

# GALENIC VALIDATION OF A DEXAMETHASONE 0.01% MOUTHWASH SOLUTION TO PREVENT EVEROLIMUS RELATED STOMATITIS

J Vicente, JL Herrero, MS Pernia, A Herranz, M Sanjurjo

Pharmacy service. Gregorio Marañón University General Hospital. St Dr. Esquerdo, 46, 28007 Madrid. Spain

## BACKGORUND AND IMPORTANCE

Stomatitis is a common adverse drug reaction of the mTOR inhibitor everolimus. HS Rugo et al (2016) reported that dexamethasone mouthwash solution prevents stomatitis grade  $\geq 2$  in patients with everolimus treatment for hormone receptor-positive and HER2-negative metastatic breast cancer.

No commercial presentation is available in our country.

## AIM AND OBJECTIVE

Development of an oral solution of dexamethasone 0.1% for mouth washing, committed to these patients, based on others still marketed.

## MATHERIALS AND METHODS

Proposal of two formulations, based on the one described on US Pharmacopeia.

Source of dexamethasone water soluble salt (phosphate). Commercially available dexamethasone 4mg/mL injectable solution (Kern Pharma®)

Study of basic pharmaceutical properties for 30 days: organoleptic characteristics and pH

Composition of solutions implicated in the whole process are shown in table 1.

## RESULTS

Transparent, homogenous solution free of visible and rare particles

Physicochemical stability guaranteed: support on pre-existing formulations to develop ours.

- Organoleptic characteristics (cleanness, colour, odour, flavour) constant
- pH stable = 3-5

Microbiologic period of validity assignment according to Risk matrix from Good Manufacture Practices of Spanish Hospital Pharmacy Society.

30 days in closed bottle and 30 days after opening under refrigeration.

**Final choice:**  
**Formula without EDTA**

Table 1. Solutions involved in this work and their components

Imitate this		Starting material		Our proposals	
Dexamethasone USP oral solution	Dexamethasone 4mg/mL injectable ampule	Dexamethasone 0.1% without added EDTA	Dexamethasone 0.1% with added EDTA		
Dexamethasone	Dexamethasone sodium phosphate	Dexamethasone sodium phosphate [10mg <sup>1</sup> ]	Dexamethasone sodium phosphate [10mg <sup>1</sup> ]		
Glycerin	-	-	-		
Propylen glycol	-	-	-		
Methylparaben	-	Preservative water <sup>2</sup> [qs 100 mL]	Preservative water <sup>2</sup> [qs 100 mL]		
Propylparaben	-	-	-		
Flavoring	-	-	-		
Sorbitol	-	-	-		
Citric acid	Sodium citrate and sodium hydroxide	Citric acid 25% sol [qs pH 3-5]	Citric acid 25% sol [qs pH 3-5]		
Sodium edetate	Sodium edetate	-	Sodium edetate [10mg]		
Water	Water for injectable preparations	2	2		
pH 3-5	pH 7-8,5	pH 4,3-4,8 [Refrigerated]	pH 4,4-4,6 [Refrigerated]		

qs. *Quantum sufficit*.

<sup>1</sup> From 2,5 mL of dexamethasone 4mg/mL injectable ampule

<sup>2</sup> Preservative water contains methylparaben (9%) and propylparaben (2,2%)

## CONCLUSION AND RELEVANCE

Formulation simple to prepare

Can be used in other hospitals

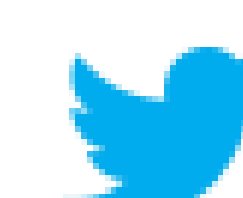
Coverage of therapeutic lagoon



<https://www.eahp.eu/25-3PC-040>

[jvicentev@salud.madrid.org](mailto:jvicentev@salud.madrid.org)

[www.madrid.org/hospitalgregoriomarañon/farmacia](http://www.madrid.org/hospitalgregoriomarañon/farmacia)



@farma\_gregorio

