

Concept for Pharma Plant Certification

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*Hazard Analysis and Critical Control Point (HACCP) is an effective and rational means of assuring safety from raw material stage to consumption. Preventing problems from occurring is the paramount goal underlying any HACCP system. Seven basic principles are employed in the development of HACCP plans that meet the stated goal. These principles include **hazard analysis, CCP identification, establishing critical limits, monitoring procedures, corrective actions, verification procedures, and record-keeping and documentation.** Under such systems, if a deviation occurs indicating that control has been lost, the deviation is detected and appropriate steps are taken to reestablish control in a timely manner to assure that potentially hazardous products do not reach the consumer.*

HACCP is a management system in which safety is addressed through analysis and control of biological, chemical, and physical hazards from raw production, procurement and handling, to manufacturing, distribution and consumption of the finished product. For successful implementation of a HACCP plan, management must be strongly committed to the HACCP concept. A firm commitment to HACCP by top management provides company employees with a sense of the importance of producing safe products. As per IRCA (International Register of Certification Auditors), ISO 9001 - 20000 QMS who are the Lead Auditors. In view of the increasing focus on safety issues and increasing demand from consumers and importers across the globe, for compliance with Food Safety Standards, the need for the introduction of Safety Management Systems Course (SMS) has become all the more relevant for organisations in the entire pharmaceuticals chain

HACCP is designed for use in all segments of the pharma industry from raw material, processing, manufacturing, distributing, and merchandising till consumption. Prerequisite programs such as current Good Manufacturing Practices (GMPs) are an essential foundation for the development and implementation of successful HACCP plans. Safety systems based on the HACCP principles have been successfully applied in Pharma Processing Plants in most advanced countries. The seven principles of HACCP have been universally accepted by government agencies, trade associations and the industry around the world.

Before moving to details, it would be worthwhile to understand each terms.

HACCP: A systematic approach to the identification, evaluation, and control of safety hazards.

HACCP Plan: The written document which is based upon the principles of HACCP and which delineates the procedures to be followed.

HACCP System: The result of the implementation of the HACCP Plan.

HACCP Team: The group of people who are responsible for developing, implementing and maintaining the HACCP system.

Hazard: A biological, chemical, or physical agent that is reasonably likely to cause illness or injury in the absence of its control.

Hazard Analysis: The process of collecting and evaluating information on hazards associated with the product under consideration to decide which are significant and must be addressed in the HACCP plan.

Critical Control Point: A step at which control can be applied and is essential to prevent or eliminate a safety hazard or reduce it to an acceptable level.

HACCP Principles

HACCP, as already explained, is a systematic approach to the identification, evaluation, and control of safety hazards based on the following seven principles:

Principle 1: Conduct a hazard analysis.

Principle 2: Determine the critical control points (CCPs).

Principle 3: Establish critical limits.

Principle 4: Establish monitoring procedures.

Principle 5: Establish corrective actions.

Principle 6: Establish verification procedures.

Principle 7: Establish record-keeping and documentation procedures.

Conducting a Hazard Analysis

The hazard analysis consists of asking a series of questions which are appropriate to the process under consideration. The purpose of the questions is to assist in identifying potential hazards.

1 Ingredients

- Does the API or the end product contain any sensitive ingredients that may present microbiological hazards (e.g., *Salmonella*, *Staphylococcus aureus*); chemical hazards (e.g., aflatoxin, antibiotic or pesticide residues); or physical hazards (stones, glass, metal)?
- Are potable water, ice and steam used in formulating or in handling the end product? What are the sources (e.g., geographical region, specific supplier)

2 Intrinsic Factors

- Physical characteristics and composition (e.g., pH, type of acidulants, fermentable carbohydrate, water activity, preservatives) of API or the end product during and after processing.
- What hazards may result if the composition is not controlled?
- Does it permit survival or multiplication of pathogens and/or toxin formation during processing?
- Will their be survival or multiplication of pathogens and/or toxin formation during subsequent steps in the supply chain?
- Are there other similar products in the market place? What has been the safety record for these products? What hazards have been associated with the products?

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3 **Procedures used for processing**

- Does the process include a controllable processing step that destroys pathogens? If so, which pathogens? Consider both vegetative cells and spores.
- If the product is subject to recontamination between processing (e.g., cooking, pasteurizing) and packaging which biological, chemical or physical hazards are likely to occur?
- What is the normal microbial content of the ingredients?
- Does the microbial population change during the normal storage time?
- Do the answers to the above questions indicate a high likelihood of certain biological hazards?

4 **Facility design**

- Does the layout of the facility provide an adequate separation of raw materials from the final product? If not, what hazards should be considered as possible contaminants?
- Is positive air pressure maintained in product packaging areas? Is this essential for product safety?
- Is the traffic pattern for people and moving equipment a significant source of contamination?

5 **Equipment design and use**

- Will the equipment provide the time-temperature control that is necessary for safe products?
- Is the equipment properly sized for the volume that will be processed?
- Can the equipment be sufficiently controlled so that the variation in performance will be within the tolerances required?
- Is the equipment reliable or is it prone to frequent breakdowns?
- Is the equipment designed so that it can be easily cleaned and sanitized?
- Is there a chance for product contamination with hazardous substances; e.g., glass?
- To what degree will normal equipment wear affect the likely occurrence of a physical hazard (eg., metal) in the product?
- Are allergen products needed in using equipment for different products?
- What product safety devices are used to enhance consumer safety?
 - metal detectors
 - magnets
 - sifters

- filters
- screens
- thermometers
- bone removal devices

6 **Packaging**

- Does the method of packaging affect the multiplication of microbial pathogens and/or the formation of toxins?
- Is the package clearly labeled "Keep Refrigerated" if this is required for safety?
- Does the package include instructions for the safe handling and preparation of the food by the end user?
- Is the packaging material resistant to damage thereby preventing the entrance of microbial contamination?
- Are tamper-evident packaging features used?
- Is each package and case legibly and accurately coded?
- Does each package contain the proper label?
- Are potential allergens in the ingredients included in the list of ingredients on the label?

