	Mixing of laboratory chemicals in to the milk where analyzing milk at the reception	GMP No (20-b)
Biological	Vegetative pathogens due to wet Surface. *Listera monocytogense*	GMP No (01-d) GMP No (18s-a,b)
2.Tranfering milk into chill tanks		
Physical	Intrinsic factors at outer surface of can contaminate.	GMP No (15-b), No (2-b) No (2-d,e)
	Contamination from maters due to uncovered area from filter cloth.	GMP No (03-b)
Chemical	-	-
Biological	-	-

3.Milk Chilling and storage		
Physical	Contamination with intrinsic factors.	GMP No (03-b,e)
Chemical	Cleaning chemical residuals	GMP No. (15-c,d,)
Biological	Proliferation of vegetative pathogens Bacteria- *Bacillus cereus* *Listreria monocytogenes* *Yersinia enterocolitica* *Salmonella spp.* *Escherichia coli* O157:H7	GMP No (03-c,d,e) No (18-b)
4. **Pumping to pre-heating tank**		
Physical	-	-
Chemical	Presence of cleaning residuals	GMP No (04), No.(15-c,d)
Biological	-	-
5. **Pre-heating (Heat Exchangers.)**		
Physical	Contamination with hot water.	GMP No (18s-a,b)
	Contamination with gasket materials. Chemical reactions	GMP No (15-a,b) Use of food grade gaskets.
Chemical	Remains of cleaning residuals.	No.(15-c,d)
Biological	-	-
6. **Mixing tank**		
Physical	Contamination of foreign material.	GMP No (09-b,c)
Chemical	Sudden drop of other mixture (ice cream)	GMP No (09-c)

Biological	Contamination by personal	GMP No (19)
7. **Balance tank**		
Physical	Sudden drop of a maintains tool	Balance tank lid should be property closed.
Chemical	-	-
Biological	Presence of Pathogenic bacteria- *Listeria monocytogenes*	GMP No (15)
8. **pasteurizer**		
(a). **Regenerator**		
Physical	Contamination with gasket material	GMP No (18-a,b) Use of food grade gaskets.
Chemical	Chemical residuals	GMP No(06-a,d),No (a,c,d)
Biological	Contamination with raw milk. (Due to leakages from craks in the plates or mistake make in connecting pipes) Presence of gram negative rod-shaped bacteria at gaskets. *Enterobacteriaceae (Serratia, Enterbacter, Citrobacter, Hafnia)*	GMP No (06-d) GMP No (18), No (15-c,d)
(b) **Heating & Holing tube**		
Physical	Contamination of gasket material	GMP No (18-b,a)
Chemical	Chemical residuals Chemical reactions	GMP No (06-a), No(18 - a,c,d)
Biological	Survival of vegetative pathogens due to improper time and temperature combination.	-

(c) **Cooling/ Cooling area**		
Physical	Contaminated with gasket martial.	GMP No (18-b,a)
Chemical	Chemical residuals	GMP No (06-a),No(15-a,c,d)
Biological	-	-
(d) **Chilling**		
Physical	Contamination of gasket material	GMP No (18-b,a)
Chemical	Contamination of Glycol	GMP No (18-b,a) No.(6-d)
	Cleaning chemical residues	GMP No (06-a). No(15-a,c,d)
Biological	-	-
9. **Homogenizer**		
Physical	Contamination with lubricant oil	GMP No (07-b) Use of food grade oils
Chemical	Chemical residuals	GMP No (06-a), No (15-a,c,d) No (07-a)
Biological	Vegetative pathogens due to bad Cleaning.	GMP No (15), No (19)
10. **Cream separator**		
Physical	Contamination with metal particles	GMP (18-a,b) Visual inspection at the assembling and dissembling.
Chemical	Presence of chemical residues	GMP (15-d,c,a)
Biological	-	-

11.**MST**		
Physical	Contamination with plastic material and sample collecting equipments.	GMP No (09-b,d,f)
Chemical	Chemical residuals. Contamination with lubricant oil	GMP No (10- b,c,e). No (15-b.c.d) Use of food grade oil
Biological	Proliferation of vegetative pathogens.	-
12. **Adding vitamin A and D_3**		
Physical	Drop of plastic mater in to the mix tank	-
Chemical	Addition of excess amount.	Only the relevant amount carry to the tank. Use of dedicated flasks, measuring cylinders to measuring process.
Biological	Contamination by personal	GMP No. (19-d)
Biological	Contaminations by filling persons. Presence of *Escherichia coli* O157:H7 at filling pipes	GMP No(12-a,b,c,d,e,g,h) No.(19) GMP N0(15-d)
13. **Temporary storage tank with attached filter**		
Physical	Contamination of foreign mater	Chill room door should be closed every time. Proper closing of the tank GMP No (11-a,b,c)

Chemical	Chemical residuals	GMP No.(15-a,c,d)
Biological	Vegetative pathogens due to wet Surface. *Listeria monocytogenes*	GMP No.(15)
14. **Bottle filers/filling**		
Physical	Contamination of Metal particles.	GMP No (18-a,b)
	Contamination of foreign mater in to bottle.	Good visual inspection
Chemical	Remaining of chemical residuals	GMP N0(15-d)
Biological	Contaminations by filling persons. Presence of *Escherichia coli* O157:H7 at filling pipes	GMP No(12-a,b,c,d,e,g,h) No.(19) GMP N0(15-d)
15.**Finished product Chilling Room**		
Physical	-	-
chemical	-	-
Biological	Proliferation of vegetative pathogens.	GMP N0(13)
16.**Dispatch of bottles**		
Physical	Physical damagers to the bottle cause presence of material	Care full handling of bottles. Use of suitable crates
chemical	-	-
Biological	Post contamination of *Listeria monocytogenes* due to bottle surface	Proper washing of bottle can surface.
17. **Transportation**		

Physical	Plastic particles may add if damages happened.	Proper stacking in carrier vehicles
Chemical	-	-
Biological	Proliferation of vegetative pathogens.	Proper cooling of vehicles before loading.
		Correct temperature maintenance.
18.**Storage at supermarket chill rooms**		
Physical	Damagers of handling	Care full handling
Chemical	-	-
Biological	Proliferation of vegetative pathogens.	Correct temperature maintenance.
19. **Display counters/ VISI coolers**		
Physical	-	-
chemical	-	-
Biological	Proliferation of vegetative pathogens.	Maintenance correct temperature.

4.1.6.5 Hazard Justification

4.1.6.5.1. Hazard justification for raw material.

Hazards associate with Skim milk powder and vitamin A and D liquid mixture was taken as suppler certify that the product is free from hazard.

Hazards associated with raw milk such as antibiotics, radio active material, pesticides, etc were not considered due to absence of such sources as large hospitals, dumping yards, chemical plants were not located in the area. Information or reported cases unable to found with regard to above

Adulterants such as sugar, starch, hydrogen peroxide, etc were tested and considered that milk shall not contain such material until recorded in future.

4.1.6.5.2 Hazard Justification- Process step - low fat milk can

Table 4.8 Hazard Justification chart for process flow of the pasteurized homogenized low fat milk can

Process step	Hazard	Justification	Hazard is to be address in the plan(Y/N)	Control measures.
1.Milk Reception platform				
Physical	Wood, dead pests and insects, dust, leaves	CQD quality reports recorded the presence of these materials. But no out breaks were reported.	Y	GMP No (02-a,b), No.(02-a,b,c,d)
	Glass particles from uncovered lamps	No out breaks reported	Y	Unmoved lamps should be covered.
Chemical	Presence of cleaning residues.	No out breaks reported	Y	GMP No (15-a,b,c,d)
	Mixing of laboratory chemicals in	No out breaks reported	Y	GMP No (20-b)

	to the milk when analyzing milk at the reception			
Biological	Vegetative pathogens due to wet Surface. *Listera monocytogense*	No out breaks reported	Y	GMP No (01-d) GMP No (18s-a,b)
2.Tranfering milk into chill tanks				
Physical	Intrinsic factors at outer surface of the cans can contaminate with milk	CQD quality reports and visual inspection reported the hazards. But no out breaks associated.	Y	GMP No (15-b), No (2-b) No (2-d,e)
	Contamination from foreign maters due to uncovered area from filter cloth.	Visual Observations. But no out breaks associated	Y	GMP No (03-b)
Chemical	-	-	N	-
Biological	-	-	N	-

3.Milk Chilling and storage				
Physical	Contamination with intrinsic factors.	CQD quality reports and visual inspection reported the hazards. But no out breaks associated.	Y	GMP No (03-b,e)
Chemical	Cleaning chemical residuals.	No out breaks reported	Y	GMP No. (15-c,d,)
Biological	Proliferation of vegetative pathogens Bacteria- *Bacillus cereus* *Listreie monocytogenes* *Yersinia enterocolitica* *Salmonella spp.* *Escherichia coli* O157:H7	CQD Micro biological records.	Y	GMP No (03-c,d,e) No (18-b)
4. **Pumping to pre-heating tank**				
Physical	-	-	N	-
Chemical	Presence of cleaning residuals	No out breaks reported	Y	GMP No (04), No.(15-c,d)
Biological	-	-	N	-

5.**Pre-heating (Heat Exchangers.)**				
Physical	Metal particle contamination	No out breaks reported. Contamination not reasonably likely to be occur.	Y	GMP No (18s-a,b)
	Contamination with gasket materials. Chemical reactions	Gasket contamination is not reasonably likely to be occur.	Y	GMP No (15-a,b) Use of food grade gaskets.
Chemical	Remains of cleaning residuals.	No out breaks reported	Y	No.(15-c,d)
Biological	-			-
6. **Mixing tank**				
Physical	Contamination of foreign material.	Out break occur due to malfunction of filter.	Y	GMP No (09-b,c)
Chemical	Sudden drop of other mixture (ice cream -ingredients)	Significant hazard would not occur due to addition of ice cream ingredients	Y	GMP No (09-c)
Biological	Contamination by personal.	No out breaks reported	Y	GMP No (19)

