



## ANALYSIS CERTIFICATE

**Lot/Analysis/Analysis N°: 241841**

Product:	AMPHOTERICIN B
Lot:	241841
Expiry date:	30/04/2027
Reference:	Cumple USP-NF2024-2
Synonyms:	
Formula:	C <sub>47</sub> H <sub>73</sub> NO <sub>17</sub>
Molecular weight:	924,0 g/mol

Assay	Result	Specification	
Identification	Conform		
Organoleptic properties	Conform		
Loss on drying	2,7 %	<= 5,0 %	
Sulphated ashes	1,8 %	<= 3,0 %	
Amphotericin A content	3,9 %	<= 15,0 %	
Antimicrobial power	924 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: 24/10/2024

Judgement:  
APPROVED

Responsible: B. Chia

Technical director: Montserrat Enrique

Manufacturer: F00374 SYNBIOTICS LIMITED

Manufacturer batch: 24E01N21

Product	Name	Capacity	Batch
1103467	AMFOTERICINA B	5 g	241841-E-1
1103468	AMFOTERICINA B	25 g	241841-G-1
1103468	AMFOTERICINA B	25 g	241841-G-2
1103470	AMFOTERICINA B	100 g	241841-J-1
1103470	AMFOTERICINA B	100 g	241841-J-2
1103473	AMFOTERICINA B	1 kg	241841-P-1
1103473	AMFOTERICINA B	1 kg	241841-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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