

C47H73NO17

924,1

CAS No 1397-89-3

Lot: 0061211.

NORTH CHINA PHARMACEUTICAL HUASHENG CO., LTD.  
CERTIFICATE OF ANALYSIS

Add: No. 8 Yangzi Road, Shijiazhuang Economic & Technological Development Zone, Hebei 052160, China  
Tel: +86-311-83090290 Fax: +86-311-83090280 Website: <http://www.ncpchs.com> E-mail: [mail@ncpchs.com](mailto:mail@ncpchs.com)

**Product name : Amphotericin B non-sterile, USP**

**(Intended for use in preparing oral dosage forms)**

Batch No.	:	HAO1104201	Manuf. date	:	2011.04.03
Quantity	:	30 kg	Report date	:	2011.04.16
Cert. No.	:	P-A-03	Retest date	:	2013.04.02

Tests	Specifications	Results
Appearance :	Yellow to orange powder, odorless or practically so.	Yellow powder
Solubility:	Insoluble in water and in ether, slightly soluble in methanol	Complies
Identification A: (UV)	Conforms to standard; absorbance in the range of 240nm to 320nm.	Complies
Identification B: (UV/Vis)	Conforms to standard; absorbance in the range of 320nm to 400nm.	Complies
Loss on drying :	Not more than 5.0%	2.0%
Residue On Ignition:	Not more than 3.0%	0.7%
Limit amphotericin A:	Not more than 15.0%	Not detected
Assay (microbial)	Not less than 750 µg/mg calculated on the dried basis	967 µg/mg
Microbial Limits:		
Total Aerobic Count	Not more than 100 CFU/gram	0 CFU/gram
Salmonella Species	Negative	Conforms
Escherichia Coli	Negative	Conforms
Residual Solvents:		
Ethanol:	Not more than 5000 ppm	1876 ppm
Acetone:	Not more than 5000 ppm	1020 ppm

**Conclusion : Complies with USP33**

Reporter: 徐静 Manager of QC division: 梁超 Manager of QA division: 赵建强