7. **Balance tank**				
Physical	Sudden drop of a maintains tool	Such droppings are not reasonably likely to be occur.	Y	Balance tank lid should be property closed.
Chemical	-	-	-	-
Biological	Presence of Pathogenic bacteria- *Listera monocytogense*	No out breaks reported	Y	GMP No (15)
8. **Pasteurizer.**				
(a). **Regenerator**				
Physical	Contamination with gasket material	Contamination of gasket martial Is not reasonably likely to be occur.	Y	GMP No (18-a,b) Use of food grade gaskets.
Chemical	Presence of cleaning residues.	No out breaks reported	Y	GMP No (15-a,c,d)
Biological	Contamination with raw milk.(Due to leakages from craks in the plates, if incorrectly designed or installed)	Out break was reported. Largest out break of salmonellosis (250000) ever reported. (Romney,T.1988. Food Science	Y	GMP No (06-d) GMP No (15-c,d), No-(18)

	Salmonella spp. Presence of gram-negative rod-shaped bacteria at gaskets. *Enterobacteriaceae (Serratia, Enterbacter, Citrobacter, Hafnia)*	and Technology Today,2, 268-71)		
(b) **Heating & Holding tube**				
Physical	Contamination of gasket material	No out breaks reported	Y	GMP No (18-b,a)
Chemical	Chemical residuals Chemical reactions	No out breaks reported	Y	GMP No (06-a), No(18 -a,c,d)
Biological	Survival of vegetative pathogens due to improper time and temperature combination. Remaining of bacterial spores	Salmonellosis (Moris, 1985) Yersiniosis Food born hazards (Walstra.p,1999,Dairy Technology)	Y	-
(c) **Cooling/ Cooling area**				

Physical	Contaminated with gasket martial.	Contamination of gasket martial Is not reasonably likely to be occur.	Y	GMP No (18-b,a)
Chemical	Chemical residuals	No out breaks reported	Y	GMP No (06-a),No(15-a,c,d)
Biological	-	-	N	-
(d) **Chilling**				
Physical	Contamination of gasket material	No out breaks reported	Y	GMP No (18-b,a)
Chemical	Contamination of Glycol	Contamination of gasket martial Is not reasonably likely to be occur.	Y	GMP No (18-b,a) No.(6-d)
	Cleaning chemical residues	No out breaks reported	Y	GMP No (06-a), No(15-a,c,d)
Biological	-	-	N	-
9. **Homogenizer**				
Physical	Contamination with lubricant oil	Contamination of lubricant oil is not reasonably likely to be	Y	GMP No (07-b) Use of food grade oils

		occur.		
Chemical	Chemical residuals	No out breaks reported		GMP No (06-a), No (15-a,c,d) No (07-a)
Biological	Vegetative pathogens due to bad Cleaning.	Information not found		GMP No (15), No (19)
10. **Cream separator**				
Physical	Contamination with metal particles	No out breaks reported	Y	GMP (18-a,b) Visual inspection at the assembling and dissembling.
Chemical	Presence of chemical residues	No out breaks reported	Y	GMP (15-d,c,a)
Biological	-	-	N	-
11.**MST**				
Physical	Contamination with plastic material and sample collecting equipments.	Contamination is not reasonably likely to be occur.	Y	GMP No (09-b,d,f)
Chemical	Chemical residuals.	No out breaks reported	Y	GMP No (10- b,c,e),

	Contamination with lubricant oil			No (15-b,c,d) Use of food grade oil
Biological	Proliferation of vegetative pathogens. Growth of Bacillus cereus, Bacillus circulans, Bacillus licheniformis, Bacillus subtilis is high if the keeping temperature is high.	No out breaks reported	Y	
12. **Adding vitamin A & D_3**				
Physical	Drop of plastic mater in to the mix tank	Contamination is not reasonably likely to be occur	Y	_
Chemical	Addition of excess amount.	Over-fortification of Vitamin D resulted vit.D toxicity. (Food Chemical News,July 8,1991)	Y	Only the relevant amount carries to the tank. Use of dedicated flasks, measuring cylinders to measuring

				process.
Biological	Contamination by personal	No out breaks reported	Y	GMP No. (19-d)
13. **Temporary storage tank and muslin filter.**				
Physical	Contamination of foreign mater	Contamination of foreign mater is not reasonably likely to be occur	Y	Chill room door should be closed every time. Proper closing of the tank GMP No (11-a,b,c)
Chemical	Chemical residuals	No out breaks reported	Y	GMP No.(15-a,c,d)
Biological	Vegetative pathogens due to wet Surface. *Listera monocytogense*	Growth of pathogens is not likely to be occur.	Y	GMP No.(15)
14. **Bottle filers/filling**				
Physical	Contamination of Metal particles.	No out breaks reported	Y	GMP No (18-a,b)
	Contamination of foreign mater in to bottle.	No out breaks reported	Y	Good visual inspection
Chemical	Remaining of chemical residuals	No out breaks reported	Y	GMP N0(15-d)

Biological	Contaminations by filling persons. Presence of *Escherichia coli* O157:H7 at filling pipes. Recontamination of coliform during bottling.	No out breaks reported	Y	GMP No(12-a,b,c,d,e,g,h) No.(19) GMP N0(15-d)
15.**Tempary Chilling Room**				
Physical	-	-	N	-
chemical	-	-	N	-
Biological	Proliferation of vegetative pathogens.	Information not found		GMP N0(13)
16.**Dispatch of bottles**				
Physical	Physical damagers to the bottle cause presence of material	No out breaks reported	Y	Care full handling of bottles. Use of suitable crates

chemical	-	-	N	-
Biological	Post contamination of *Listera monocytogense* due to bottle surface	Contamination of pathogens is not likely to be occur.	Y	Proper washing of bottle can surface.
17. **Transportation**				
Physical	Plastic particles may add if damages happened.	No out breaks reported	N	Proper stacking in carrier vehicles
Chemical	-	-	N	-
Biological	Proliferation of vegetative pathogens.	No out breaks reported	N	Proper cooling of vehicles before loading. Correct temperature maintains throw out the transportation
18.**Storage at supermarket chill rooms**				
Physical	Damagers of handling	CQD product return records.	N	Care full handling

Chemical	-	-	N	-
Biological	Proliferation of vegetative pathogens.	CQD quality records.	N	Correct temperature maintenance.
19. **Display counters/ Visi coolers**				
Physical	-	-	N	-
chemical	-	-	N	-
Biological	Proliferation of vegetative pathogens.	CQD quality records.	N	Maintenance correct temperature.

4.1.6.6. CCP Identification-Raw material-low fat milk

Table. 4.9 Decision tree analysis for Raw material-low fat milk

Ingredient	Hazard	Q1	Q2	Q3	CCP
1. Raw milk	Physical	Y	Y	N	Not a CCP
	Chemical	Y	N	-	Not a CCP
	Biological	Y	Y	N	Not a CCP
2. Skimmed milk powder	Physical	N	-	-	Not a CCP
	Chemical	N	-	-	Not a CCP
	Biological	N	-	-	Not a CCP
3.Water	Physical	Y	Y	N	Not a CCP
	Chemical	Y	N	-	Not a CCP
	Biological	Y	Y	N	Not a CCP
4.Vitamin A,D_3	Physical	N	-	-	Not a CCP
	Chemical	N	-	-	Not a CCP
	Biological	N	-	-	Not a CCP

4.1.6.7. CCP Identification-Process Flow- Low fat

Table. 4.10 Decision tree analysis for process flow –Low fat milk can

Process step	Hazard	Q1	Q2	Q3	Q4	Q5	CCP
1.Milk reception platform	Physical	Y	Y	N	Y	Y	Not a CCP
	Chemical	Y	Y	N	N	-	Not a CCP
	Biological	Y	Y	N	Y	Y	Not a CCP
2. Transferring milk in to chill tanks through muslin filter.							
	Physical	Y	Y	N	N	-	Not a CCP
	Chemical	-	-	-	-	-	-
	Biological	-	-	-	-	-	-
3.Milk Chilling and storage							
	Physical	Y	Y	N	N	-	Not a CCP
	Chemical	Y	Y	N	N	-	Not a CCP
	Biological	Y	Y	Y	-	-	CCP-1(B)

4. Pumping to pre-heating tank							
	Physical	-	-	-	-	-	-
	Chemical	Y	Y	N	N	-	Not a CCP
	Biological	-	-	-	-	-	-
5. Heat Exchangers.							
	Physical	Y	Y	N	Y	Y	Not a CCP
	Chemical	Y	Y	N	N	-	Not a CCP
	Biological	-	-	-	-	-	-
6. Mixing tank							
	Physical	Y	Y	N	Y	Y	Not a CCP
	Chemical	Y	Y	N	N	-	Not a CCP
	Biological	Y	Y	N	Y	Y	Not a CCP
7.Balance tank							
	Physical	Y	Y	N	N	-	Not a CCP
	Chemical	-	-	-	-	-	-
	Biological	Y	Y	N	N	-	Not a CCP
8.Pasteurizer							
(a). Regenerator							
	Physical	Y	Y	N	Y	Y	Not a CCP
	Chemical	Y	Y	N	N	-	Not a CCP
	Biological	Y	Y	N	N	-	Not a CCP
(b). Heating & Holding tube							
	Physical	Y	Y	N	Y	Y	Not a CCP
	Chemical	Y	Y	N	N		Not a CCP
	Biological	Y	Y	Y	-	-	CCP-2(B)
(c). Cooling/ Cooling area							
	Physical	Y	Y	N	Y	Y	Not a CCP
	Chemical	Y	Y	N	N	-	Not a CCP
	Biological	-	-	-	-	-	-
(d)Chilling							
	Physical	Y	Y	N	Y	Y	Not a CCP
	Chemical	Y	Y	N	N	-	Not a CCP
	Biological	-	-	-	-	-	-
9.Homogenizer							
	Physical	Y	Y	N	N	-	Not a CCP
	Chemical	Y	Y	N	N	-	Not a CCP

