

工业药剂学

## 不同辅料对辛伐他汀片剂稳定性的影响

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摘要

目的 选择适合辛伐他汀片剂的辅料, 为其制剂的开发提供有益的参考。方法 将辛伐他汀与各种辅料混合制备片剂, 并将其置于不同影响因素条件下, 测定样品中主药及有关物质的含量, 并与0 d样品比较, 根据二者含量的变化考察片剂中药物的稳定性。结果 酸性剂枸橼酸在高湿条件下使辛伐他汀片剂的有关物质含量增加; 润滑剂硬脂酸镁及硬脂酸在高温条件下使辛伐他汀片剂的药物含量下降, 有关物质含量显著增加; 抗氧化剂丁羟基茴香醚在高温高湿条件下使辛伐他汀片剂的有关物质含量增加; 润滑剂山嵛酸甘油酯使辛伐他汀片剂相对稳定。结论 枸橼酸、硬脂酸、硬脂酸镁和丁羟基茴香醚不适宜用作辛伐他汀片剂辅料, 山嵛酸甘油酯适宜作辛伐他汀片剂辅料。

关键词 [药剂学](#) [辅料](#) [反相高效液相色谱法](#) [辛伐他汀片](#) [稳定性](#)

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## Effects of different excipients on the stability of simvastatin tablets

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Abstract

Objective To select suitable excipients for simvastatin tablets. Methods Various kinds of simvastatin tablets were prepared with different excipients, and the stability of the simvastatin in tablets was investigated under different conditions. The drug content and related substances in the samples were determined by RP-HPLC method and compared with those of 0 d samples. Results Citric acid increased the related substance of simvastatin in tablets under high humidity; simvastatin tablets using magnesium stearate or stearic acid as lubricants were unstable under high temperature, and the content of simvastatin decreased significantly and the amount of the related substances increased; the addition of butylated hydroxyanisole as an antioxidant also increased the amount of the related substance of simvastatin in tablets under high humidity and high temperature. In contrast, tablets using glyceryl behenate as a lubricant could maintain the stability of simvastatin. Conclusions Citric acid, magnesium stearate, stearic acid and butylated hydroxyanisole are unsuitable to be used as excipients for simvastatin tablets with the exception of glyceryl behenate.

Key words

[pharmaceutics](#) [excipient](#) [RP-HPLC](#) [simvastatin tablet](#) [stability](#)

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