MASTER FORMULA RECORD

Master formula record is a master document for any pharmaceutical product. It contains all information about the manufacturing process of the product.

MFR is prepared by the research and development team of the company and all other documents like BMR (Batch Manufacturing Record) and BPR (Batch Packaging Record) are prepared using MFR by the manufacturing units.

What is Master Formula Record?

"A document or set of documents specifying the starting materials with their quantities and the packaging materials, together with a description of the procedures and precautions required to produce a specified quantity of a finished product as well as the processing instructions, including the in-process controls."

There shall be Master Formula records relating to all manufacturing procedures for each product and batch size to be manufactured. These shall be prepared and endorsed by the competent technical staff i.e. head of production and quality control.

The master Formula shall include:

- Product details:
  - Name, logo and address of the manufacturing company.
  - Dosage form name.
  - Brand name.
  - Generic name.
  - Product code
  - Label claim of all ingredients
  - Product description
  - Batch size
  - Pack size and packing style
  - Shelf life
  - Storage conditions
  - MFR number and date
  - Effective batch number
  - Authorization by the production and quality assurance head

- The patent or proprietary name of the product along with the generic name
- A statement of the processing location and the principal equipment to be used

- Name, quantity, and reference number of all the starting materials to be used. Mention shall be made of any substance that may disappear in the courts of processing.
- A statement of the expected final yield with the acceptable limits, and of relevant intermediate yields, where applicable. Include the theoretical, actual yield of the batch.
- The methods, or reference to the methods, to be used for preparing the critical equipment including cleaning, assembling, calibrating, sterilizing.
- Detailed stepwise processing instructions and the time taken for each step.
- Flow Chart:
  - Steps of the manufacturing process to be monitored.
  - Flowchart of the material movement from dispensing to the final product to stores.
  - A simple flow chart of manufacturing process flow should be added in MFR
- The instructions for in-process control with their limits
- The requirements for storage conditions of the products, including the container, labelling and special storage conditions where applicable.
- Calculations:
  - Include the calculation steps of all active materials to get the 100% of the active material.
  - The calculation shall be done using water or LOD to get 100% potency.
- Manufacturing Process:
  - Write all steps in all stages of the manufacturing process.
  - All process steps like shifting, milling, lubricating, granulation, compression and coating should be written in detail including the process time and yield.
  - It also includes atmospheric conditions as temperature, humidity, and storage conditions.
- **Packing Process:**
  - List of all packing materials with their quantity is written.
  - Line clearance, reconciliation of printed and unprinted packing materials should be included in details.
- **NOTE:** Any special precautions to be observed during trial batches