	Biological	Y	Y	N	Y	Y	Not a CCP
10.Cream separator							
	Physical	Y	Y	N	N	-	Not a CCP
	Chemical	Y	Y	N	N	-	Not a CCP
	Biological	Y	Y	N	Y	Y	Not a CCP
11.MST							
	Physical	Y	Y	N	Y	Y	Not a CCP
	Chemical	Y	Y	N	N	-	Not a CCP
	Biological	Y	Y	Y	Y	N	CCP-3(B)
12.Adding vitamin AD_3							
	Physical	Y	Y	N	Y	Y	Not a CCP
	Chemical	Y	Y	N	N	-	Not a CCP
	Biological	Y	Y	N	N	-	Not a CCP
13. Temporary storage tank and filter.							
	Physical	Y	Y	Y	-	-	CCP-4 (P)
	Chemical	Y	Y	N	N	-	Not a CCP
	Biological	Y	Y	N	N	-	Not a CCP
14. Bottle filers/filling							
	Physical	Y	Y	N	N	-	Not a CCP
	Chemical	Y	Y	N	N	-	Not a CCP
	Biological	Y	Y	N	N	-	Not a CCP
15. Temporary Chilling Room							
	Physical	Y	Y	N	N	-	Not a CCP
	Chemical	Y	N	N	N	-	Not a CCP
	Biological	Y	Y	Y	-	-	CCP-5 (B)
16. Dispatch of bottles							
	Physical	Y	Y	N	N	-	Not a CCP
	Chemical	-	-	-	-	-	Not a CCP
	Biological	Y	Y	N	N	-	Not a CCP
17. Transportation	Physical	Y	Y	N	N	-	Not a CCP
	Chemical	Y	Y	N	N	-	Not a CCP
	Biological	Y	Y	Y	-	-	CCP-6 (B)

(Source :SLSI)

4.1.7Critical limit Validation for Pasteurized homogenize Fresh milk and Low Fat milk cans.

Table. 4.11 Critical limit Validation chart for Pasteurized homogenize Fresh milk and Low Fat milk cans

CCP	Justification	Validation for Critical limits
CCP-1(B)	Proliferation of microbial to unacceptable level due to favorable temperature of milk	Maintain temperature below $+4^0$C (Walstra, 1998) not later than 3 hours.
CCP-2(B)	Remains of pathogenic microorganisms and spores due inadequate time-temperature combination.	Temperature above 72^0C for at least 20 seconds. (SLS 181:1983)
CCP-3(B)	Growth of microbial count to unacceptable hazards level during storage due to use of above 80^0C deactivate natural bacteria inhibitors.	Need to be maintain temperature lower than 4^0C
CCP-4(P)	Presence of Physical materials that can be contamination in the process line. (Gasket material, Metal partials.)	Use of a 100 mesh sized mesh. Visual inspection.
CCP-5(B)	Finish products are keep for several hours/days before distributed. High possibility of proliferation of microbial.	Vehicle temperature need to be maintain below 4^0C
CCP-6(B)	Transportation to remote out lets takes about 2-10 hours. Possibility of increase the temperature which favorable for microbial proliferation.	Maintain the internal temperature below 4^0C through out the transportation period.

4.1.8 Process Control Chart and Capability Analysis

4.1.8.1Process Control Chart and Capability Analysis - Milk reception chill bath

Once the critical limits were established for the identified CCPs. the control charts need to the HACCP plan. Control charts are grown according to statistical calculations. These calculations have characteristic errors due to change of operational conditions. Technically correct control process may be interpreted in differently in statistical control charts.

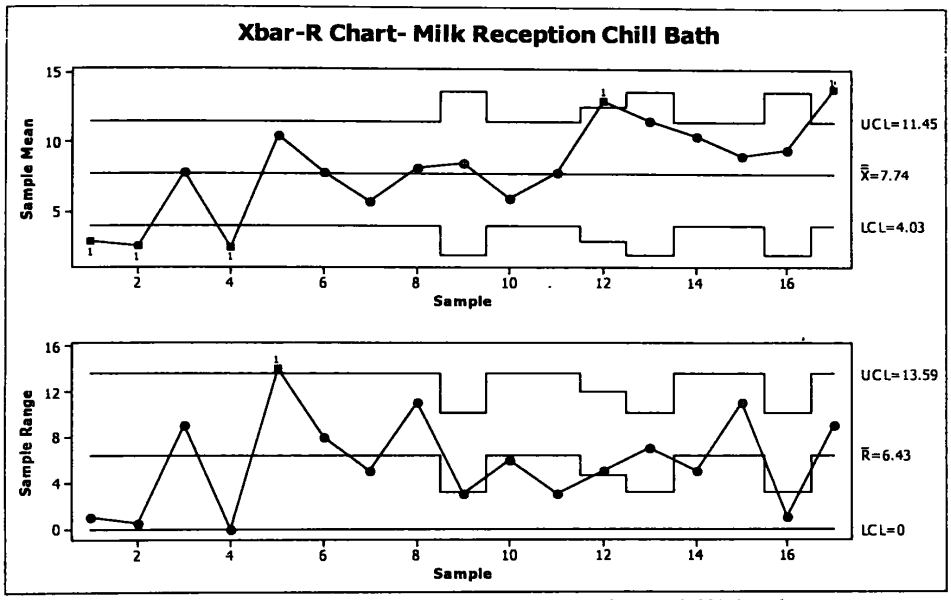


Fig. 4.6 Process control chart-milk reception chill bath

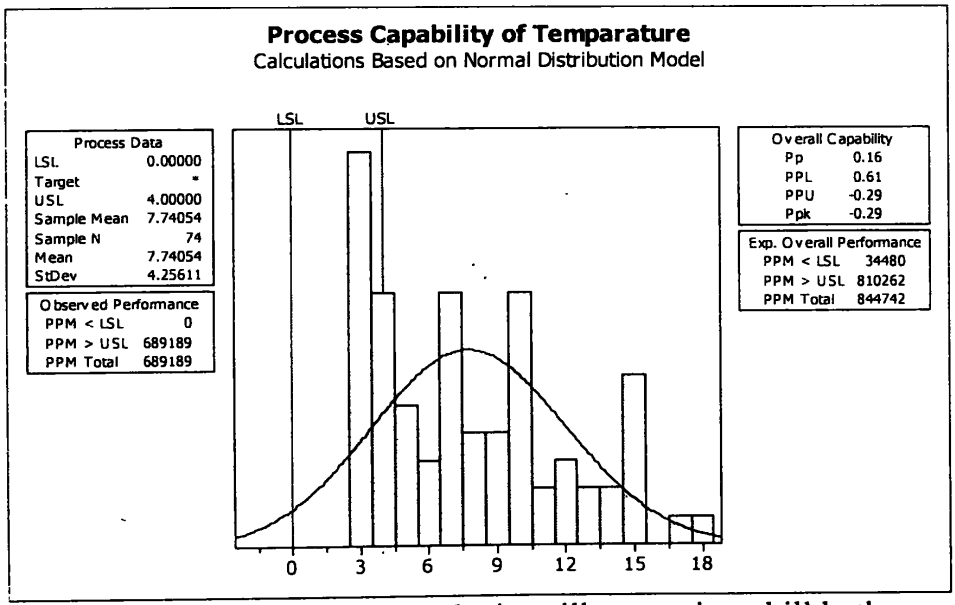


Fig. 4.7 Process capability analysis-milk reception chill bath

Calculated P_PK value indicates the process need to be further improver to increase the efficiency of the chilling process.

4.1.8.2. Process control Chart and Capability Analysis -Milk Storage Tank (MST)

Process control Chart

HACCP control charts were used to analyze and monitor the application of critical limits for all CCPs. The upper control limit can be used as a measure to indicate drift in the process and it is help to adjust the process to maintain control before the CCPs are actuality deviates from its critical limits.

According to the following graph the upper control limit is 4.639^{0}C. Critical limits for the MST is 4^{0}C. But statically controls and technical controls were wary due to some other factors. That may due to regular opening of room door or activations of defrost cycles. Those factors need to be further analyze to come to a proper conclusion about the process.

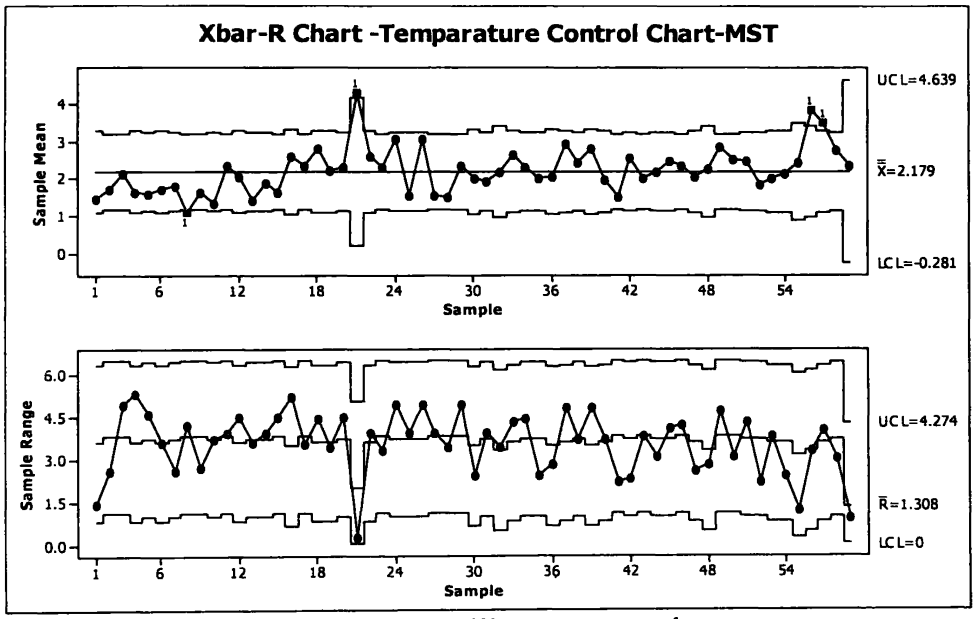


Fig. 4.8 Process control chart-milk storage tank

Process Capability Analysis

As a part of the HACCP plan the critical limit for each critical point within the process has been established. These limits may have both maximum value and minimum value.

