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Lifecycle of Legacy Powder For Oral Suspension: Stage 3 Validation Monitoring

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ABSTRACT This paper delivers structured techniques for science- and risk-based continual process improvement decision making with Stage 3 heightened sampling and testing of oral powder for suspension products. The prognostic study uses sound pharmaceutical manufacturing science principles along with proven statistical tools. The methods are applicable for determining product/process robustness and variability of legacy powder for oral suspension products. The approach discussed in this paper attempts to minimize the sources of variability, where possible, such that the impact of processing and...

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