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DETERMINATION OF STABILITY OF THE COMBINED OINTMENT CONTAINING ISOHYDRAFURAL AND FLUOCINOLONE ACETONIDE

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Introduction

The combined ointment with isohydrafural and fluocinolone acetonide contributes to the diversification of the treatment of dermatitis and psoriasis associated with infections (Fig. 1). Complex stability studies were performed to ensure the quality of it during the shelf life.

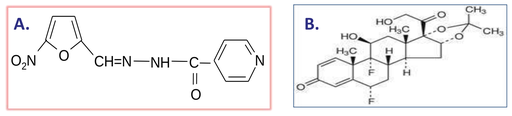

Fig. 1 Chemical formulas of: A. Isohydrafural and B. Fluocinolone acetonide

Keywords

Combined ointment, stability, shelf life.

Purpose

Stability study and determination of shelf life of the combined ointment containing isohydrafural and fluocinolone acetonide content.

Material and methods

Three series of ointment were tested by the real-time method (temperature 25±2°C; relative humidity 60±5%) over a period of 30 months, periodically determining the appearance, homogeneity, pH, viscosity, identity, purity and assay. It was used: OHAUS DV215 CD electronic balance, Shimadzu LC-20 A HPLC, Consort C861 pH meter and Fungilab rheometer.

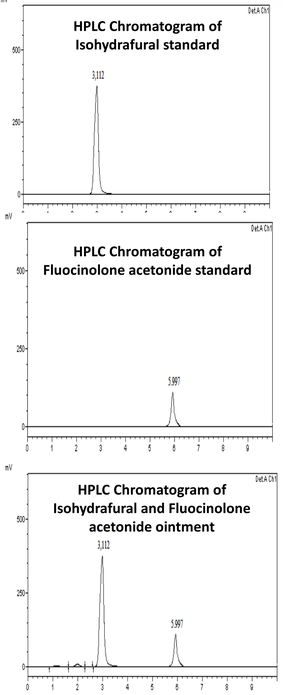

Fig. 2 HPLC Chromatograms

Results

At 24 months after storage, the three series of the ointment proved to be homogeneous, with a pH between 5.76 and 5.53 (Table 1). The rheograms showed a pseudoplastic behavior, with a slight thixotropy, with a viscosity between 65 and 75 cP. The active substances were detected at the characteristic retention times: isohydrafural-3 minutes, fluocinolone acetonide-5.9 minutes and no additional peaks occurred (Fig. 2). The content of active substances was within the permitted limits: 0.098-0.11% (m/m) for isohydrafural and 0.0248-0.025% (m/m) for fluocinolone acetonide (Table 1).

Table. 1 The results of stability studies of the combined ointment (Batch 1)

The date of testing	Appearance and Homogeneity	pH (mean±SD, n=3) 4.0–6.0	Viscosity 65 - 75 cP	Identity and purity, HPLC	Assay: HPLC g/100 g ointment	
					IHF: 0.09995-0.09930	FLAc:0.02505-0.02485
0 months	corresponds	5.76±0.01	73.5±0.6	corresponds	0.10013	0.02504
3 months	corresponds	5.75±0.01	71.0±0.1	corresponds	0.09996	0.02500
6 months	corresponds	5.73±0.01	70.5±0.4	corresponds	0.09984	0.02498
9 months	corresponds	5.71±0.01	69.7±0.1	corresponds	0.09976	0.02495
12 months	corresponds	5.68±0.01	69.1±0.1	corresponds	0.09960	0.02493
18 months	corresponds	5.63±0.01	68.9±0.1	corresponds	0.09946	0.02492
24 months	corresponds	5.53±0.02	68.2±0.1	corresponds	0.09932	0.02490
30 months	does not correspond	5.37±0.01	69.4±0.2	does not correspond	0.09872	0.02268

Note: SD – standard deviation; HPLC – High Performance Liquid Chromatography; IHF – isohydrafural; FLAc – fluocinolone acetonide.

Conclusions

The combined ointment containing isohydrafural and fluocinolone acetonide was found to be stable under the storage conditions stipulated in the quality specification. The established shelf life is 24 months.

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