3PC-003 SODIUM THIOSULPHATE GEL 25% FOR THE TREATMENT OF CALCIPHYLAXIS

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Background and importance Calciphylaxis is a disease characterised by fat necrosis due to hypoperfusion from calcium accumulation in the arterioles of the skin.

In the treatment of calciphylaxis, intravenous sodium thiosulphate is usually used due to its chelating of 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 (12.5 g in 50 mL) was recommended.

Aim and objectives To develop and validate a magistral formula of topical sodium thiosulfate and establish quality controls.

Material and methods A bibliographic search was conducted to find possible topical master formulations of sodium thiosulfate.

The galenic development and validation of the formula were achieved 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 (smell, colour), physical, chemical (pH controls (PN/L/CP/001/00)), and a microbiological control as Procedure 5.1.4 of the Royal Spanish Pharmacopoeia. For this purpose, five samples were taken and analysed at the beginning and after 1 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 (smell, colour), physical (phase separation), chemical (pH) and microbiological characteristics remained stable during the study month. At the beginning the pH values obtained were 6.45±0.09 and after 1 month 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.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

3PC-004 INSULIN EYE DROP FORMULATION: EFFECTIVENESS, SAFETY AND PATIENT SATISFACTION

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Background and importance Recently, the insulin eye drops formulation 1 IU/mL has been included in the Pharmacotherapeutic Guide. Recent studies demonstrate its efficacy and safety in the treatment of keratitis and dry eye.

Aim and objectives To analyse the patient profile and describe the characteristics of insulin eye drops treatment, as well as its effectiveness, tolerance and patient satisfaction.

Material and methods Retrospective observational study in a tertiary hospital. All patients treated with insulin eye drops during the period January–September 2021 were included. The variables collected were: demographics, indication, duration of treatment, line of treatment, clinical response and adverse effects (both described in the clinical history) and patient satisfaction (using the 'Treatment Satisfaction Questionnaire for Medication' version 1.4: 14 questions, distributed in four domains: effectiveness, side effects, convenience and overall satisfaction).

A descriptive statistical analysis was performed with measures of central tendency and dispersion for quantitative variables (mean and standard deviation (SD)) and absolute frequencies for categorical variables.

Results A total of 34 patients treated with insulin eye drops 1 UI/mL were included. The mean age was 58.89 (SD 15.79) years. A total of 47.10% were women. 35.29% were diagnosed with non-herpetic keratitis, 20.59% with herpetic keratitis, 17.65% with corneal erosion, 14.71% with dry eye, 8.82% with pterygium and 2.94% others. The duration of treatment was 120.01 (SD 43.81) days. A total of 17.59% were treated in the fourth or successive lines, 17.65% in the third, 8.82% in the second and 2.94% in the first. Almost all (91.18%) the patients responded to treatment and 8.82% of patients showed toxicity (conjunctival hyperemia and ocular pain). Patients were satisfied or betterrior with the treatment: 91.17% in terms of effectiveness, 8.53% adverse effects, 88.23% convenience and 94.12% overall satisfaction.

Conclusion and relevance The insulin eye drops formulation 1 IU/mL is a good therapeutic alternative as a rescue treatment in patients refractory to the usual treatments. The preparation, by the pharmacist, of formulas allows coverage of possible therapeutic gaps in the treatment of herpetic and non-herpetic keratitis.

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3PC-005 SELECTION OF AN OSMOLARITY VALIDATION MODEL FOR NOMINATIVE PARENTERAL NUTRITION

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Background and importance Osmolarity is one of the pharmaceutical controls carried out on the nominative parenteral nutritions (NPN) produced at the pharmacy for a given patient (magistral formula). According to a previous method validation, we use the Pereira Da Silva equation (PDS) when the theoretical osmolarity (TO) determined by this model is greater than 1000 mosmol/L and we use the manufacturers' data (MD) equation when the TO according to the PDS equation is below 1000 mOsmol/L. This method is associated with an osmolarity nonconformity (NC) rate of 7.0%.