



YICHANG SANXIA PHARMACEUTICAL CO., LTD.

NO.8, ZIYANG ROAD, DIANJUN DISTRICT, YICHANG CITY, HUBEI PROVINCE, P.R.CHINA

CERTIFICATE OF ANALYSIS

ISSUING DATE:2014-07-30

PRODUCT NAME:NEOMYCIN SULPHATE	BATCH NO.:201407044
PACKING:20BOU/DRUM	MFG DATE:2014-07-23
QUANTITY: 1120BOU	RE-TEST PERIOD:2018-07-22

Items		Specification:EP8	Results
Characteristics		White or yellowish-white powder, odorless or almost, hygroscopic	Complies
Identification		A; B The positive reaction.	Complies
Solubility		Very soluble in water; very slightly soluble in Alcohol, practically insoluble in acetone	Complies
PH		5.0-7.5	6.2
Specific optical rotation		+53.5° TO +59.0°	+58.2°
Related Substance (HPLC)	Impurity A	≤2.0%	0.35%
	Impurity C	3.0%-15.0%	12.73%
	Any other impurity	≤5.0%	1.36%
	Total of other impurities	≤15.0%	2.96%
	Any unspecified impurities	≤1.0%	Complies
	Disregard limit	≤1.0%	Complies
Sulphate		27.0%-31.0%	29.1%
Loss on drying		≤8.0%	5.3%
Sulphated ash		≤1.0%	0.22%
Microbiological Enumeration		TAMC ≤1000CFU/g	30
		TYMC ≤100CFU/g	<10
Assay		≥680IU./mg	684 IU./mg(DRY) 648 IU./mg(MOIST)
Conclusion: The product meets the requirements of EP8			

Analysts:

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Supervisor:

Chen Yongqiang

THE BATCH HAS BEEN MANUFACTURED IN FULL COMPLIANCE WITH GMP NUMBER:鄂J0351, ISSUE DATE:2008/12/26, VALIDITY DATE:2015/12/31 AND "BATCH PRODUCTION RECORD CHECKED AND APPROVED, NO DEVIATION,NO REWORKING AND REPROCESSING."

COS NO.:RO-CEP 2011-029-Rev 01

MANUFACTURER: YICHANG SANXIA PHARMACEUTICAL CO., LTD.

YICHANG SANXIA
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宜昌三峡制药有限公司