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Understanding effect of formulation and manufacturing variables on the critical quality attributes of warfarin sodium product

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ABSTRACT

Warfarin sodium (WS) is a narrow therapeutic index drug and its product quality should be thoroughly understood and monitored in order to avoid clinical performance issues. This study was focused on understanding the effect of manufacturing and formulation variables on WS product critical quality attributes (CQAs). Eight formulations were developed with lactose monohydrate (LM) or lactose anhydrous (LA), and were either wet granulated or directly

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