**Process validation of Pantoprazole and Rabeprazole Lyophilized Product**

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# ABSTRACT

Since process validation is essential for fulfillment of regulatory requirements and quality, the prospective validation of the new manufacturing process of lyophilized Pantoprazole and Rabeprazole injections I.P was carried out. Three initial production batches of the same batch size, method and equipment and validation criteria were taken. The critical parameters involved in manufacturing like environmental condition, sterilization process, filtration, filling, sealing and unloading were identified and evaluated as per process validation protocol. All the instruments were calibrated and equipments were validated as per standard operating procedure. The RSD for content uniformity was optimum in the batch as it was below 6% and the drug content of reconstituted powder was within the limit i.e. 85% - 115% for both Pantoprazole and Rabeprazole. The critical parameters and conditions were under prescribed control during the manufacturing processes. The outcome showed that the

data obtained by process validation of three batches of Pantoprazole and Rabeprazole provided high degree of assurance that all the process variables were optimized and meets the proposed criteria. The lyophilized pantoprazole and Rabeprazole for injection were found to meet their predetermined specifications and quality attributes.

**Key words:** Pantoprazole, Rabeprazole, Lyophilized Product, Process Validation, Critical parameters, Process Variables.