

CERTIFICATE OF ANALYSIS

Product : **AMPHOTERICIN B SUSPENSION 100 mg/ml**
 Product number : A0192
 Batch number : E498
 Date of manufacturing : 14-07-2016
 Date of analysis : 29-07-2016
 Expiry date : 30-06-2018

Packaging and storage : store at room temperature

	SPECIFICATION	RESULT	UNITS	REMARKS
Appearance	conform	complies		
Colour	conform	complies		
Odour	conform	complies		
Homogeneity :				
- Visual examination	conform	complies		
- Screen size	conform	complies		
Identity:				
- Amphotericin B	conform	complies		UV
- Parabens and sodium benzoate	conform	complies		HPLC
- Erythrosin	conform	complies		UV/visible
-Sodium metabisulphite	conform	complies		
pH	5.3 – 5.8	5.4		25 °C
Sedimentation	≤ 1	< 1	%	
Relative density	1.05 – 1.09	1.07		20 °C
Viscosity	≥ 200	352	mPa.s	25 °C
Extractable volume	≥ 40	41	ml	
Total microbiological count	≤ 100	< 10	ufc/ml	
Total yeasts and moulds count	≤ 500	< 10	ufc/ml	
Absence of E.Coli	conform	complies		
Assay amphotericin B	90 – 110	96	mg/ml	HPLC
Total paraben	1.35 – 1.65	1.49	mg/ml	HPLC
Assay sodium benzoate	1.80 – 2.20	1.99	mg/ml	HPLC

This certificate of analysis is conform the results of the manufacturer.

Conclusion: approved

Released by:

drs. M. van Wissen, pharmacist
 Department of Quality Control Duchefa B.V.

Date: 05-05-2017



The buyer is responsible to test each batch to ensure the product is suitable for their specific purpose.