

Process Validation of Metformin Hydrochloride Tablet

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ABSTRACT

The aim of the present work was to carry out Retrospective as well as Concurrent Process Validation of Metformin Hydrochloride Tablets. Initially Retrospective validation was performed to confirm that the parameters lie within established specifications using 20 consecutive batches. Thereafter three consecutive process validation batches of same size, method, equipment and validation criteria were taken and subjected to concurrent validation. The critical parameters involved in Sifting, Granulation, Drying, Blending, Compression and Coating were identified and evaluated as per validation master plan. All the instruments were calibrated as per standard operating procedures. All the raw materials were verified for release status.

% Assay in Granulation was optimum in 15 minutes as % Standard deviation was 0.3754 to 0.7030. Drying time of 25 minutes was suitable for obtaining moisture content within 0.0058 to 0.07 %. Blend uniformity was optimum in 25 minutes as % Standard deviation for % LOD, Bulk Density and Assay was respectively 0.0058 to 0.0321, 0.0057 to 0.01 and 0.2 to 0.3828. Compression speed was optimum at 25 RPM as % Standard deviation of Average weight was 0.0023 to 0.0046, Thickness was 0.0338 to 0.0703, Diameter was 0.0125 to 0.1233 Hardness was 0.2601 to 0.3584, Friability was 0.0192 to 0.0639 and Assay was 0.1721 to 0.6349. For Coating % Standard deviation of Average weight was 0.0029 to 0.0048, Thickness was 0.0294

to 0.0343, Diameter was 0.0299 to 0.0498, Hardness was 0.5831 to 0.6398, Friability was 0.0535 to 0.0605, Dissolution was 0.1015 to 0.2505 and Assay was 0.1724 to 0.9473. Result of Microbeal Limit Test for Total Viable Count was within limit of NMT 100 CFU/gm and fungus, E.Coli and Salmonella Was absent in the Metformin Hydrochloride Tablet. The outcome indicated that data obtained by process validation of three batches provides high degree of assurance that manufacturing process of Metformin Hydrochloride Tablet produces product meeting its predetermined specifications and quality attributes.

Key Words: Process Validation, ConCurrent Validation, Retrospective Validation, Metformin Hydrochloride Tablet, Tablet Dosage Form.