That is temperature needs to maintain below 4^{0}C for microbiological safety and above 0^{0}C for retention of product quality. (Milk freezing point is –0.53^{0}C. Organoleptic quality of milk decrease at lower temperature than that.)(Davis,2001).

According to the chart P_PK value is 0.38. That showed process need to be improved. Even though statistical control limits are not meet the requirement technical controls are with in the expected limits.

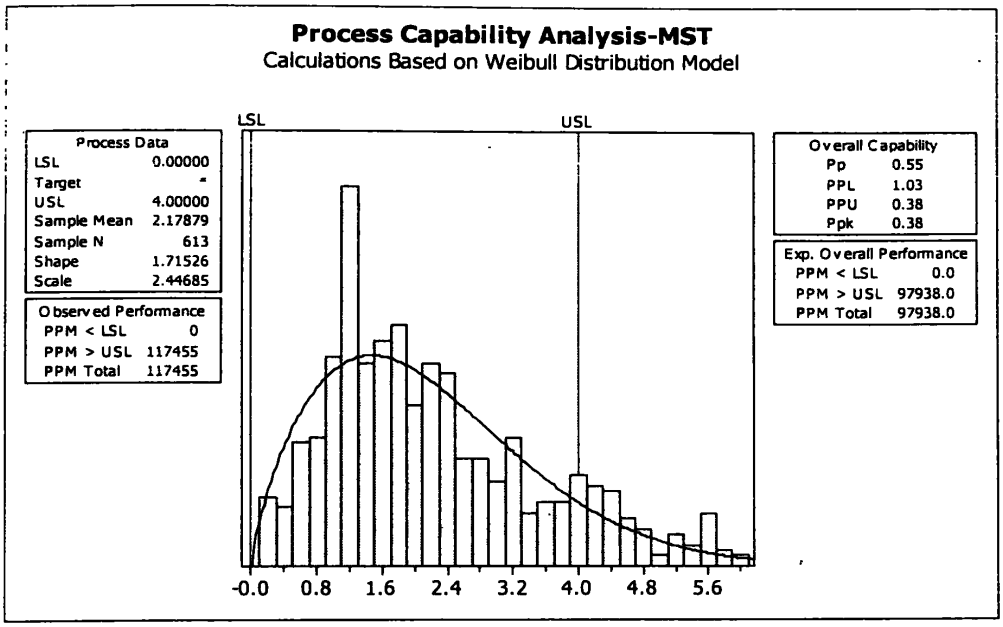


Fig. 4.9 Process capability analysis-milk storage tank

4.1.8.3 Process control Chart and Capability Analysis -Holding-Tube

Process control Chart

HTST pasteurizing temperature is given as minimum 72^0C for 20 seconds. This time-temperature is taken as the critical limit. According to the operational data, limits were wary from 82^0C to 91.58^0C. Operational limits were well above the critical limits to fulfill the minimum temperature requirement.

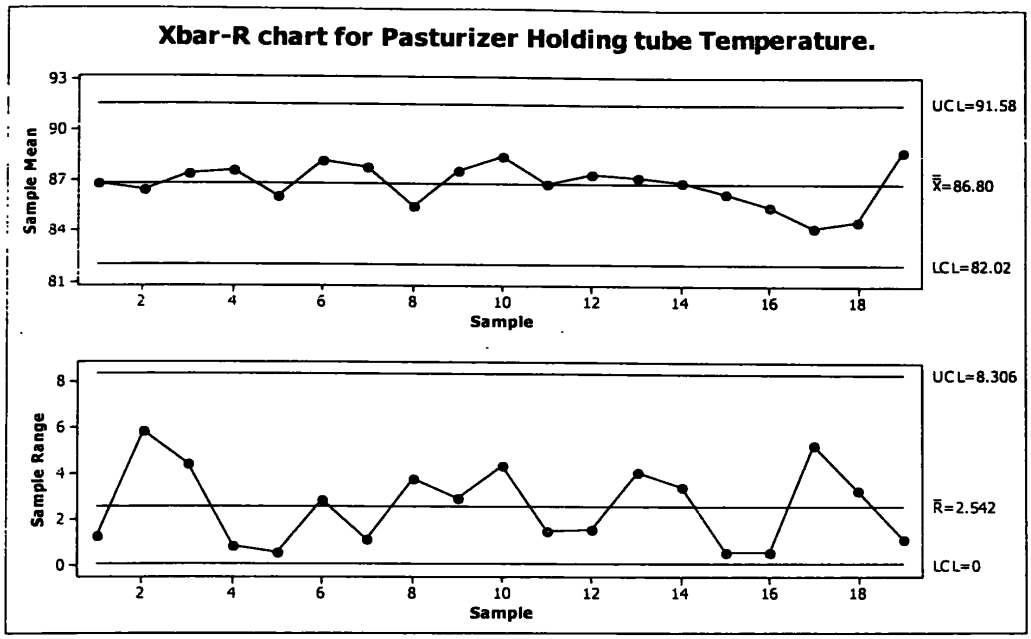


Fig. 4.10 Process control chart-Pasteurizer-Holding Tube

Process Capability Analysis

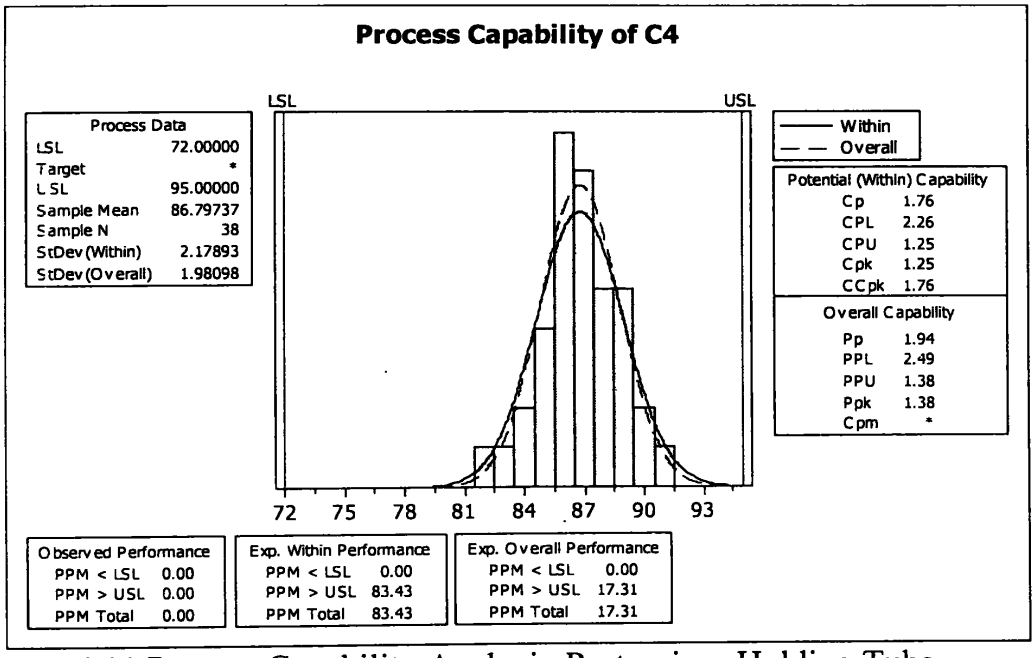


Fig. 4.11 Process Capability Analysis-Pasteurizer-Holding Tube

According to the calculated data C_PK value was 1.25. This value is just below the reference C_PK value of 1.33 symbolized highly capable processes. Further according to reference C_PK above 1 – 1.33 is taken, as process is barely Capable Process. Since C_PK 1.25=<1.33 it is taken as a highly capable process.

4.1.8.4 Process control Chart and Capability Analysis - Finish product storage chill room

Process control Chart

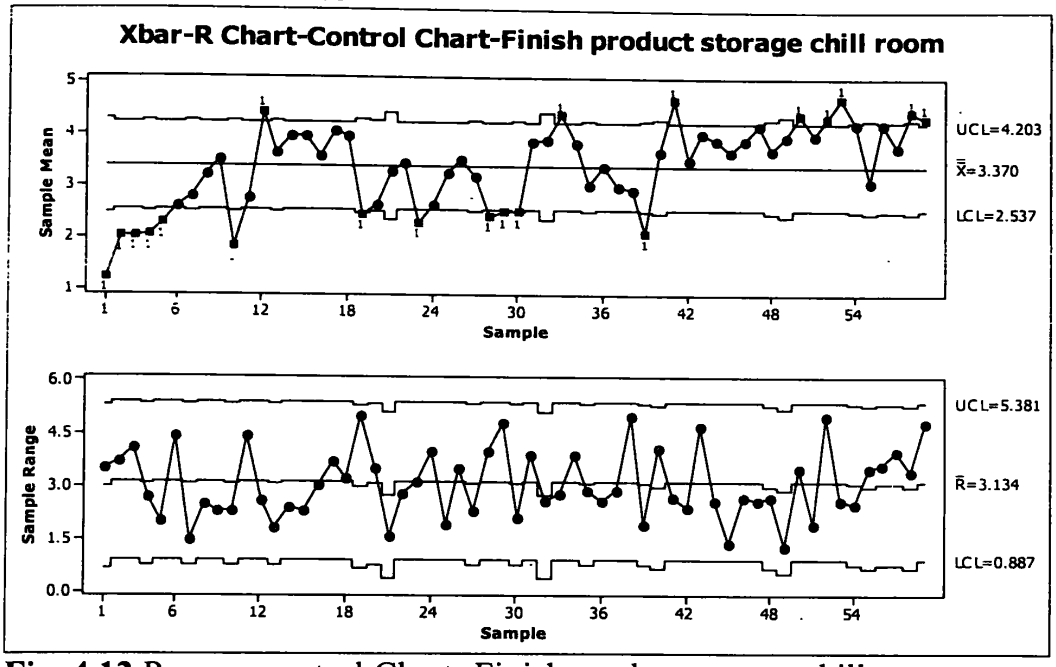


Fig. 4.12 Process control Chart- Finish product storage chill room.

