Epicutaneous patch test preparation in identifying allergenic components in a cosmetic cream: A case report

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Background and importance

Cosmetic products often contain multiple ingredients, some of which may cause undesirable effects such as hypersensitivity. For this reason, cosmetovigilance is crucial and healthcare professionals are required to report serious adverse reactions linked to the use of cosmetic products. Once reported, the manufacturer may provide the ingredients in a form that is not suitable for direct skin application. The Pharmacy Department plays a key role in preparing patch tests to allow diagnosis.

Aim and objectives

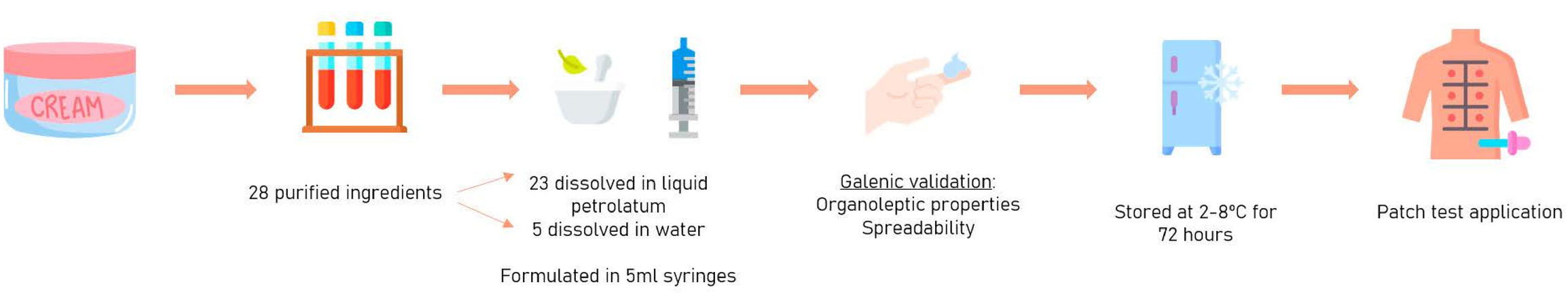
To describe the work procedure for patch tests preparation in the Pharmacy Department to meet the demand for epicutaneous patches.

Material and methods

The Dermatology Department reached out to the Pharmacy Department concerning an unusual case of allergic contact dermatitis in a 71-year-old woman following the use of a cosmetic cream. The manufacturer was notified of the adverse reaction and provided 28 purified ingredients. A literature review (manufacturers datasheets, PubChem, European Pharmacopoeia) was conducted to select the appropriate vehicle (petrolatum or glycerin) for each ingredient based on their solubility (octanol-water partition coefficient) and desired concentration.

Results

The 28 patch tests were prepared in a non-sterile compounding area, with one ingredient (perfume) prepared in a Class IIB biosafety cabinet due to its irritant nature. The required concentrations (0.1% to 30%) were formulated in 5 mL polypropylene syringes. Of the 28 ingredients, 23 were dissolved in liquid petrolatum, and 5 in water. Due to the lack of stability studies, a 72-hour shelf life at 2-8°C was assigned to the preparations. Organoleptic properties and spreadability were assessed for galenic validation. The 28 preparations were applied to the patient's back, and patch test results were evaluated at 48 and 72 hours. At both time points, allergic reactions (erythema, edema) were observed with 1% p-hydroxyacetophenone (SymSave® H), a preservative commonly used in cosmetic products, and 0.1% Bakuchiol, used for its anti-aging properties. These findings were promptly communicated to the manufacturer's cosmetovigilance department.



Graphical workflow of epicutaneous patch test preparation.

Conclusion and relevance

This case has led to the establishment of a work procedure for patch test preparation in a tertiary care hospital and shows the importance of cosmetovigilance and documentation of allergic reactions, offering valuable insights for future allergic reactions caused by this or other cosmetic products.

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