

DESIGN AND DEVELOPMENT OF A MAGISTRAL FORMULATION OF MOUTHWASH FOR THE TREATMENT OF MUCOSITIS: A CASE REPORT

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BACKGROUND AND IMPORTANCE

Oral mucositis is an inflammatory condition from cancer therapies, which causes pain, infection and ulceration. Standard treatment with mouthwashes and systemic analgesics is not always effective, leading to the use of more personalized therapeutic options, such as the design of a magistral formulation (MF).

AIM AND OBJECTIVES

To formulate a mouthwash by galenic validation and describe its use in the treatment of mucositis.

MATERIALS AND METHODS

A 17-year-old patient with severe spinal cord aplasia developed grade four of mucositis, with severe pain and oral aphthous ulcers. After the failure of conventional treatments, such as oral viscous lidocaine and chlorhexidine, a MF was formulated and designed through a literature review (pharmacopeia, PubMed®). Galenic validation included organoleptic (smell, color), chemical (ph measurement) and microbiological controls.

RESULTS

Components of the MF:

- Lidocaine (pain)
- Dexchlorpheniramine (irritation)
- Triamcinolone (inflammation)
- Nystatin (prevent superinfections)
- Sodium bicarbonate (regulate mucosal pH)

Excipients: Tween 80, glycerin, and 1% carboxymethylcellulose.

Galenic validation of the MF was carried out for one month.

In the second week:

- pH = 8
- No crystals
- No color variations

In the third week:

- pH = 9
- Small crystals
- Microbiological control negative.

Shelf life of **14 days** stored in a topaz glass container and kept in a refrigerator at 2-8°C.

After one month of treatment with a dosage regimen of 10 ml three times a day, the patient experienced a significant improvement in oral aphthous ulcers and pain, avoiding the use of morphics and improving oral tolerance.

Preparation of 250 mL:

•Mix triamcinolone acetonide (0.125 g) and nystatin (460 mg); add tween 80 (3 drops), glycerin (25 mL), and 1% carboxymethylcellulose (40 mL), homogenizing after each addition.

•In a separate container, mix lidocaine (5 g) and sodium bicarbonate (2.5 g); add glycerin (25 mL), dexchlorpheniramine solution 0,4 mg/ml (40 mL) and 1% carboxymethylcellulose (40 mL), homogenizing after each addition.

•Combine in a beaker, and adjust the volume to 250 mL with 1% carboxymethylcellulose, then homogenize.

CONCLUSIONS AND RELEVANCE

The MF was validated and proved effective for the treatment of mucositis.