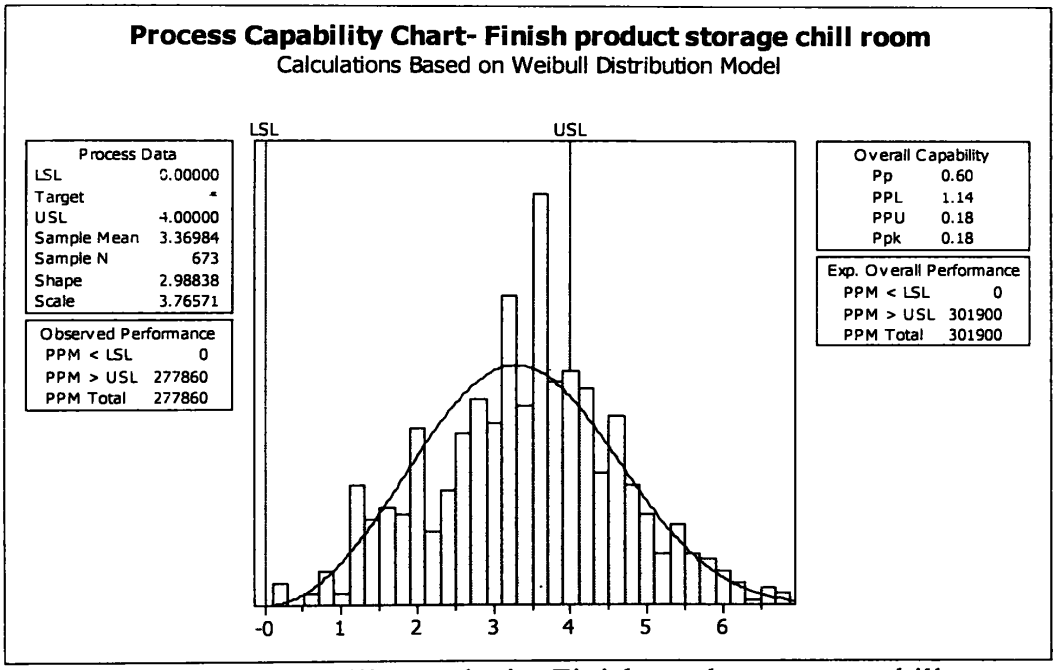


Fig. 4.13 Process capability analysis- Finish product storage chill room.

According to the control chart the temperature is just above the critical limit that has been established. P_PK value of process capability chart is 0.38. This reveal the process is needed to be improved according to statistical calculations. Technical controls and other factors need to be analyzed.

4.1.8.5. Process control Chart and Capability Analysis - Transportation

HACCP control charts need to be constructed according to the temperature of the milk transport vehicles. It was not established due to lack of available time and opportunity to collect data from the vehicles.

4.1.9Established Critical limit for Pasteurized homogenize Fresh milk and Low Fat milk cans

Table. 4.12 Established Critical limit chart for Pasteurized homogenize Fresh milk and Low Fat milk cans

CCP	Justification	Validation for Critical limits
CCP-1(B)	Proliferation of microbial to unacceptable level due to favorable temperature of milk	Maintain temperature below 4^0C (Walstra, 1998) not later than 3 hours.
CCP-2(B)	Remains of pathogenic microorganisms and spores due inadequate time-temperature combination.	Temperature above 72^0C for at least 20 seconds. (SLS 181:1983)
CCP-3(B)	Growth of microbial count to unacceptable hazards level during storage due to use of above 80^0C deactivate natural bacteria inhibitors.	Need to be maintain temperature lower than 4^0C
CCP-4(P)	Presence of Physical materials that can be contamination in the process line. (Gasket material, Metal partials.)	Use of a 100 mesh sized mesh. Visual inspection.
CCP-5(B)	Finish products are keep for several hours/days before distributed. High possibility of proliferation of microbial.	Vehicle temperature need to be maintain below 4^0C
CCP-6(B)	Transportation to remote out lets takes about 2-10 hours. Possibility of increase the temperature which favorable for microbial proliferation.	Maintain the internal temperature below 4^0C through out the transportation period.

4.1.10 HACCP plan for Pasteurized homogenized fresh milk and low fat milk cans

Table 4.13 HACCP plan

Process step	Identified Hazard	Control limit	Monitoring procedure.	Corrective action	HACCP Records	Verification Procedure.	Responsibility
Milk reception chill bath. CCP-1	Biological	Maintain temperature below 4^0C	What Temperature How Digital thermometer. Who Mixing OA Frequency Hourly	oInform to maintenance department. oImmediately thermized the milk and store in another chill tank.	o Chill bath temperature records. o Maintains records	oQuality Assurance Executive collects the records. Reported to factory engineer. oEngineering Executive check records every day	Team leader-Maintenance department.
Pasteurizer-Holding Tube CCP-2	Biological	Minimum heat temperature of 72^0C for 20 seconds	What Temperature How Computer Display Who Mix team leader Frequency 30 minuets interval at machine in operation.	oMonitor the auto recycling. oInform to maintain department.	o Log sheets oMaintains Log sheets.	o	Team leader-Maintenance department.

MST CCP-3	Biological	Regular maintain temperature below 4^0C	<u>What</u> Temperature <u>How</u> Digital Display/control panel at the maintenance control room <u>Who</u> Technical Assistant <u>Frequency</u> Hourly	o Discard the lot if the microbial count exceeds the hazard limit. oImmediate filling into bottles.	o MST log sheet. oMaintenance logsheet.	oTechnical Assistant repots to the QA department. oEngineering Executive check records every day	Team leader-Maintenance department.

Temporary storage tank filter. CCP-4	Physical	Use of 100 Mesh sized filter.	<u>What</u> • Patches and torn areas • Proper isolation of the filter to the pump <u>How</u> Naked eye <u>Who</u> Production team leader <u>Frequency</u> Beginning of the filling process	Replace a new mesh. Re filter.	oMaintains log.	o Mixing team leader inform to Maintenance team leader. oEngineering Executive check records every day	Team leader-Maintenance department.
Finish product storage tank CCP-5	Biological	Keep temperature below 4^0C through out the period.	<u>What</u> Temperature <u>How</u> Digital Display/control panel at the maintenance control room <u>Who</u> Technical Assistant <u>Frequency</u> Hourly	Stop delivery and discard if the count is unacceptable.	oTemperature control log.	o Mixing team leader inform to QA department and to maintenance department. oEngineering Executive check records every day	Team leader-Maintenance department.

Transportation. CCP-6	Biological	Vehicle temperature keep below 4^0C during milk tans potation	<u>What</u> Temperature <u>How</u> Dial Display at chill truck body. <u>Who</u> • Security persons at the factory gate. • Store keepers at cargills outlets <u>Frequency</u> Each Delivery	Reject the delivery if acidity and COB test is positive if the temperature is above the limit.	o Temperature log sheet that is carried by the delivery person. o Log sheet at the factory gate.	o Cold room Team leader inform to maintenance department and QA department. o Team leader check records for every delivery.	Team leader-Maintenance department.

4.2. Discussion.

With regard to development process of hazard analysis plan, seven principles were concerned which guided a systematic process to identifying Critical Control Point to implementing of the plan to the establishment.

In this project work the hazard analysis was done to the existing practices of the establishment as given in the guidelines. HACCP Plan tried to address the possible hazards that were associated with the product. As a general rule before implementing or developing the HACCP plan, relevant Good Manufacturing Practices (GMP) need to implement. GMP manual was developed according to the considering processing steps of the two milk cans and other general standards with reference to SLSI and other published data relating to factory operations. GMP needed a proper implementation with relevant modifications.

Supplier Quality Assurance (SQA) certification makes sure that the raw material does not contain hazards. Company needed to have specification about the raw material. According to SQA there was no hazards to be identify with the raw martial. There was no positive results for some adulterants such as starch, salt, tested in the laboratory. Information or reported cases were unable found with regard to radio active compounds, antibiotic etc. Since milk is taken from the villages around the factory would not contain such elements due to absence of large hospitals, chemical factories, dumping sites etc. But periodic testing is recommended.

Good Agriculture Practices (GAP) and hygienic collection of milk at collecting centers shall prevent some of possible hazards. Chemical contaminations and adulterations prevent at household level and periodic systematic testing identifies such suppliers and necessary actions are possible. For skim milk powder and Vitamin A and D fortification liquid mixture the supplier certification was considered.

Milk contains initial bacterial count to certain extent, depending on the hygienic handing of milk. Irrespective of the keeping temperature a lower initial count ensures longer time taken to be spoiled. Combination of low initial count and low storage temperature is preferred. There is no real point in lowering the temperature to below 4^0C. But globally it is accepted as most suitable temperature to avoid rapid proliferation of common micro organisms that present in milk.

Milk chill bath at the milk reception flat form was taken as the first Critical Point to be controlled. Generally raw milk is transported on "Land Master Tractors", bicycles etc, in stainless steel or aluminum cans under the direct sun light. It results in reaching

a favorable temperature for bacterial growth. Average temperature remains near to environment temperature. High initial bacterial count would require different time-temperature combination than the standard. Ability of rapid cooling is very important in chill tank. Process control charts illustrate that the cooling process need to be improved. Since the milk kept for several hours before thermization keeping them below 4^0C is needed and time need to be recorded every hour as given in the manual.

