3PC-021 AMPHOTERICIN AND COLISTIN GELS FOR NECROTISING WOUNDS: GALENIC AND MICROBIOLOGICAL VALIDATION

A Font*, E Wilhelmi, M Villaronga, D Gavrus, J Vendrell, LE Veloz, JD Yunga, A Casaldàliga, CJ Moreno, R Farré. *Hospital Sant Joan De Déu, Pharmacy, Barcelona, Spain*

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Background and Importance In the intensive care unit, wound infections are complications with highly associated morbimortality, especially in immunocompromised patients. In some circumstances, a combination of endovenous and topical therapies may be required. Due to the lack of adequate commercial presentations, a compounded topical treatment could be a solution to manage a specific infection.

Aim and Objectives Developing a sterile topical gel of Amphotericin B-deoxycholate (Amfob-dc) and colistin to treat severe necrotic wound caused by *Aspergillus fumigatu*, *Acinetobacter baumanii* and *Rhizopus arizus refractory* to surgical debridement in a critical patient. Galenic and microbiological validation.

Material and Methods Bibliographic research was done first and based on the information compiled, it was decided to use sterile water-soluble gel(Varihesive Hydrogel®) as an excipient base. Varihesive Hydrogel is used on the debridement of necrotic wounds. When used with AmfoB-dc 0,15% and colisitin 0,5% in sterile conditions, both refrigerated, remained 7-days stable based on the risk matrix (low risk) of Good Pharmacy Practices. For galenic and microbiological validation, 3 samples of both gels were stored in refrigerator and in room temperature protected from light. Organoleptic characteristics (colour and fluidity), pH and weight were controlled and validated at days 0,7,14,21 and 28 of preparation. Microbiological validation was performed at day 28. Efficacy of treatment was studied with wound reduction and granulation one month after the initiation of the treatment, which was applied 3 tid.

Results Particle-free, homogeneous and viscous gels were obtained. The AmfoB-dc gel exhibited yellow colour and the colistin-based gel gray-translucent. No microbial growth was observed between days 0 to 28. Organoleptic characteristics remained constant throughout the period, however, once stored at cold tempatures they exhibited more viscosity.There were no differences in pH levels or weight variation of >10% (table 1).

Clinical Outcomes were excellent one month after the initiation resulting in an 80% reduction and granulation of the wounds and negative microbiological cultures.

Abstract 3PC-021 Table 1

AmfoB-dc					
pH (Day)	**0**	**7**	**14**	**21**	**28**
RT	7	7	7	7	7
Refrigerator	7	6.5	7	7	7
Weight (Day)	**0**	**7**	**14**	**21**	**28**
RT	7.5	7.6	7.1	7.0	7.0
Refrigerator	8.9	8.9	9.0	8.9	8.8
Colistin					
pH (Day)	**0**	**7**	**14**	**21**	**28**
RT	7	7	6	6	7
Refrigerator	7	7	6	6	6
Weight (Day)	**0**	**7**	**14**	**21**	**28**
RT	9.1	9.1	9.0	8.7	9.1
Refrigerator	9.2	9.2	9.2	9.2	9.2

Conclusion and Relevance These formulations are simple and give accurate results as a targeted therapy for necrotising infected wounds. The individualised topical preparations allow to solve problems of unavailability of adequate commercial forms. According to our validation, the galenic stability of the product seemed to be extended. However, further stability and quantitative studies should be conducted.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

3PC-027 STABILITY OF TACROLIMUS ORAL SUSPENSION IN DISPOSABLE POLYPROPYLENE SYRINGE

[1]JA Hernandez Ramos*, [1]S Pablos Bravo, [2]M Rolo, [1]MA Bruni Montero, [1]A Gonzalez Gomez, [1]A Castro Frontiñan, [1]JM Ferrari Piquero. *[1]Hospital Universitario 12 De Octubre, Servicio De Farmacia, Madrid, Spain; [2]Hospital Universitario 12 De Octubre, Servicio De Microbiologia Y Parasitologia, Madrid, Spain*

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Background and Importance Within the post-operative period following a solid organ transplantation, multidisciplinary teams prioritise tacrolimus administration *per os* to minimise the neurotoxicity associated with its use via continuous intravenous infusion. Despite being classified as a hazardous drug, there is no tacrolimus liquid dosage form commercially available ready for direct administration by oral route.

Aim and Objectives To validate physical, chemical and microbiological stability of an affordable extemporaneous tacrolimus oral solution/suspension in single-dose disposable polypropylene syringe.

Material and Methods A search on chemical compatibility between tacrolimus and polypropylene was accomplished. The formulation developed for study case was split in three samples stored at 20–25°C and three others at 2–8°C, ensuring every assay was performed in triplicate.

Stability parameters were tested every 7 days for a 28-day period. The analysis included organoleptic properties, sedimentation time, homogeneity, pH, redispersibility, crystal growth and weight variation. In order to identify and quantify any potential colony-forming unit (CFU), cultures with blood agar were read after 24 and 48 hours from incubation at 37°C, whereas Sabouraud agar cultures were read after 24, 48, 72 and 96 h.

Results Chemical stability of tacrolimus 1 mg/mL suspension formulated with 1:1 Ora Plus® and Ora Sweet® in polypropylene syringe was reported.

For the present study, tacrolimus 1 mg/mL suspension based on a 2:1 blend of simple syrup and carboxymethylcellulose 1.5% aqueous gel was developed since its composition is simpler and saves € 8,51/100 mL.

Physical and chemical parameters remained constant during all the study period regardless of storage temperature: The formulation was homogeneous, sheer with yellowish hue and sweet. No crystal growth or sediment were observed. Median weight variation was 0.96% for the fraction stored at 20–25°C (0.38%–1.65%) and 0.75% for the stored at 2–8°C (0.58%–1.08%). Average pH values were 5.70 (5.60–5.76) and 5.72 (5.70–5.76) respectively.