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提高他克莫司胶囊含量均一性的工艺研究

Study on the Technique of Improving the Content Uniformity of Tacrolimus Capsule

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中文摘要:

目的 研究提高他克莫司胶囊含量均一性的工艺。方法 在普通湿法制粒机增设弯管式定位加料系统控制加料位置和流速、选用合适的辅料与工艺参数制得他克莫司胶囊, 用HPLC测定含量。结果 他克莫司胶囊含量均一性良好, 中间体粉末RSD<2.0%, 含量均匀度A+1.80S<15, 溶出度>85%。结论 使用弯管定位加料, 选用乳糖G200及合适的工艺参数, 制备的他克莫司胶囊含量均一, 适合产业化生产。

英文摘要:

OBJECTIVE To study the technique of improving the content uniformity of tacrolimus capsule. METHODS Adding a bended pipe under the entrance of the wet granulating machine in order to fix the flowing position and control the velocity of flow. Appropriate excipients were selected. Process parameters were optimized. Content uniformities were detected by HPLC. RESULTS The content uniformity of tacrolimus capsule was acceptable, and the RSD<2.0%, the A+1.80S<15. CONCLUSION Adding liquid mixtures through a bended pipe, selecting lactose G200 as the appropriate excipient and optimizing the granulating parameters could produce uniform tacrolimus capsule. It's industrialized.

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