Pasteurizer–holding tube was the next Critical Control Point to monitor. HTST pasteurization limit is the critical limit to kill or reduce the microbial hazard to an acceptable level. It is generally 20 seconds at 75^0C temperature. Presently factory holding tube operates at 80^0C-87^0C for 20 seconds. Virtually all vegetative microorganisms are killed but not bacterial spores. The equipment specially designed to re-circulate the milk if it not heated beyond 80^0C in the holding tube. Recording the time of holding tube has to be done (Walstra, 1999).

Pasteurized milk is stored at MST for several hours (5-12 hours) before filled to the bottles. At heat treatment about 85^0C for 20 seconds the bacterial growth inhibitors are eliminated than standard HTST treatment. Destruction of bacterial inhibitors would reduce the shelf life of this product than normal HTST treated one. Because of that reason next processing steps up to consumption of the product needed to be monitored to prevent occurrence of a biological hazard. Heat resistant bacterial spores and some bacteria such as *Bacillus cereus* can proliferate in short period of time if the conditions would not property controlled. Below the 4^0C temperature need to be maintained.

Even though the GMP is effective there is every possibility that milk would contaminate with metal, plastic or a gasket material from pasteurizer, homogenizer, storage tanks, etc where vibrations and rotating parts are present. Dropping of milk sampling equipment, a plastic cup or a lid would possible when collecting samples and fortification steps. The filter attached to temporary storage tank shall need to be inspected for its proper working condition such as no damaged areas or no torn places.

Finished bottles are stored in finish product storage chill room for few hours to one to three days depending on delivery schedules of two products. Rapid proliferation of microorganisms results a hazard product to end consumer. To avoid that temperature need to be kept lower than 4^0C.

Finished bottles are transported to far away place which takes about 2-10 hours. Temperature need to be monitored to keep it below 4^0C through out the delivery period.

Characteristic organoleptic qualities of milk destruct at the freezing point of milk, -0.53^0C. Because of that lower control limit is taken as 0^0C to save such qualities.

CHAPTER 05

Conclusion and Recommendation

5.1 Conclusion

- GMP manual was developed for the current processing steps and highlighting other general aspects. Number of hazards to be controlled by applying effective GMP programme.
- Several biological, chemical and physical hazards were identified which associated with the pasteurized homogenized fresh milk and low fat milk processes.
- No hazards were identified in raw materials of two milk products.
- Critical Control Points were determined with the application of CODEX decision tree.
- Following Critical Control Points were identified as common to both milk can processes.
    - Milk reception chill bath
    - Pasteurizer – Holding tube
    - Milk storage tank
    - Filter attached to temporary storage tank before bottle filling.
    - Finished product storage chill room
    - Transportation.
- Milk reception chill bath temperature need to maintain below 4^0C to avoid the rapid proliferation of bacterial count. HTST (72^0C for 20 second) is the minimum temperature is to monitor with the pasteurizer.
- Filter enclosed to temporary tank needs to monitor to prevent of occurrence of physical mater in the final product. Mesh size 100 is taken as suitable for the filter and naked inspections need to be done at the beginning of the filling process.
- The temperature 4^0C is taken as the control limit for those after pasteurization process such as MST, Finish product storage chill room and transportation to ensure a safe product to customer.
- Below 0^0C is taken as minimum temperature to prevent destruction of organoleptic qualities given that those changes may occur at -0.53^0C, the freezing point of milk.

5.2 Recommendation

- Introduction of metal detector after the bottle filling process before dispatching.
- Current GMP practices needed to be updated to successful implementation of HACCP plan.
- Current Supplier Certification Process needed to be revised.
- Some areas/steps of current product flow path need to be reconsidered.
- Development of separate finished product chill room or separated area on current chill room is recommended.
- Process steps that were identified at Statistical Process Capability Studies needed to be improved with considering Technical Process Capabilities.
- Computerized processing system's software/equipment and relevant sensors (thermo, pressure, etc) needed to be calibrated.

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Appendix A

GMP manual

No. (01) **Raw material reception**

(a). Suppler certification for all ingredient and all raw material.

(b). Water should be chlorinated & dechlorinated, when using well water in the factory ground and the water that is taken from the out side sources.

(c). Water should be treated with relevant chemicals to remove excess hardness to be found with the water.

(d). Society milk should be bring to the factory within 3 hours of milking & immediately chill after the platform tests and recording the weights of the milk.

(e) Peroxide test should be carried out for every sample.

(f) Delvo test/ culture activity test (for Antibiotic) should be carried out according to pre-determined sampling processes.

No. (02) **Milk reception platform**

(a). Once finish the routine tests to the raw milk, it should be filtered with appropriate mesh sized muslin clothes.

(b). Mesh and filter should be cleaned at the beginning of the milk collection.

(c). The milk sample, which used for testing should be discarded, instead of adding back to the processes.

(d). Milk that taken in to the laboratory should not be re-collected to the process.

(e). Milk carrying persons should not take part in the weighting or milk filling process in to the chilling tank and factory worker should where protective clothiers.

(f). The milk puncher and the milk sample collecting cups should not keep on the ground and all the equipments should be cleaned at the end of the milk collection.

No. (03) **Chilling tank**

(a). Chill tank should be clean according to the given documented instructions using cleaning chemicals at the beginning and the end of the collecting process.

(b). Chill tank should be kept close all the time.

(c). Raw milk should be processed within 36 hours from acceptance if the milk has been kept at not more than 6 C^0(Walstra, 1999).

(d). Raw milk must be processed within 48 hours from acceptance if the milk has been kept at 4 C^0

(e). Raw milk which has not been refrigerated must be processed as soon as possible after acceptance at the processing establishment. (such circumstances when the chilling bath breaks down).

No. (04) **Temporary storage tank**

(a). Cleaning should be done at the beginning and at the end of the processing according to the cleaning manual.

No. (05) **Heat Exchangers (Pre-heating)**

(a). CIP cleaning should be done according to the given cleaning manual.

(b). Replacing of plates, manual cleaning of plates, inspections need to be carried out according to the given instructions.

No. (06) **Pasteurizer**

(a). Automated self cleaning process should allow to the pasteurize. (Necessary chemicals should be supplied according to the required concentration.

(b). Correct time & temperature should be maintained all the time.

(c). Appropriate pressure should be maintain all the time, of pasteurize in operation.

(d). Replacing of parts such as plates, gaskets, valves, etc need to be done according to maintains schedules.

No. (07) **Homogenizer**

(a). CIP cleaning should be done at the beginning and at the end of the process.

(b). Any leakage should be avoided.

No. (08) **Cream Separate**

(a). Manual cleaning should be done at the beginning and end of the operation.

(b). Cream collection should be done in to suitable vessels and cream should be use in a other processes (Manufacturing of ice cream) or discard appropriately.

No. (09) **Mixing tank**

(a). Mixing tank should be properly clean at the times according to the instructions.

(b). Polythene, cardboard, Bag stings or any other foreign material should not drop in to the mix tank/mixer.

(c). Mixing tanks door should be closed all the time except ingredient adding occasions.

No. (10) **MST**

(a). Scheduled temperature should be maintain all the time.

(b). Cleaning should be done according to the cleaning manual.

(c). Manual cleaning should be done in given time schedules.

(d). MST tanks lids should be properly closed in all the time, except the sample collection occasions.

(e). Sample-collecting equipment should be cleaned/sterilized.

(f). Sample collector should be worn a special clothiers that covers arm, face, hair.

(g). Should take all the action to avoid dropping of any item (Sampling cup and equipment) in to the tank. Sudden drop of such should be reported to the mix control unit and to the QA & D.

No. (11) **Temporary storage tank and muslin filter**

(a). Stable filter should be install at the beginning of the process.

(b). Filter should be cleaned at the beginning and at the end of the process.

(c). Muslin filter should be inspect for damages at the starting and the end of the process and should be replace immediately if there is a torn.

No. (12) **Bottle filling**

(a) Manual bottle filing persons should wash hands using hand wash chemicals, worn protective clothiers including hair covers masks.

(b) Filling nozzles need to be clean at the begin and the end of the filling process.

(c) Surface sterilization of filling table, filling nozzles need to be done using steam at the beginning of the filling processes.

(d) Bottles and caps should be properly washes with chlorinated water.

(e) Caps should be immediately sealed and once finish the capping, bottles should be washed by lukewarm water to remove overflowed milk at the outer surface.

(f) Physical damages to the bottles such as droppings, tamping, pressing should be avoided.

(g) Un sealed or broken sealed bottles should be re-capped.

(h) Bottles should immediately need to chill at chilling rooms in under 4 C^0 temperature.

No. (13) **Temporary Chilling room/ Rework Room.**

(a). Maintaining correct temperature of below 4 all the time. (Except de-frost time)

No. (14) **Dispatching and loading**

(a). Bottle should be dispatch only from the dispatch area.

(b). Finish bottles should not store or transport throw raw material storage area or any other pathways.

(c). All the action should be taken to cross contamination.

(d). Carefully larding need to be done to avoid any physical damages to the finished bottles.

No. (15) **Cleaning and disinfections**

(According to SLS 872:1989, 4.2)

(a). Cleaning and disinfections should be carried out foe every process step.

(b). Milk suppliers and milk societies has to given fully instruction about cleaning and safe handling of milk.

(c). All the machineries and equipment should be clean at the beginning and at the end of the each operation according to cleaning manuals. Occasional manual cleaning and disinfections of machinery need to be carried out to pre-determined machinery.

(d). Cleaning manual should consist of all the instructions about cleaning processes including CIP systems, COP systems and chemical concentrations and preparation instructions, rinsing cycles, use of chlorinated water, use of de-chlorinated water, use of hot and cold water, use of anti-bacterial agents, use of steam and relevant other information about safety dandling of such compounds and activities.

No. (16) **Pest control**

(According to SLS 872:1989,4.2)

(a). Electrical fly traps should be located on ceiling at suitable entrances.

(b). Pest control activities/ fumigation should be carried out according to pre determined time periods.

