COMPOUNDING AND PHYSICOCHEMICAL STABILITY STUDY OF DEXAMETHASONE MOUTHWASH 0.1 MG/ML TO PREVENT STOMATITIS ASSOCIATED WITH EVEROLIMUS

C.L. CRESPO MARTINEZ[1] , E. GANDULLO SANCHEZ[1] , N. CHOCHO-MONTAÑEZ[2] , M. MAGARIÑOS-TRIVIÑO[2] , A. SANTOVEÑA-ESTEVEZ[2] , A.C. RODRIGUEZ NEGRIN[1] , M.J. MEDINA VELASCO[1] , N. GONZALEZ ALEMAN[1] , R.D.C. FALCON ALONSO , M. COLOGAN RUIZ[1].
HOSPITAL PHARMACY DEPARTAMENT , COMPLEJO HOSPITALARIO UNIVERSITARIO INSULAR MATERNO-INFANTIL[1] , GRAN CANARIA. FACULTAD DE FARMACIA [2], UNIVERSIDAD DE LA LAGUNA, TENERIFE. SPAIN

Background and Importance

Stomatitis = **Inflammation of the oral mucosa**

→ **Usually with swelling and ulcerous and painful lesions**

Common adverse effect secondary to antineoplastic (including everolimus)

Dexamethasone mouthwash → **Anti-inflammatory properties** → **Used to alleviate these symptoms** ✓

No commercially available in Spain ✗

Aim and Objectives

To determine the physicochemical stability of a compounded dexamethasone 0.1 mg/ml mouthwash formula

Materials and Methods

1

- **Bibliographic search** of different formulations and pharmacotechnical forms
- Review technical data of raws material to ensure **compatibility**

2

Composition of the developed formulation

Dexamethasone 21 sodium phospate	0.013g
Sorbitol powder	15g
Water preserved without propylene glycol q.s.	100mL

3

7 batches of 2 amber glass containers were prepared and stored refrigerated **at 5ºC**

4

Appearance, organoleptic properties and precipitation	Visual inspection
Mass uniformity test	Accordance with Ph. Eur. 2.9.27 test for multidose liquid preparations
Chemical stability of the formulations stored at 5 ± 0.1 ºC at times 0, 7, 14, 28, and 60 days for closed containers and under normal use conditions	Ultra High Performance Liquid Chromatography
pH of the formulations	pH Meter

Results were expressed as a percentage of the remaining declared value (%DV)

Results

No significant changes in organoleptic characteristics

- Colorless
- Odorless
- Sweet taste
- Light viscous consistency

Developed formulation **met** with the **mass uniformity test** ✓

Stability period established at 5ºC

★ **Under normal conditions** **28 days** (103.09 ± 1.2 %DV)

★ **Closed containers** **60 days** (96.4 ± 0.7 %DV)

Conclusion and relevance

- ✓ This study demonstrates the **physicochemical stability** of the compounded **dexamethasone 0.1 mg/ml mouthwash for 28 days under normal use** conditions **and 60 days in closed** containers **at 5°C.**
- ✓ **Further studies, including microbiological stability testing**, are underway to ensure long-term safety and efficacy.

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Servicio Canario de Salud
eahp european association of hospital pharmacists

Contact data
ccremar@gobiernodecanarias.org