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TOPICAL RAPAMYCIN IN RARE TUBEROUS SCLEROSIS DISEASE: LIPOSOMAL FORMULATION STABILITY

CORTELL C[1], MARTÍNEZ MA[1], CERCÓS AC[1], CLIMENTE M[1]
[1]DOCTOR PESET HOSPITAL , PHARMACY, VALENCIA, SPAIN

AIM

To develop a liposomal formulation and to determine the validity period according to chemical, physical and microbiological stability in rare tuberous sclerosis disease.

METHOD

A **LIPOSOMAL FORMULATION** of rapamycin 0,4% was prepared in biological safety cabinet.
Packing and conservation: 20G bottle protected of ambient light and stored in a cold room at 5ºC±3ºC.
Composition: sirolimus 0.4%, transcutol-P 10%, liposomal solution 25%, cholesterol 0.1%, isopropile miristrate 10%, propyleneglycol 10%, carbopol 2%, NaOH 10% q.s. pH 7.5, WFI q.s. 20g.

CHEMICAL STABILITY

Analytical method: extraction of rapamycin with apolar solvents and **HPLC analysis**. The percentage of remaining sirolimus content (**%CR**) was determined by triplicate at t=0, 2, 7, 14, 21, 28, 35, 42, 56, 70 and 84 days. **T90** was established when %CR was ≤ 90%.

PHYSICAL STABILITY

Parameters: pH, uniformity, extensibility, absence of crystals and **absence of phase separations** were evaluated on a transparent surface according to 3 levels: level 1, the least favorable and level 3, the most favorable, at t=0 days. **Mean particle size, zeta potential** and **encapsulation efficiency (EE%)** was determined by triplicate at t=0 days.

MICROBIOLOGICAL STABILITY

Culture samples in blood-agar media were incubated at 37°C by duplicate at t=28, 56 and 84 days.

RESULTS

CHEMICAL STABILITY

%CR at t=28 days ± SD	110.1 ± 15.9
%CR at t=56 days ± SD	107.5 ± 21.1
%CR at t=84 days ± SD	124.0 ± 20.4
T90	> 84 days

MICROBIOLOGICAL STABILITY

Culture samples	Negatives

PHYSICAL STABILITY

pH	7.5
Uniformity, extensibility, absence of crystals and absence of phase separations	Level 3
Mean particle size, PdI	178.9 nm, PdI 0.093
Zeta potential (mV) ± SD	-41.1 ± 13.4
EE% ± SD	89.2 ± 4.6

Liposomal formulation

CONCLUSIONS

This study describes a new liposomal formulation to improve the previously treatment for facial angiofibromas in tuberous sclerosis and it also provides favorable stability data. However, more dermokinetic and clinical studies are needed to confirm that liposomes are most appropriate to ensure effectiveness, safety and high patient satisfaction.