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Sirolimus 1% oily ointments used to treat facial angiofibromas in tuberous sclerosis patients can produce acne, making them reject the treatment.

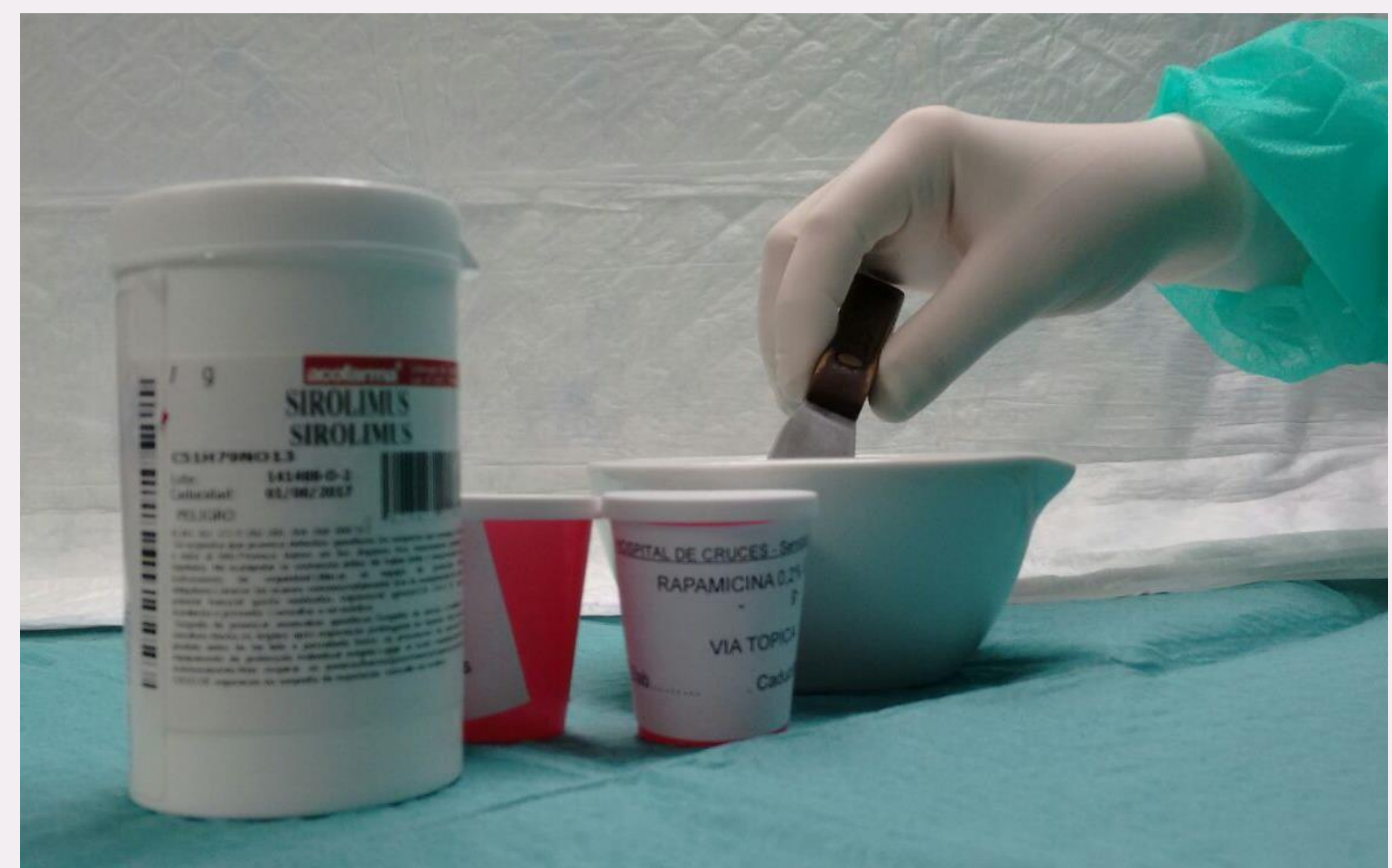
Purpose

- Elaboration of a non-oily formula of topical sirolimus

Material and Methods

Literature review of:

- Alternative topical sirolimus formulations
- Physicochemical properties of sirolimus



Results

0,2% sirolimus gel

- 2% Carmelose gel preparation
 - Aqua conservans (Nipagin® 0,25g + Nipazol® 0,11g + distilled water 500mL) warmed to 50 °C
 - Mix 2g of sodium carboxymethylcellulose and 10g of glicerol in a mortar
 - Add the content of the mortar to 88g of heated aqua conservans and stir the mixture until room temperature is reached
 - Weigh 0.2g of sirolimus and add a few drops of glycerol to it
 - Slowly pour the carmelose gel on the sirolimus, mixing them by stirring, until the 100g are added
 - Let it stand for 12h until the gel is homogeneous
- * Expiry date: 2 months in an opaque container and at room temperature (below 25°C)
- * Caution: Use mask and gloves during the procedure

Conclusion and Discussion

- Compounding of topical sirolimus in non-oleous excipients is possible
- Further studies to determine the efficacy on angiofibromas and the improvement of acne are needed