BATCH FORMULA RECORD

Batch manufacturing record is a written document from the batch that is prepared during the pharmaceutical manufacturing process. It contains actual data of the batch manufacturing and whole manufacturing process step by step. There are several stages of the pharmaceutical product manufacturing process. All stages are included in the batch manufacturing record from the issuance of the raw material to the final packaging. Every batch has a separate BMR having the batch history of batch production. Documents and the proofs are attached to the BMR during the manufacturing process.

A good Batch Manufacturing Record format should contain following parts:

1. Batch Record: A very first page of the BMR has all records about the batch as batch number, batch size, composition, master formula record referred the weight of the batch, shelf life, storage conditions, manufacturing license number, manufacturing date, expiry date, date of starting and date of completion.

2. General Instruction for Manufacturing: Health and safety instructions to the operators and the manufacturing chemist are written those should be followed during the manufacturing process regarding the material and equipment used during manufacturing.

3. Equipment Cleaning Record: Checklist of the cleaning of all equipment is prepared; those are used in the manufacturing of the batch including the previous product, batch and date of cleaning. Cleaning of the equipment should be checked by the quality assurance.

4. Bill of Materials: List of the raw material should have the quantity of the materials with their AR numbers. Weights of the materials should be verified by quality assurance. If tablets are coated then coating material should be included.

5. Manufacturing Process: Manufacturing process should be written step by step in easy language. Milling, sifting, drying, lubrication, compression coating and packing having all instruction with process time should be written. Checklist for line clearance should also be attached before starting ever process. After completion of every stage, tablets must be checked for the compliance of the specification of that stage. Results should be attached with the batch manufacturing record.

6. Yield: Yield of the batch should be calculated at the end of every stage to calculate the process loss. Final yield should be calculated at the end of the manufacturing that should not be less than 99.00%.

7. Abbreviations: List of the abbreviations used in the document should be made to understand the BMR easily.

8. History of Changes: At the end, the document should have a list of the changes in the document including the revision number and the date of the change.