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STABILITY STUDIES OF COMBINED EAR DROPS FOR THE TREATMENT OF OTITIS

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INTRODUCTION

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. Stability studies of ear drops containing ciprofloxacin, dexamethasone, loratadine and volatile basil oil.

MATERIAL AND METHODS

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.

Figure 1. Modification of the concentration of active ingredients following stress degradation

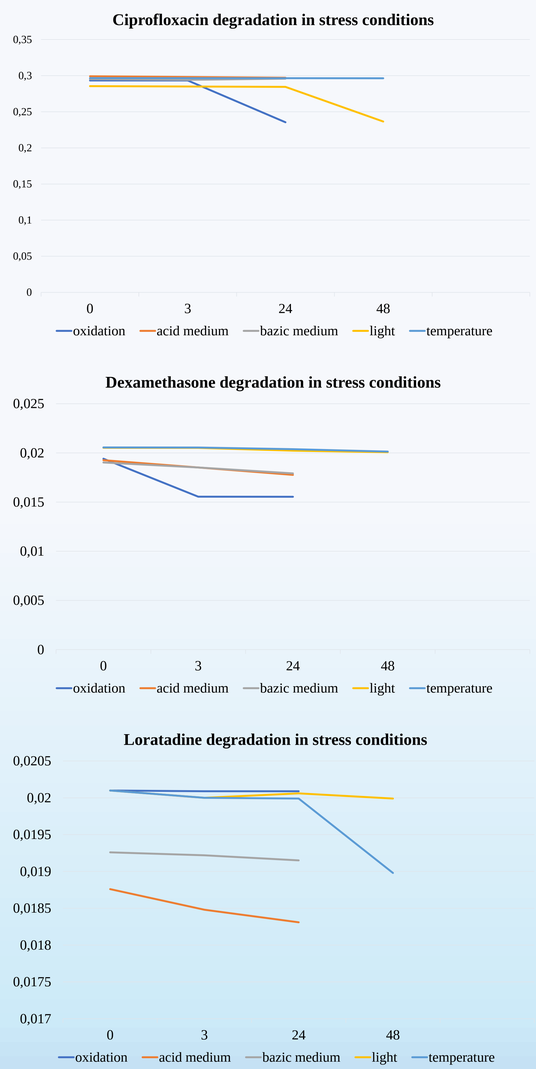

Table 1. The result of real-time ear drops stability studies

Periodicity of testing, months	ANALYZED PARAMETERS AND ADMISSIBILITY CONDITIONS						
	Appearance milky suspension, with a yellowish shade, witha specific smell, bitter taste	**Identity HPLC (Ret. time)** Ciprofloxacine hydrochloride 1.53-1.57 Dexamethasone 4.10-4.45 Loratadine 5.40-5.43	**pH** 4.5 – 6.0	**Viscosity** 10 - 30 P·10^2	**Assay, HPLC**		
					Ciprofloxacine hydrochloride 0.29-0.31g	**Dexamethasone** 0.019-0.021g	**Loratadine** 0.019-0.021g
Batch 1							
0	Corresponds	Corresponds	5.5	25.7	0.30012	0.02000	0.02010
3	Corresponds	Corresponds	5.5	25.8	0.30010	0.02001	0.02009
6	Corresponds	Corresponds	5.4	25.8	0.30009	0.02000	0.02000
9	Corresponds	Corresponds	5.5	25.8	0.29999	0.02000	0.01995
12	Corresponds	Corresponds	5.6	25.7	0.29996	0.01999	0.01979
18	Corresponds	Corresponds	5.7	25.9	0.29950	0.01998	0.01977
24	Corresponds	Corresponds	5.7	25.9	0.29949	0.01997	0.01976
Batch 2							
0	Corresponds	Corresponds	5.6	27.4	0.30012	0.02000	0.01958
3	Corresponds	Corresponds	5.6	27.4	0.30013	0.02001	0.01957
6	Corresponds	Corresponds	5.4	27.5	0.30010	0.02000	0.01958
9	Corresponds	Corresponds	5.5	27.5	0.29952	0.02000	0.01958
12	Corresponds	Corresponds	5.7	27.5	0.29951	0.01999	0.01957
18	Corresponds	Corresponds	5.6	27.6	0.29951	0.01987	0.01955
24	Corresponds	Corresponds	5.7	27.7	0.29951	0.01987	0.01954
Batch 3							
0	Corresponds	Corresponds	5.4	26.1	0.29949	0.01999	0.01998
3	Corresponds	Corresponds	5.4	26.2	0.29939	0.01999	0.01997
6	Corresponds	Corresponds	5.5	26.2	0.29950	0.01999	0.01999
9	Corresponds	Corresponds	5.5	26.1	0.29939	0.01999	0.01995
12	Corresponds	Corresponds	5.6	26.2	0.29921	0.01999	0.01993
18	Corresponds	Corresponds	5.6	26.2	0.29926	0.01989	0.01993
24	Corresponds	Corresponds	5.6	26.1	0.29926	0.01989	0.01992

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.

Keywords: *stability, combined ear drops, otitis, shelf life.*

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