



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 240663

Product:	AMPHOTERICIN B
Lot:	240663
Expiry date:	30/10/2026
Reference:	Cumple USP-NF2023-3
Synonyms:	
Formula:	C ₄₇ H ₇₃ NO ₁₇
Molecular weight:	924,0 g/mol

Assay	Result	Specification	
Identification	Conform		
Organoleptic properties	Conform		
Loss on drying	2,6 %	<= 5,0 %	
Sulphated ashes	0,30 %	<= 3,0 %	
Amphotericin A content	4,2 %	<= 15,0 %	
Antimicrobial power	965 mcg/mg	>= 750 mcg/mg	
STORE IN REFRIGERATOR (2-8°C)			
Residual solvent: Methanol	< 3000 ppm	<= 3000 ppm	#
Residual solvent: acetone	< 5000 ppm	<= 5000 ppm	#
Elemental impurities	Conform	Test USP	#

Organoleptic characteristics:

Conservation: In tightly closed containers. Protect from light. FRIDGE (2-8°C)

Date of analysis: 19/04/2024

Judgement:
APPROVED

Responsible: B.Chia

Technical director: Montserrat Enrique

Manufacturer: F00374 SYNBIOTICS LIMITED

Manufacturer batch: 23L01N35

Product	Name	Capacity	Batch
1103467	AMFOTERICINA B	5 g	240663-E-1
1103467	AMFOTERICINA B	5 g	240663-E-2
1103468	AMFOTERICINA B	25 g	240663-G-1
1103468	AMFOTERICINA B	25 g	240663-G-2
1103468	AMFOTERICINA B	25 g	240663-G-3
1103470	AMFOTERICINA B	100 g	240663-J-1
1103470	AMFOTERICINA B	100 g	240663-J-2
1103470	AMFOTERICINA B	100 g	240663-J-3

1103473	AMFOTERICINA B	1 kg	240663-P-1
1103473	AMFOTERICINA B	1 kg	240663-P-2

This certificate is not initialled as it is computer processed, it is validated with the originals available at Acofarma.

Original manufacturer's certificate available on request.

(#) Parameter controlled by the manufacturer

(=) UE certificate

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