

STABILITY STUDY OF 25% SODIUM THIOSULPHATE GEL FOR CALCIPHYLAXIS

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BACKGROUND AND IMPORTANCE

Calciphylaxis is characterised by calcification of the middle layer of small arteries and arterioles, leading to painful skin lesions that progress to ulcers, mainly in the lower limbs. **Thiosulphate** acts as an **antioxidant and vasodilator**, providing rapid pain relief, and as a calcium salt chelator. It is **not commercially available** in our country and **is used mainly as an intravenous magistral formula**, although it is **also used intralesionally and topically**.

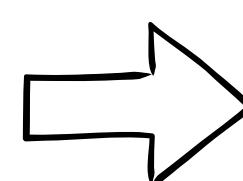
AIM AND OBJECTIVES

To study the **galenic and microbiological stability** of a 25 % sodium thiosulphate gel formulation.

MATERIALS AND METHODS



- Sodium thiosulphate 5H₂O Ph. Eur.25.00 g
- Sodium carmellose Ph. Eur.2.50 g
- Purified water Ph. Eur. q.s.100.00 g

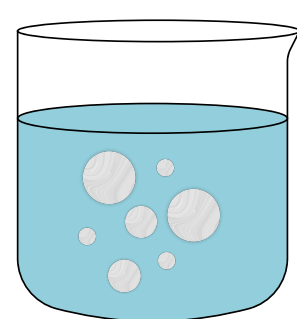


TWO samples: one kept at **room temperature (RT)** (22-25°C) and one in a **refrigerator** (4-8°C), both in **opaque plastic containers**.

TESTS PERFORMED FOR GALENIC STABILITY STUDY:



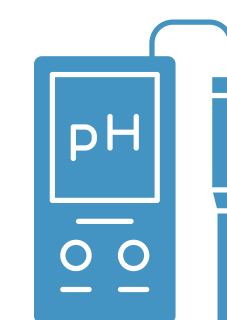
Physical and organoleptic characteristics: colour, odour, evanescence, apparent extensibility, apparent consistency and transparency.



Existence of **aggregates**.

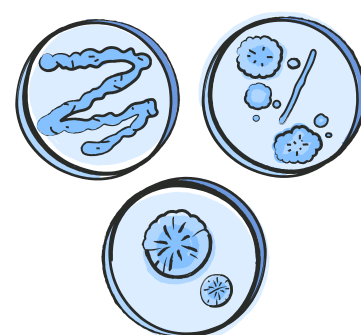


Existence of **exudation**.



Determination of **pH**.

TESTS PERFORMED FOR MICROBIOLOGICAL STABILITY STUDY

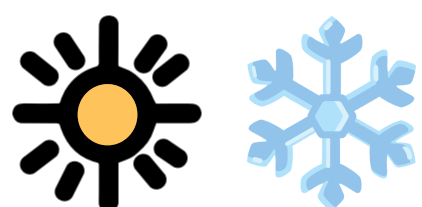


Growth of **aerobic** (environmental) **microorganisms**.

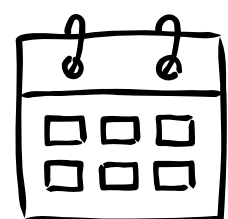
Both samples were tested on **days 1, 6, 13, 35, 42, 48 and 51** after preparation.

RESULTS

Both samples



Days 1 to 51



All maintained their colour (colourless), odour (slightly plastic), evanescence (very high), apparent extensibility (very high), apparent consistency (medium) and transparency (transparent).

None of the samples, either RT or refrigerated, showed aggregates or exudation, all maintained a pH of 6.5 (within the maximum stability pH of sodium thiosulphate: 6-8.4)

Aerobic bacteria culture was negative

CHECK THIS OUT!



3PC-024

CONCLUSIONS

Our 25% thiosulphate gel formula has proven to be stable from a galenic and microbiological point of view for at least 51 days at both RT and refrigerated.