SODIUM THIOSULPHATE GEL 25% FOR THE TREATMENT OF CALCIPHYLAXIS.

Hospital General Universitario Santa Lucía

García Matillas CN, Chica Marchal AM, Fernández Martínez IM, Montoya Egea JM, Martínez Marcos JM, Fernández Vela J.
Hospital General Universitario Santa Lucia
Cartagena (Murcia)

Carmen García Matillas
cgarmat7@gmail.com
638881314

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BACKGROUND AND IMPORTANCE

Calciphylaxis is a disease characterized by fat necrosis due to hypoperfusion from calcium accumulation in the arterioles of the skin.

In the treatment of the calciphylaxis, intravenous sodium thiosulphate is usually used due to its chelating on calcium ions, a vasodilator, and antioxidant. Topical use can be an effective and well-tolerated alternative, and it also allows early treatment. This active ingredient is not marketed in any of their presentations. In these cases, a concentration of 25% thiosulphate (12.5g in 50 mL) was recommended.

AIM AND OBJETIVES

The objective is to develop and validate a magistral formula of topical sodium thiosulfate and establish quality controls.

MATERIALS AND METHODS

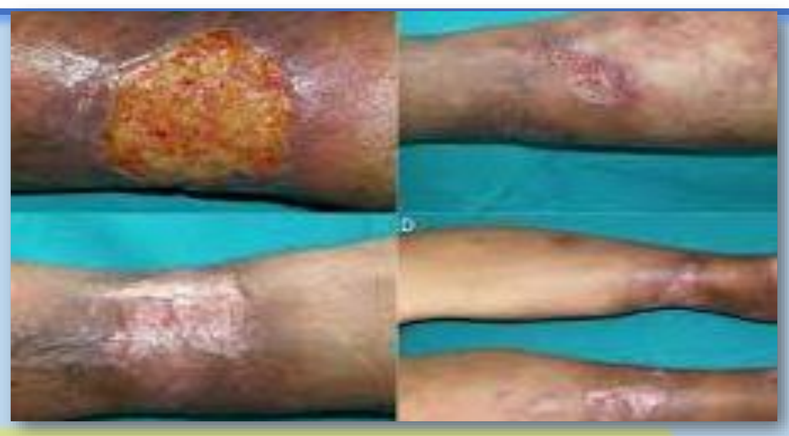
It was realized a bibliographic search to find possible topical master formulations of sodium thiosulfate.

The galenic development and validation of the formula were realized following the procedure for elaborating gels described in the National Formulary (PN/L/FF/003/00) and through quality control.

The quality control of the formula was carried out as established in the National Formulary: control of organoleptic characteristics, physical, chemical (pH controls and a microbiological control as procedure 5.1.4 of the Royal Spanish Pharmacopoeia. For this purpose, five samples were taken and analyzed at the beginning and after one month.

The risk matrix for non-sterile formulae based on the "Guide to good practice in the preparation of medicines in hospital pharmacy services" was applied to establish the validity period.

The samples were prepared in the non-sterile preparation area in the cleanroom. They were prepared following the Standard Operating Procedure (SOP).



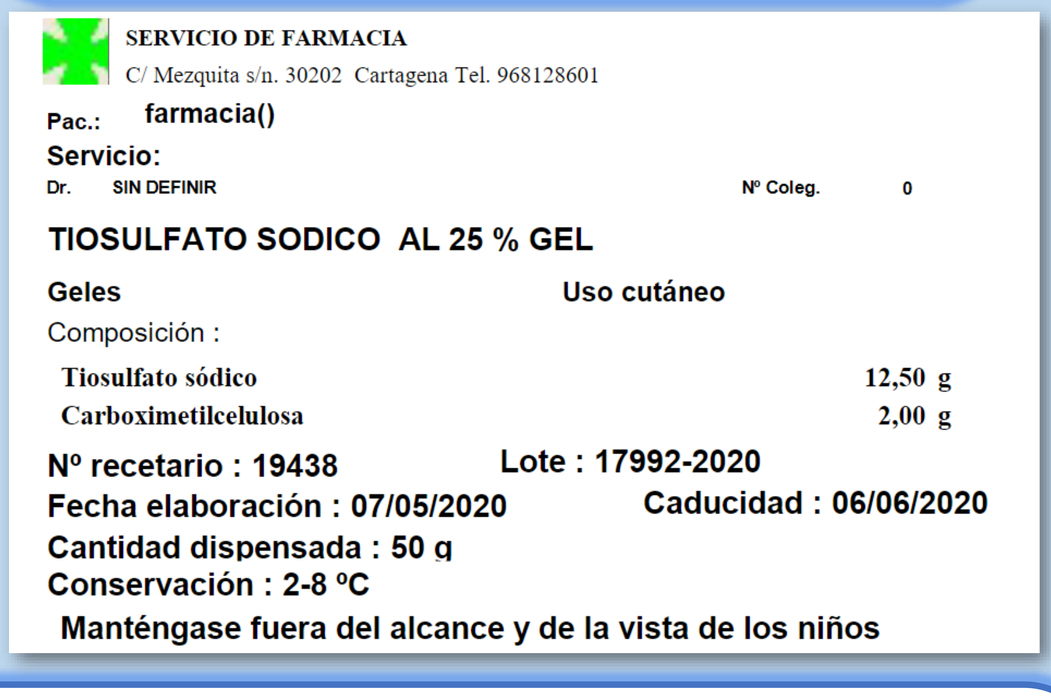
RESULTS

A shelf life of 30 days was established based on the risk matrix for non-sterile preparations with medium risk.

The organoleptic characteristics, physical, chemical and microbiological remained stable during the study month. At the beginning, the pH values obtained were 6.45±0.09 and a month after were 7.34±0.1.

CONCLUSION AND RELEVANCE

The formula remained physical, chemical, and microbiological stable for 30 days and met the requirements from the galenic point of view for topical application, serving as an alternative to intravenous administration of the active ingredient.



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TIOSULFATO SODICO AL 25 % GEL

Geles — Uso cutáneo

Composición :

Tiosulfato sódico	12,50 g
Carboximetilcelulosa	2,00 g

Nº recetario : 19438 Lote : 17992-2020
Fecha elaboración : 07/05/2020 Caducidad : 06/06/2020
Cantidad dispensada : 50 g
Conservación : 2-8 ºC
Manténgase fuera del alcance y de la vista de los niños

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