Process Validation of Ofloxacin film coated tablet and Diazepam tablet.

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ABSTRACT

The aim of present project work was to carryout Concurrent validation of Ofloxacin film coated tablet and prospective process validation of Diazepam tablet. For concurrent validation of Ofloxacin film coated tablet. Three initial process validation batches of same size, method, equipment and validation criteria were taken. The critical parameters involved in sifting, mixing, drying, blending, compression and coating were identified and evaluated. All the instruments were calibrated as per standard operating procedures. Uniformity of dry mixing was optimum for 10 minutes; standard deviation was between ± 0.11 to ± 0.85 for. Granulations time for all three batches was 20 minutes. Optimum drying time of 15 minutes e for obtaining moisture content of NMT 3%. Blending was optimum for 18 minutes; standard deviation was between 0.24 to ± 0.60. Compression was optimum at 24 RPM. Because SD of Thickness was between ±0.022 to ±0.044, weight variation between ±0.63 to ±1.02 hardness between ±0.28 to ±0.31 and friability was between ±0.065 to ±0.103 for Ofloxacin tablet. Coating was optimum at 2 RPM for Ofloxacin tablet.The

outcome indicated that data obtained by process validation of three batches provides high degree of assurance that manufacturing process of Ofloxacin tablet produces product meeting its predetermined specifications and quality attributes.

For prospective validation of Diazepam tablet .Three initial process validation batches of same size, method, equipment and validation criteria were taken. The critical parameters involved in sifting, mixing, drying, blending and compression were identified and evaluated as per validation master plan. All the instruments were calibrated as per standard operating procedures. Uniformity of dry mixing was optimum for 5 minutes; standard deviation was between ±2.011 to ±2.180. Granulations time for all three batches was 20 minutes. Optimum drying time of 20 minutes was suitable for obtaining moisture content of 3% - 4%. Blending was optimum for 20 minutes, standard deviation was between ± 0.849 to ±1.784.Compression was optimum at 24 RPM and 35 RPM. Because SD of ±0.0342 to ± 0.0389, weight variation between ± 1.118 to ±1.518, hardness between ±2.511 to ±3.307 and friability was between ±0.0047 to ±0.009.The outcome indicated that data obtained by process validation of three batches provides high degree of assurance that manufacturing process of Diazepam tablet meeting its predetermined specifications and quality attributes.

Key words: Process validation, Tablet dosage forms, Ofloxacin Tablets, Diazepam tablet.