No. (17) **Microbiological testing**

(a) Salmonella

According to SLS 516:1992,5

(b) Coliforms, Fecal coliforms and *Escherichia coli*

According to SLS 516:1991,3

(c) Yeast and Molds

According to SLS 516:1982,2

(d) *Fecal streptococci*

According to SLS 516:1982,4

(e) Colony count technique

According to SLS 516:1991,1

Necessary testing should carried out including raw milk, bottles and caps, filling equipments, MST, factory floor, bottle filters hands, finished milk cans, etc.

No. (18) **Machine and equipment**

(According to SLS 872.1989.4.2)

(a) All the machine and equipments in the plant should be maintained properly.

(c) Appropriate calibrations, checking and installations (new/re) should be done according to the relevant instructions.

No. (19) **Personal hygiene and sanitation**

(a) All persons that are work in the factory should be wear protective clothier, need to wear boots or shoes, hair protectors or head covers, etc

(b) Jewelry should be removed before enter in to the working area. Hand bands, strings, etc should be removed.

(c) Any sick or disease persons should not enter in to the working areas.

(d) All persons should wash their hands by brushing with recommended sanitizer and brush.

No. (20) **Laboratory testing**

(a). Good laboratory practices (GLP) need to be maintain.

(b). All tests should be done in the laboratory except from platform tests.

(c). Safety protective clothier, waggles, masks should be use at necessary steps

(d). Relevant analysis to be done at external laboratories at pre-determined schedules.

Appendix B

Date	Time	Temparature	Date	Time	Temparature
2-Jun	6:00	2.5	12-Jun	10:00	10
	7:00	2.5		11:00	4
	8:10	3.3		12:00	6
	9:00	2.5		13:00	5
	10:00	3.5		14:00	5
3-Jun	12:00	3	13-Jun	12:00	7
	14:00	2.5		13:00	10
	15:00	2.5		14:00	8
	16:00	2.5		15:00	7
	18:00	2.5		16:00	7
	11:00	13	14-Jun	10:00	14
	12:00	11		10:30	15
	13:00	6		11:00	10
	13:30	5			
	14:00	4			
5-Jun	6:00	2.5	15-Jun	10:00	8
	7:00	2.5		11:00	15
	8:00	2.5			
	8:30	2.5			
	9:00	2.5			
6-Jun	9:30	18	16-Jun	10:00	12
	10:30	13		11:00	12
	11:00	10		12:00	7
	11:45	7		13:00	11
	13:00	4		14:00	10
7-Jun	10:00	12	19-Jun	6:00	7
	11:00	10		7:00	4
	13:00	8		10:30	15
	14:00	5		12:00	9
	14:30	4		14:00	10
8-Jun	10:30	9	20-Jun	10:00	10
	11:10	7		11:00	9
	11:50	5			
	12:00	4			
	12:30	4			
9-Jun	9:30	15	21-Jun	10:00	17
	10:00	9		11:00	14
	10:30	6		12:00	8
	11:00	7		13:00	15
	13:00	4		14:00	15
10-Jun	10:30	10			
	11:00	7			
	*	*			
	*	*			
	*	*			

Appendix C

26-May	16:00	Low fat mil	87.4
	18:30	Fresh milk	86.2
29-May	6:00	Fresh milk	83.5
	6:30	Fresh milk	89.3
30-May	16:00	Fresh milk	89.6
	16:30	Fresh milk	85.2
31-May	17:00	Low fat mil	87.2
	17:30	Low fat mil	88
1-Jun	15:30	Fresh milk	86.3
	16:00	Fresh milk	85.8
2-Jun	13:00	Low fat mil	89.6
	15:00	Fresh milk	86.8
3-Jun	13:00	Fresh milk	88.3
	13:30	Fresh milk	87.2
5-Jun	7:00	Fresh milk	87.3
	7:30	Fresh milk	83.6
6-Jun	13:00	Fresh milk	89
	13:30	Fresh milk	86.1
7-Jun	14:00	Fresh milk	90.6
	15:00	Low fat mil	86.3
8-Jun	12:40	Fresh milk	87.5
	13:00	Fresh milk	86.1
9-Jun	12:30	Law fat mil	88.1
	13:30	Fresh milk	86.6
10-Jun	13:30	Law fat mil	89.2
	14:00	Law fat mil	85.2
12-Jun	*	Fresh milk	88.6
	*	Fresh milk	85.2
13-Jun	17:00	Fresh milk	86
	17:30	Fresh milk	86.5
14-Jun	13:40	Law fat mil	85.2
	14:30	Fresh milk	85.7
15-Jun	13:30	Fresh milk	86.8
	14:00	Fresh milk	81.6
16-Jun	13:00	Law fat mil	83
	14:00	Fresh milk	86.2
17-Jun	16:00	Law fat mil	88.2
	17:00	Fresh milk	89.3

Appendix D

	30-Apr	1-May	2-May	3-May	4-May	5-May	6-May	7-May	8-May	9-May	10-May	11-May	12-May
8:00	0.8	3.2	0.9	0.7	0.3	1.1	2.9	0.7	1.5	2.5	0.5	1.8	1.2
10:00	*	2.3	4.4	5.6	6.1	4	1.9	3.8	3.2	4	4.4	4.1	3.8
12:00	2.1	2	3.2	8.4	2.5	3.8	1.8	0.4	1.8	0.8	2.5	5.9	0.9
14:00	1.7	1.1	1.2	1.1	1.1	2	2.3	1	1.8	2.7	0.7	0.9	1.2
16:00	1.2	1.3	1	*	0.7	1.1	2.8	1.1	3.1	0.5	1.1	0.7	2.1
18:00	1.3	0.6	2.1	1.1	1.7	1.9	2.2	0.6	1.1	1.1	1.5	2.3	1.1
20:00	1.5	1.7	5.4	1.1	1.4	1	2.7	0.7	1.6	*	2.2	5.2	0.2
22:00	*	2.8	3.8	1.1	4.8	1	2.2	4.3	1.8	0.6	3.5	9.6	3.6
0:00	1.4	1.6	1	2.8	2.6	6.8	0.5	0.1	1.7	0.7	2.9	1.9	0.7
2:00	2.2	1.4	0.9	1.4	1.2	6.2	0.3	0.1	1	0.7	3.4	0.9	0.5
4:00	1.1	1.7	1.1	0.3	0.9	0.4	0.3	0.1	0.5	0.7	4	1.2	0.2
6:00	1.1	0.8	0.5	0.9	0.2	0.8	*	0.1	0.6	0.3	1.5	1.7	*

	13-May	14-May	15-May	16-May	17-May	18-May	19-May	20-May	21-May	22-May	23-May	24-May	25-May
8:00	2.6	0.9	0.3	2.9	1.3	1.9	1.1	9.5	1.5	2.7	1.4	1	1.4
10:00	7.4	4.7	5.5	2.7	6.7	4.5	5.3	12.6	4.4	4.5	8.3	1.1	8.3
12:00	1.8	2.4	4.3	0.9	9.6	*	4.3	13.5	4.2	3.1	4	0.1	4
14:00	0.3	2.1	2.7	0.9	2.6	2.3	0.8	16	10.7	2.9	4.2	0.7	4.2
16:00	1.3	1.1	1.1	3.2	1.5	*	*	*	3	2.4	5.8	0.6	5.8
18:00	1.1	1	7	4.4	1.1	1.1	2.4	16	3.1	1.8	0.9	7.4	0.9
20:00	1.9	1.2	2.3	2	1.1	3.1	1.3	*	4.2	1.4	0.9	1	0.9
22:00	4.2	2.6	11.9	3.6	4.5	1.9	1.1	*	5.8	3.1	5.6	4	5.6
0:00	4	0.6	6.2	1.8	5.5	3	1.4	4.4	3	2	3.8	3	3.8
2:00	1.2	0.2	4.1	1.5	5.3	1.8	2.3	4.3	1.5	1.3	3.1	2.1	3.1
4:00	0.5	1.3	0.5	1.3	1.6	1.4	1.8	4.2	0.5	1.2	1.2	0.7	1.2
6:00	1.7	1.2	2.7	3	3.5	1.2	3.7	*	0.8	1.3	2.7	2.9	2.7

	26-May	27-May	28-May	29-May	30-May	31-May	1-Jun	2-Jun	3-Jun	4-Jun	5-Jun	6-Jun	7-Jun
8:00	1	1.9	0.2	*	1	0.5	2	5.2	1.1	1.3	1.1	1.5	0.8
10:00	1.1	2.8	3.4	8.9	4.4	*	6.8	1.2	3	8.6	5.4	4	6.1
12:00	0.1	2.2	2.4	1.5	3.5	2.2	4.4	4.6	3.1	3.5	9	4.8	*
14:00	0.7	2.6	1.2	2.8	0.7	3.4	4.3	1.8	0.9	3.9	4	2.1	5.6
16:00	0.6	3.6	1.9	2.6	3.4	*	4.2	6.2	*	1.4	3	1.8	2.2
18:00	1.4	2.2	1	1.6	1.2	1.6	2.9	2.1	1.2	1.1	2.7	1.8	*
20:00	1	0.7	3.9	0.9	2	*	2.1	1.6	1.9	2.3	5.9	*	1.8
22:00	4	0.6	5.1	7	6.2	3.9	4.2	4.7	2.3	6.3	7	4	1.2
0:00	3	0.5	2.4	1.9	1.6	1.3	6.3	1.2	1.5	6	3.2	2.5	4.5
2:00	2.1	0.5	2.7	3.3	0.5	3.4	1.8	0.8	3.3	1.3	1.6	1.8	1.6
4:00	0.7	0.4	3.1	2.3	1.9	1.2	0.1	1	1.2	1.6	1.1	1.1	2
6:00	2.9	0.2	1.1	1.2	1.2	*	0.3	1	2.6	2.2	1.3	1.2	5.6

