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## **Industrial process validation of metformin tablets to facilitate the scale up of commercial production: A GMP and validation perspective**

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Process validation testing is generally done on the first three batches of a product with the production equipment. The number of process validation batches or runs required to demonstrate that a pharmaceutical process operating in a validated state is also based on sound statistical principles. Concerning the application in the production, a lot of scientific approaches stop at the level of feasibility studies and do not manage the step to production scale and process application. The present work puts the scale up of an active production process into focus, which is a step of highest importance during the pharmaceutical development. The validation study of Metformin tablets were carried out by considering critical process parameters to develop a stable and robust manufacturing process. The validated critical process parameters of granulation, drying, blending, lubrication, compression, coating and finished product tests were found to be consistent and reproducible during three validation batches. Three validation batches of commercial scale batch size were taken successfully and set up the in process critical parameters for commercial batches. Thus, Metformin Hydrochloride tablets were prepared within the specification limits to meet all quality attributes.

### **Biography**

Gannu Praveen Kumar graduated from H.K.E's society college of Pharmacy, Gulbarga University in 1997, post graduation from BITS, Pilani in 1999 and PhD from Kakatiya University in 2009. Since 2009, he was appointed as an examiner for post graduation and has guided 24 M. Pharm students. He has published in both National and International journals and compiled few chapters for text books. He was honored Gem of India award.

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