7 **Sanitation**

- Can sanitation have an impact upon the safety of the equipment or the product processed?
- Can the facility and equipment be easily cleaned and sanitized to permit the safe handling?
- Is it possible to provide sanitary conditions consistently and adequately?

8 **Employee health, hygiene and education**

- Can employee health or personal hygiene practices impact upon the safety of the plant or the product
- Do the employees understand the process and the factors they must control?
- Will the employees inform management of a problem which could impact upon safety?
- Conditions of storage between packaging and the end user
- What is the likelihood that the end product will be improperly stored?
- Would an error in improper storage lead to a microbiologically unsafe product?

9 **Intended use**

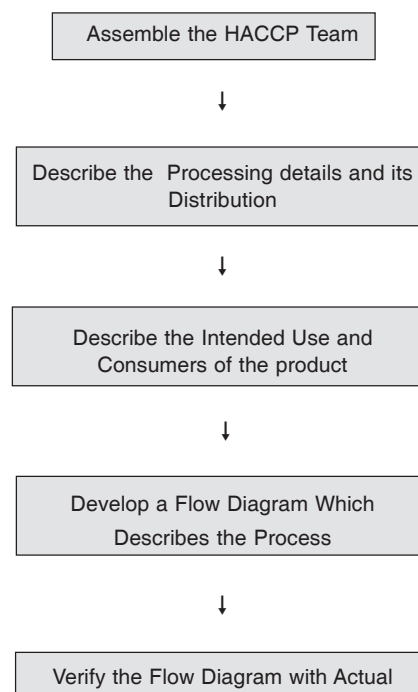
- Will it meet the stringent laws that govern marketing the end product?
- Will there likely be leftovers?

10 **Intended consumer**

- Is the food intended for the general use or specific use?
- Is the product intended for consumption by a population with increased susceptibility to illness (e.g., infants, the aged, the infirmed, immuno compromised individuals)?
- Is the end product going to be used for institutional or at home?

Annexure - I

Development of the HACCP Plan



Annexure - II

Typical HACCP Record Keeping Ledger

- A. Record for ingredients for which critical limits have been established.
 1. Supplier certification records documenting compliance of an ingredient with a critical limit
 2. Processor audit records verifying supplier compliance
 3. Storage records (e.g. time, temperature) for when ingredient storage is a CCP
- B. Processing, storage and distribution records
 1. Information that establishes the efficacy of a CCP to maintain product safety

2. Data establishing the safe shelf life of the product, if age of product can affect safety
3. Records indicating compliance with critical limits when packaging materials, labeling or sealing specifications are necessary for the safety
4. Monitoring records
5. Verification records

C. Deviation and corrective action records

D. Employee training records that are pertinent to CCPs and the HACCP plan

E. Documentation of the adequacy of the HACCP plan from a knowledgeable HACCP expert

Case Study

A typical case for HACCP Application in a Retail Packaging Plant in India is illustrated below

Background :

- A well known Indian company selling branded energy food decided to convert all Re-packaging stations into HACCP compliant units.
- This was necessary for the manufacturer to export their products to Middle East and also to earn an unique distinction in Indian market

The scope was to cover :

- HACCP compliance in : (i) receipt and storage of bulk quantity of energy food (ii) feeding and packaging operation thereafter (iii) storage of packages till despatch
- Not only the area under operation but also the operators were to trained to meet HACCP compliance
- Audit and Certification by an international accreditation agency was to be obtained
- The study revealed that (a) though the pattern of packaging and style of working was similar in all stations, the structural rectifications required were vastly different (b) The grasping level of the operators were different (c) The design of enclosure and air conditioning need were different at different station

Details

Existing packaging machines were either 1000 pack/ hr or 2000 pack/hr capacity with hot sealing device

- The packing machines were connected with feed units having auger type metering arrangements

- Most stations had no proper storage facility for Bulk and retail packs
- The operational layout was haphazard and operators were moving in all directions
- All operators were not trained about importance of maintaining hygienic standard
- The documentations maintained were not as per standard

What was required to be done

- Study the existing practices and working condition at each packaging station since no two sites were alike
- Suggest modifications that were minimum to meet the HACCP requirements within allotted budget
- Prepare QSP and QSM in line with process
- Train the operators

Design Implemented

- Entry of all personnel restricted - mandatory through the washroom and change room and over foot wash
- Apron , head cap and hand gloves made mandatory
- Workmen exit only through designated gate with permission but must enter through washroom

- Wearing jewelry or bindi by women workers prohibited
- Any workmen having cut or bandaged fingers were debarred
- All entry points fitted with air curtain & fly catchers installed at strategic points
- All ventilators fitted with wire mesh
- Glass covers (daylight windows/FTL) replaced with acrylic
- Storage of bulk bags or finished packs only on plastic crates (not directly on floor)
- Crack/crevice free floor with proper slope & surface finish

Important Data

- Temperature of 25 ± 5 °C and RH of 55 ± 5 maintained inside enclosure using circulation of pressurized cold air through HEPA / micron filter
- PUF Insulated prefab panels with weatherproof surface used for enclosure and the entry door with auto closure
- Automatic vibratory screen with metal detector installed at feeding point
- All equipment/ accessory having product contact were changed to stainless steel
- Daily record keeping verified by authorised signatory

The layout of a typical packaging station is in Annexure-III

