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HPLC测定盐酸林可霉素滴眼液有关物质

Determination of Related Substances of Lincomycin Hydrochloride Eye Drops by HPLC

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英文关键词: [lincomycin hydrochloride eye drops](#) [related substances](#) [HPLC](#)

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中文摘要:

目的 建立测定盐酸林可霉素滴眼液有关物质RP-HPLC。方法 采用Phenomenex Luna C₁₈柱(4.6 mm×250 mm, 5 μm), 流动相: pH 6.1缓冲液(取34 g磷酸溶于900 mL水, 用浓氨水调节pH值至6.1加水稀释至1 000 mL)-甲醇-乙腈(77:8:15), 流速: 1.0 mL·min⁻¹, 检测波长: 210 nm, 柱温: 50℃。结果 林可霉素在24.68~370.28 μg·mL⁻¹内, 峰面积与浓度呈良好线性关系($r=1.000\ 0$), 最低检出限为1.05 ng。结论 本法林可霉素与相邻杂质之间及防腐剂之间的分离度良好, 可用于盐酸林可霉素滴眼液有关物质的检测。

英文摘要:

OBJECTIVE To establish a method for determination of related substances in Lincomycin Hydrochloride Eye Drops by HPLC. METHODS The determination was performed on Phenomenex Luna C₁₈ column(4.6 mm×250 mm, 5 μm), and the mobile phase consisted of 77 mL buffer(dissolved 34 g phosphoric acid in 900 mL water and adjust to pH 6.1 with concentrated ammonia and diluted to 1 000 mL with water), 8 mL methanol and 15 mL acetonitrile at the flow rate of 1.0 mL·min⁻¹. The detection wavelength was 210 nm. The column temperature was 50℃. RESULTS The linearity was found in the range of 24.68-370.28 μg·mL⁻¹ for lincomycin($r=1.000\ 0$). The detection limit of lincomycin

was 1.05 ng. CONCLUSION The method can separate lincomycin effectively from its degradation product and antimicrobial, and is suitable for the determination of impurities in Lincomycin Hydrochloride Eye Drops.