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Research Paper

Process Validation of Clopidogrel Bisulphate USP Tablet

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Drugs are significant elements for human health. They must be manufactured to the maximum quality levels. Validation is best viewed as an impartment and integral part of cGMP. It is an important step in achieving and maintaining the quality of the final product. If each step of production process is validated we can assure that the final product is of the best quality. Validation of product should be performed as per guideline. In this study the concurrent process validation of Clopidogrel Bisulphate USP 75mg tablet was performed. It gives detail about the validation of each step of the manufacturing process like blending, lubrication, compression, analysis of finished product. During this process critical parameters such as blend uniformity, bulk density, flow property of drug, uniformity of dosage unit, uniformity of weight, average weight, hardness test, thickness, disintegration time, friability, dissolution test and assay were studied. Based on result and conclusion, it is established that the employed manufacturing process is capable to produce the product consistently which meets all the predetermined specification and quality attributes. Hence the manufacturing process stands validated and can be used for routine manufacturing of Clopidogrel bisulphate USP tablet.

Key Words: Validation, concurrent process validation, cGMP, Quality, Manufacturing process.