

Prospective and Concurrent Process Validation of Ranitidine Film Coated Tablet BP 150 mg and Amlodipine Tablet BP 10 mg

Submitted By

Gupta Neha Sureshbhai

Supervised By

Dr. Suresh M. Jain.

M. Pharm., PhD.

Associate Professor and HOD, Dept. of Pharmaceutical Quality Assurance

S Kant Healthcare Ltd

G.I.D.C, phase 3, Vapi, Gujarat- 396190

ABSTRACT

The aim of present project work was to carryout prospective validation of ranitidine film coated tablet BP 150 mg and concurrent process validation of amlodipine tablet BP 10 mg.

For both of the process validation , three consecutive validation batches were taken. For prospective validation of ranitidine tablet, Critical process parameters involved in sifting, granulation, drying of granules, compression and coating of tablet, were identified and evaluated. All the instruments were calibrated as per standard operating procedure. All the raw materials used were verified for their release status. Uniformity of dry mixing was optimum for 10 minutes; assay for uniformity of dry mixing was found 100 ± 2 %. Optimum drying time of 20 minutes for obtaining moisture content of 0.6 – 1.0 %. Blending was optimum for 1 minute. Assay for uniformity of drug after lubrication was found 99 ± 1 % ;standard deviation was between 0.74 - 0.87. Compression attributes were optimum at 12 RPM. Coating was optimum at 2 - 6 RPM for Ranitidine tablet.

For concurrent validation of Amlodipine tablet, Uniformity of dry mixing was optimum for 15 minutes. Assay for uniformity of dry mixing was found 99 ± 1 %.standard deviation was 0.56. Optimum drying time of 1 hour 15min minutes was suitable for obtaining moisture

content of 2 - 3%. Blending was optimum for 2 minutes. Assay for uniformity of drug after lubrication was found 99 ± 1 % standard deviation was 1.02. Compression was optimum at 20 RPM. The results indicated that data obtained by process validation of three batches provides high degree of assurance that manufacturing process of Ranitidine tablet and Amlodipine tablet meeting its predetermined specifications and quality attributes.

Key words: Process validation, Prospective, Concurrent, Tablet dosage forms, Ranitidine Tablets, Amlodipine tablet.