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Telephone: +91-9099978530, Web: www.synbiotics.in, QIN: U24232GJ1960PLC000992




## CERTIFICATE OF ANALYSIS

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Product	: Amphotericin B (Oral Grade)	Batch No.	: 16K01N68
Date of Sampling	: 08/10/16	Date of Mfg.	: Oct. 2016
A. R. No.	: AMPH/O/1668	Date of Exp.	: Sep. 2019
Quantity Mfg.	: 20,350 kg	Date of Release	: 14/10/16

Reference Specification: Amphotericin B EP SPE/FP/015

TESTS	OBSERVATIONS	SPECIFICATION
Appearance	Yellow powder	A yellow or orange powder.
Solubility	Practically insoluble in Water, soluble in Dimethylsulphoxide, slightly soluble in Dimethylformamide, very slightly soluble in Methanol, practically insoluble in Alcohol.	Practically insoluble in Water, soluble in Dimethylsulphoxide, slightly soluble in Dimethylformamide, very slightly soluble in Methanol, practically insoluble in Alcohol
Identification: (A) UV-VIS spectrophotometry  Ratio at 362 / 381  381 / 405	  0.59  0.89	  0.57 to 0.61.  0.87 to 0.93.
(B) Infrared absorption spectrophotometry	The positions and relative intensities of the absorption bands of the spectrum of the substance conform to those of the reference spectrum.	The positions and relative intensities of the absorption bands of the spectrum of the substance should conform to those of the reference spectrum.
(C) Color development with phosphoric acid and addition of water	A blue ring is immediately produced at the junction of liquids. On mixing an intense blue color produced. On addition of water the solution becomes pale yellow	A blue ring is immediately produced at the junction of liquids. On mixing an intense blue color must produced. On addition of water the solution must become pale yellow.
(D) Related substances	The principal peak in the chromatogram obtained with the test solution at 383nm is similar in retention time to the principal peak in the chromatogram obtained with reference solution (a).	The principal peak in the chromatogram obtained with the test solution at 383nm is similar in retention time to the principal peak in the chromatogram obtained with reference solution (a).

Prepared By	Reviewed By	Approved By
 14/10/16	 14/10/16	 14/10/16
QC (Signature and Date)	QC (Signature and Date)	QA (Signature and Date)

Regd. Office: Synbiotics Ltd, Sarabhai Campus, Gorwa Road, Vadodara - 390 023, India  
Telephone.: (O) +91 265 2280117, Fax : +91 265 2281894

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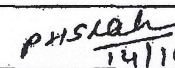
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### Reference Specification: Amphotericin B EP SPE/FP/015

TESTS	OBSERVATIONS	SPECIFICATION
<b>Related Substances</b>		
Impurity A at 303nm	0.93 %	Not more than 5.0%.
Any other impurity at 303nm	Nil	Not more than 1.0%.
Impurity B at 383nm	1.60 %	Not more than 4.0%.
Any other impurity at 383nm	1.30 %	Not more than 2.0%.
Total impurity at 303nm and 383nm	7.39 %	Not more than 15.0%
Loss on Drying	3.72 %	Not more than 5.0%.
Sulphated Ash	0.16 %	Not more than 3.0%.
Assay	944 IU per mg	Not less than 750 IU per mg (Calculated on dried basis).
<b>Additional Tests</b>		
<b>Residual Solvents</b>		
Methanol	404 ppm	Not more than 3000 ppm.
Acetone	2603 ppm	Not more than 5000 ppm
Total Aerobic Microbial Count	30 cfu/gm	Less than 1000 cfu/gm
Total Combined Yeast/Mould Count	Not detected in 1:10 dilution	Less than 100 cfu/gm
<b>Pathogens</b>		
Escherichia coli	Absent	Must be Absent
Staphylococcus aureus	Absent	Must be Absent
Pseudomonas aeruginosa	Absent	Must be Absent
Salmonella Species	Absent	Must be Absent

**Comments :** The above Product meets the requirements of EP.

**Storage :** Preserve in tight, light resistant containers between 2°C and 8°C.

Prepared By	Reviewed By	Approved By
 14/10/16 QC	 14/10/16 QC	 14/10/16 QA
(Signature and Date)	(Signature and Date)	(Signature and Date)

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Director Técnico