Stability study of an alternative galenic formulation to sirolimus 0.1% cream in a context of raw material shortage.

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ABSTRACT

Sirolimus cream 0.1% is a preparation cream indicated for the treatment of angiofibromas caused by tuberous sclerosis of Bourneville. An unavailability of the excipient Excipial® Hydrocrème, used in the preparation of the cream led us to look for an alternative. A formulation based on Codexial® Obase has been proposed.

OBJECTIVE

Check the physicochemical stability of sirolimus cream 0.1% following the change of one of the excipient.

MATERIALS AND METHODS

Stability study using Bougueon *et al.* method carried out at Day 0 to 30 (D0, D7, D14, D21 and D30):

- Sirolimus determination via HPLC-UV in triplicate

Column	SupelcosilLC-18, 15cm*4,6mm,5µm
Mobile phase	Eau Milli Q /Méthanol 20%/80%
flow	1ml/min
Temperature samplev/ column	25°C/50°C
Detection	UV à 278 nm
Injected volume	10µl
Analysis time	10 min
Pressure	850 psi

- **pH measurement**

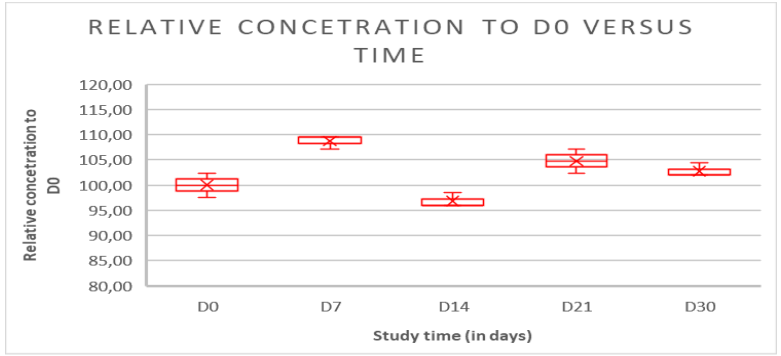
Equipment	Meddler Toledo five esay plus
Electrode	Meddler toled Inlab Visqous

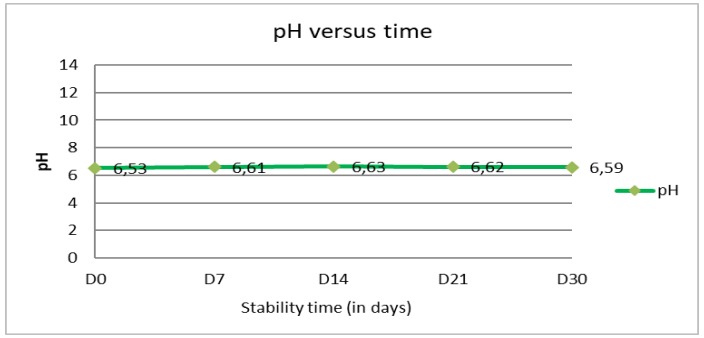
- Viscosity measurement in triplicate

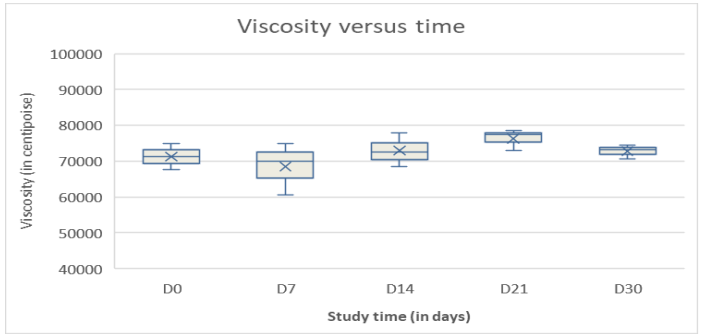
Equipment	Brookfield Amettek
Spindle	S64 Brookfield Amettek

RESULTS

During the study period, D0 to D30 :







- ✓ pH stability over time
- ✓ Content stability and conformity over time
- ✓ Viscosity stability over time
- ✓ No dégradations products observed

DISCUSSION-CONCLUSION

Controls carried out on this alternative formulation led us to conclude a stability for 30 days. For this formulation of 0.1% sirolimus cream from Codexial® Obase, it would be interesting to complete the study with an anti-microbial preservation test.

Reference : Bouguéon G, Lagarce F, Martin L, Pailhoriès H, Bastiat G, Vrignaud S. Formulation and characterization of a 0.1% rapamycin cream for the treatment of Tuberous Sclerosis Complex-related angiofibromas. Int. J. Pharm. (2016)