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

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).

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.

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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REFERENCES
