Process Validation of Solid Dosage Form - Tablet

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A Thesis Submitted to
"Gujarat Technological University"
in partial fulfilment of the requirements for the degree of

"Master of Pharmacy"

in **Pharmaceutical Quality Assurance**

June-2011

Baroda College of Pharmacy

Parul Trust, Limda, Ta. Waghodia, Dist. Vadodara 391760

Abstract

The purpose of research was to study prospective validation of Cimetidine 400 mg tablet dosage formulation. Quality cannot be adequately assured by in-process and finished inspections and testing but it should be built in to the manufacturing process. These processes should be controlled in order that the finished product meets all quality specifications. Therefore building of quality requires careful attention to a number of factors, such as the selection of materials, product and process design, control variables, in process control and finished product testing. Three initial process validation batches of same size, same equipment, method, material and validation criteria was taken. In solid dosage forms the film coating tablets was used because of the protect from light, temperature, moisture mask of undesirable taste or odour improves the appearance, provide tablets identity, facilitate swallowing and control and modify release of the drug. Film coating applied as a thin polymeric film to the surface of the tablet. The critical process parameter involved in sifting, dry mixing, preparation of granulating agent, wet mixing, wet milling, drying, sizing, lubrication, compression stages and coating parameter were identified and evaluated as per validation plan. Film coating of tablet were evaluated for coating uniformity, coating process efficiency and surface roughness. The spray 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. Therefore based on results of process validation batch at each of the stages for the specified parameters it was summarized and concluded that with the prospective process validation for the Cimetidine 400 mg tablet produces the batches with no significant deviation and reported documented evidence, that process can be effectively produce a product which complies with the present specification and reproducible quality standards.