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Development and preparation of a gel for urethral administration of 5-fluorouracil and lidocaine for the treatment of condyloma acuminatum

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BACKGROUND AND IMPORTANCE

Condyloma acuminatum refers to anogenital warts caused by human papillomavirus (HPV). It is estimated that between 9% and 17% of men with external warts have intraurethral warts, which have the potential for malignancy. [1]

Treatment options are based on characteristics such as **size**, **location**, and **number of lesions**, and range from topical therapies to ablative treatments, such as surgical excision of lesions. Systemic immunotherapy may also be used. [2]

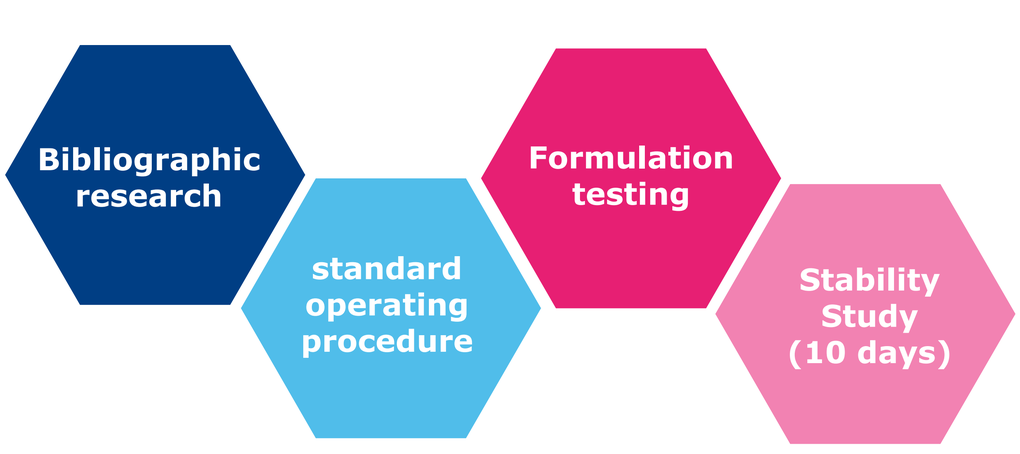
However, some disease manifestations do not find a therapeutic response on the market. Because of this shortage, the Urology Department requested collaboration in the study and the availability of an **alternative for local application**, with **5-fluorouracil** (5-FU) and **lidocaine** in its composition, which meets the requirements associated with the route of administration. [3,4]

AIM AND OBJECTIVES

- ✓ **Galenic development** and **preparation of a compounded medication (CM)** containing 5-FU and lidocaine for the treatment of condyloma acuminatum,
- ✓ **Quality control of compounded medication.**

MATERIALS AND METHODS

✓ **Galenic development of compounded medication**:



✓ **Quality control of compounded medication:**

RESULTS

5-FU

An antimetabolite analogue of uracil, used alone or in combination in the local treatment of condyloma acuminatum, and is generally well tolerated. [3,4]

Lidocaine

Anesthetic, which may also have antitumor properties, with the potential to impact disease progression, as well as increase the effects of 5-FU. [5,6]

Literature related to associations between APIs prepared extemporaneously using **non-sterile** ointments has been found. [3]

Based on the research, a gel containing 2.5% 5-FU and 1% lidocaine was prepared in a sterile environment - suitable for preparing cytotoxic medications - and in a closed system (Figure 1).

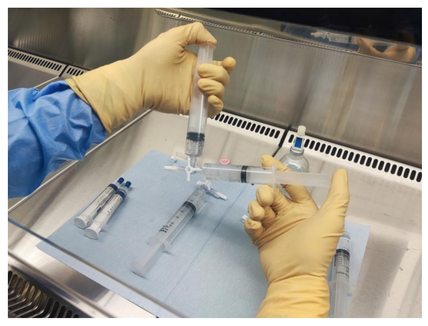


Figure 1 - Sterile gel preparation in a closed circuit

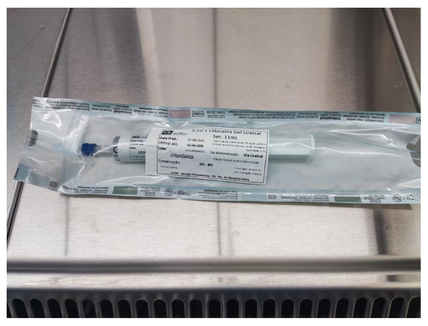


Figure 2 - Sterile gel with 2.5% 5-FU and 1% lidocaine ready to be administered

✓ **Quality control of the compounded medication:**

2-8°C

	Day 1	Day 10
Appearance	clear, homogeneous, and free of visible particle	No change observed
pH	8	8

10 days

No alterations → BUD: 10-day (general rules of the American Pharmacopoeia. [7])

CONCLUSION AND RELEVANCE

The pharmaceutical intervention described enabled the availability of a personalized therapy. The method used ensures the **safe preparation** of CM, guaranteeing its **quality**, particularly in terms of **sterility.**

In light of the results and following authorization for the introduction of CM, the preparation protocol was institutionalized. The administration was well tolerated by the patient, with no significant incidents.

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