

AMPHOTERICIN AND COLISTIN GELS FOR NECROTISING WOUNDS: GALENIC AND MICROBIOLOGICAL VALIDATION

SJD Sant Joan de Déu
Barcelona · Hospital

A. FONT, E. WILHELMI, M. VILLARONGA, D. GAVRUS, J. VENDRELL, L.E. VELOZ, J.D. YUNGA, A. CASALDÀLIGA, C.J. MORENO, R. FARRÉ
HOSPITAL SANT JOAN DE DÉU, PHARMACY, BARCELONA, SPAIN.

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 therapies may be required: **ENDOVENOUS**  + **TOPICAL** .

Aim and objectives

→ Developing a **sterile topical gel of Amphotericin B-deoxycholate (Amfob-dc) and colistin** to treat severe necrotic wound caused by *Aspergillus fumigatus*, *Acinetobacter baumannii* and *Rhizopus arzus* in a critically ill pediatric patient.

→ Galenic and microbiological validation.

Material and methods

Bibliographic research was done first-> it was decided to use sterile **water-soluble gel (Varihesive Hydrogel®)** as an excipient base.

Water-soluble gel used with **AmfoB-dc 0,15% and colistin 0,5%** in sterile conditions, both refrigerated, remained 7-days stable based on the risk matrix (low risk) of Good Pharmacy Practices.

3 samples of both gels were stored in refrigerator and in room temperature protected from light.

→ **Galenic validation:** days 0, +7,+14, +21 and +28 Organoleptic characteristics (color and fluidity), pH and weight.

→ **Microbiological validation:** day: +28.

Efficacy of treatment was studied with wound reduction and granulation one month after the initiation of the treatment, which was applied 3 times/day.

Results

→ **Organoleptic characteristics remained constant** throughout the period, however, once stored at cold temperatures they exhibited more viscosity.

→ There were no differences in pH levels or weight variation of >10%.

→ **No microbial growth** was observed between days 0 to 28

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

AMFOB-DC					
pH (Day)	0	7	14	21	28
Room temperature	7	7	7	7	7
Refrigerator	7	6.5	7	7	7
Weight (Day)	0	7	14	21	28
Room temperature	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
Room temperature	7	7	6	6	7
Refrigerator	7	7	6	6	6
Weight (Day)	0	7	14	21	28
Room temperature	9.1	9.1	9.0	8.7	9.1
Refrigerator	9.2	9.2	9.2	9.2	9.2

*Mean values of the three samples



Particle-free, homogeneous and viscous gels.

Conclusion and relevance

→ These formulations are simple and give accurate results as a targeted therapy for necrotizing infected wounds.

→ The individualized 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.

