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Stability studies of combined ear drops for the treatment of otitis

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Abstract

Background: The stability of a drug is an important factor in ensuring its quality.The studied combined ear drops have an increased tendency of degradation, which requires an extensive stability study and obtaining data to determine the shelf life and establish the storage conditions. The purpose of the work: Stability studies of ear drops containing ciprofloxacin, dexamethasone, loratadine and volatile basil oil.
Material and methods: International Harmonized Guideline ICH Q1A (R2) stability testing methodology; 3 series of ear drops; reference standards for the active substances (Sigma Aldrich, USA); Shimadzu LC-20AD liquid chromatograph with UV-VIS detector; Fungilab Smart R viscometer; pH meter inoLab 7110; solvents, reagents in accordance with the European Pharmacopoeia.
Results: Ciprofloxacin is stable in acid medium, degrades in alkaline medium after 3 hours (approximately 10.0%), under oxidation (19.7%) and light action (17.1%). Dexamethasone degrades in acid medium (by 7.7%) and under oxidation (by 19.9%), it is stable in alkaline medium and under the action of light. Loratadine degrades in acid medium (by 3.0%), is stable in alkaline medium, under oxidation and action of light. In real-time storage conditions (25°C±2°C and RH 60%±5%), it was found that the pharmaceutical form did not change its quality parameters for 24 months.
Conclusions: The stability studies under stress and in real time conditions allowed us to select the packaging, the optimal storage conditions and to establish the provisional shelf life for the combined auricular pharmaceutical form during 2 years.
Key words: stability, combined ear drops, otitis, shelf life.

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