PROCESS VALIDATION OF PROTHIONAMIDE TABLET DOSAGE FORM

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Abstract

Validation is best viewed as an impartment and integral part of cGMP. The word validation simply means "assessment of validity" or action of proving effectiveness. This process involves addition of granulating agent to the dry mixed material and converting into granules. The goal of quality system is to consistently produce products that are suitable for their intended use. In this study concurrent process validation was carried out for Prothionamide tablets BP 250 mg. In tablet dosage form, critical parameters like dry mixing, granulation, drying, sifting and milling, lubrication and compression were taken up for validation studies. In-process quality monitoring of all critical processing steps was done for three production batches. End product testing of production batches was done to provide documented evidence that manufacturing process is within the state of control. LOD of the dried, milled and lubricated granules were within the limit 2.0 – 3.0 % w/w. Assay after lubrication was within the specified limit, indicating blend uniformity. Particle size distribution and bulk densities of milled and lubricated granules were recorded. Film coating of tablet were evaluated for coating uniformity, coating process efficiency and surface roughness. The spry rate , atomization air pressure, distance of nozzle from tablet bed, inlet air temperature, pan differential pressure ,pan speed and % solid content these affect the final film quality of coated tablets. Blister packing was carried out for the tablets. During packing operation, blisters were checked for physical appearance, sealing quality and found satisfactory. All the tests were found to have satisfactory results. Thus process validation of Prothionamide tablets BP 250 mg was successfully completed and found within the specifications.

Keywords: Prothionamide, Process validation, Control variables.