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US FDA issues API bulk & tapped density guidance

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Singapore: The US Food and Drug Administration (FDA) has issued guidance to the Active Pharmaceutical ingredient industry on bulk density and tapped density of powders.

The norms revolve around the Q4B evaluation and recommendation of pharmacopoeial texts for use in the ICH regions. The norms specified provide clarity during exports of bulk drugs, claimed the Indian active pharmaceutical ingredient (API) industry. The regulatory authority has pointed out that the implementation of the Q4B annexes is intended to avoid redundant testing by industry.

The ICH Steering Committee, based on the evaluation by the Q4B Expert Working Group (EWG), recommended the analytical procedures described in the official pharmacopoeial texts for the bulk density and tapped density of powders, determination of bulk and tapped densities, and USP General Chapter on bulk density and tapped density of powders which can be used as interchangeable in the ICH regions of EU, UK, US and Japan.

The regulator explained that when manufacturers change their existing methods to the implemented Q4B evaluated pharmacopoeial texts that are referenced in section II.A (2.1) of this annex, any change notification, variation, or prior approval procedures should be handled in accordance with established regional regulatory mechanisms pertaining to compendial changes.