	8-Jun	9-Jun	10-Jun	11-Jun	12-Jun	13-Jun	14-Jun	15-Jun	16-Jun	17-Jun	18-Jun	19-Jun	20-Jun
8:00	6.4	1.7	1.4	1.2	1.7	1.7	1.6	2.6	2.5	2.1	2.3	5.2	1.1
10:00	6.1	2.4	1.6	1.8	7.5	7.3	5.2	*	12	5.9	4.5	1.2	3
12:00	4.2	3.1	3.6	4.6	2.1	2.3	2.1	*	*	5.2	4.3	4.6	3.1
14:00	3.2	1.2	3.7	1.2	2.5	1.9	2.7	2.2	*	2.9	1.8	1.8	0.9
16:00	1.8	1.1	2.1	1.1	2.3	2.2	1	2.2	*	3.1	1.4	6.2	*
18:00	1.8	1.1	2.7	2.3	2.1	2.4	1.7	2.3	2.3	2.2	2.6	2.1	1.2
20:00	1.9	0.9	3.3	1.4	1.5	2.1	1.9	1.7	1.1	1.6	1.4	1.6	1.9
22:00	0.5	1.2	7.2	4.8	3.9	5.6	3.6	3.8	3.9	4.9	2.5	4.7	2.3
0:00	1.6	1.1	3.1	1	1.6	1.5	3.1	1.2	1.9	2.1	2.8	1.2	1.5
2:00	1.6	1.2	3.3	1.1	1.3	1.8	2	1.6	2.3	1.6	2.3	0.8	3.3
4:00	1.4	1.4	1.6	1.9	1	2	2.4	1.5	2.1	1.5	2.1	1	1.2
6:00	1.6	1.4	1.7	1.8	4.1	3.5	1	1.6	2.1	1.2	2.1	1	2.6

Appendix E

	30-Apr	1-May	2-May	3-May	4-May	5-May	6-May	7-May	8-May	9-May	10-May	11-May	12-May
8:00	0.5	4.2	1.9	1.9	2.1	5.7	3.1	2.8	3.8	2.5	5.6	3.5	6.7
10:00	*	9.3	1.6	1.9	2.9	2.8	3.7	3.4	10.3	3	3.3	4.4	3.8
12:00	3.6	1.9	1.2	1.3	2.9	2.7	2.7	3.2	7.2	2.8	3	4.5	4.7
14:00	2	0.8	1.4	3.1	2.3	2	2.3	2.9	7.3	1.9	2.2	5.3	4.2
16:00	2.2	1.6	5.3	2.7	2.5	1.3	2.7	2.6	4.4	2.8	1.6	4.6	3.9
18:00	1.8	1.6	2.6	*	3.2	1.3	2.6	2.5	3.7	1.2	1.2	4.5	3
20:00	1.5	1.8	1.6	1.6	2	2	3.3	2.3	3.1	*	1.9	4	3.4
22:00	*	3.8	2.7	1.8	2.8	3.1	2.6	3.3	3.8	2.1	3.9	4.1	4.1
0:00	0.2	1.1	1.2	1.5	2	2.5	3.2	2.4	3.5	0.8	3.2	4	3.5
2:00	0.2	0.8	1.6	1.1	1.2	1.4	2.2	3.8	2.1	0.7	2	3.8	3
4:00	0.1	0.5	1.4	3.8	1.7	1.6	2.3	4.4	2.9	0.7	1.2	4.1	2.9
6:00	0.2	2.5	1.8	1.8	1.7	4.6	*	4.8	4.3	1.6	4	6.1	*

	13-May	14-May	15-May	16-May	17-May	18-May	19-May	20-May	21-May	22-May	23-May	24-May	25-May
8:00	5.5	4.1	2.9	4.2	5.4	4.2	1.2	8.9	2.6	2.7	2.3	4.4	3.9
10:00	5.2	5.3	4.1	5.5	5	5.8	2.1	7.5	7.9	4.3	3.5	4.5	3.9
12:00	8.8	4.1	4	6.6	5.6	*	2	7.6	4.9	3.1	3.1	3.1	3.4
14:00	4.1	3.9	3.3	11.8	3.6	8.5	3.5	8.2	4.2	2.9	1.7	3.2	5.4
16:00	3.1	3.6	2.5	4.9	4.6	*	*	*	2.8	2.4	2.8	2.8	4.6
18:00	4.1	3.6	1.9	3.8	3.6	1.8	3.7	8.7	7.2	1.8	1.6	3.2	3.3
20:00	4	3.8	1.9	3.7	2.4	1.7	2.3	*	3.3	1.4	1.8	2.6	3.6
22:00	3.6	4	4.8	4.2	3.4	2.4	2.7	*	3.6	3.1	6.7	3.3	3.9
0:00	3.2	3.5	4.6	2.9	4.6	0.8	4.7	3.1	4.5	2	5.2	3.2	2.4
2:00	3.6	3	3.2	3	3.5	1.9	3.4	3.6	3.2	1.3	2.5	3	2.6
4:00	3.7	3.1	4.9	3.1	2.7	1.2	1.6	2	3	1.2	1.2	3	1.9
6:00	3.9	5.3	4.5	3.1	3.1	1.2	1.8	*	2.1	1.3	2.5	2.7	3

	26-May	27-May	28-May	29-May	30-May	31-May	1-Jun	2-Jun	3-Jun	4-Jun	5-Jun	6-Jun	7-Jun
8:00	4.5	4.9	6.2	*	7.7	3.9	7.9	4.6	4	4.2	4	4.1	3.1
10:00	2.5	3.3	1.6	3.1	4.8	*	5	1.2	4	4.7	4	6	3.2
12:00	3.1	2.7	1.5	4	6.4	3.3	4.7	5.1	4.1	4.3	4.1	3.4	3.2
14:00	2.3	2.5	1.7	2.7	4.8	4.3	4.2	5	3.6	3.2	3.6	3.1	2.7
16:00	2.7	2.4	1.6	2.3	4.4	*	4.2	3.2	*	7.2	1.2	2.7	1.4
18:00	*	2.5	2	2.1	3.2	5.6	4.6	3	1.2	3.4	2.8	2.3	1.4
20:00	2.8	2.1	1.4	1.9	3.1	*	3.4	3.9	2.8	3	3.5	3.2	*
22:00	4.6	1.9	2.3	2.4	3.6	3.9	5.8	4.8	3.5	3.7	2.7	2.5	2.1
0:00	3	1.9	3.9	2.3	2.7	3.5	6.2	4	2.7	2.5	3.4	1.5	1.7
2:00	3.4	2	3.1	2	3.4	10	3.8	3	3.4	2.4	1.2	1	1.7
4:00	3.2	1.9	2	1.9	2.5	3	36.6	3.4	2	2.1	2.6	2.6	1.3
6:00	2.8	0.9	2.7	2.7	3.7	*	3.4	4.7	2	7.2	2.6	2.6	1.3

	8-Jun	9-Jun	10-Jun	11-Jun	12-Jun	13-Jun	14-Jun	15-Jun	16-Jun	17-Jun	18-Jun	19-Jun	20-Jun
8:00	9	5.9	3.7	2	5	4.1	5.2	4.1	4	4.3	4.5	4.6	6.2
10:00	10.1	5.3	3.8	3.8	5.2	4.6	4.5	7.4	*	7.6	4.3	4.9	5.7
12:00	*	5.3	5	4.6	4	4.1	3.7	7.2	*	*	4.7	4.8	4
14:00	6.9	4.8	3.5	6.7	4.5	3.4	4.7	5	5.4	*	5.9	3.7	6
16:00	5.3	4.1	3.8	8.4	4.3	3.2	8.6	8.2	4.2	*	5.7	4.9	3.7
18:00	*	3.2	3.5	8.8	3.2	3.6	3.7	4.5	3.9	4	5.6	4.4	5.6
20:00	4.8	5.6	4.5	4.2	3.2	3.5	8	4.3	2.7	4.1	3.4	3.3	5.3
22:00	5.2	3.7	2.9	4.3	3.7	3.9	5.2	4.3	3.9	4.4	4.6	4.4	3.1
0:00	2.6	9	3	3.2	2.8	3.4	3.7	4.6	3.6	4	3	3	4.6
2:00	1.2	4.6	2.9	3.5	2.6	3.5	2.9	5.6	2.8	3.8	2.4	3.1	1.2
4:00	3.1	4.9	2.6	3.6	3.7	3.3	2.5	3	3.7	4.4	4.2	3.4	3
6:00	3.8	4.9	2.6	5.2	4.2	3.2	3.5	4.1	2.8	3.1	4	3.4	3.2

Appendix-F

Pre –audit information request form for suppler quality assurance.

1. Company name?
2. Address, contacts?
3. Ownership details, including organizational structure and number of personnel.
4. Production site for this product.
5. How long has the factory been in operation and was the building purpose built?
6. Are their any other types of product manufactured at your factory? (Specify)
7. Does the company operate a food safety management system based on the principles of HACCP?
8. Does the manufacturing site operate to a formal quality system such as ISO 9000, ISO 22000, ISO 14000 and is it certified?
9. Is microbiological testing carried out on site, and if so does this include pathogen testing? (Specify the tests)
10. Are any external contract laboratories used? (to what extend you used them)
11. Is the manufacturing site covered by a pest control contract and, if not, what pest control procedures are in place? (method used, Chemicals used,etc)

    Any external organization involving pest control activity? (Specify)
12. Where is protective clothing laundered? If a contract laundry is used, has it been audited? (Washing quality parameters)
13. Who is responsible for plant hygiene? If contract cleaners are used, how often do they visit?
14. Are any raw materials, intermediate or finished products stored at out side places who is responsible for the condition of these facilities? (Specify the responsibility persons)
15. Are specifications held for all raw materials and finished products?
16. Are written work of procedures and personal hygiene standards available in the company
17. Information about training of staff? (Workers)
18. What vehicles are used for distribution (own/contract), and who monitors their condition?
20. On your knowledge what legislation applicable to the company's operations?

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