



YICHANG SANXIA PHARMACEUTICAL CO., LTD.

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

CERTIFICATE OF ANALYSIS

ISSUING DATE:2012-07-03

PRODUCT NAME:NEOMYCIN SULPHATE -	BATCH NO.:201206054
PACKING:15BOU/DRUM	MFG DATE:2012-06-25
QUANTITY: 675 BOU	EXP DATE:2016-06-24

Items	Specification:EP7	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°	+58.7°
Related Substance (HPLC)	Impurity A $\leq 2\%$	Complies
	Impurity C 3%-15%	Complies
	Any other impurity $\leq 5\%$	Complies
	Total of other impurities $\leq 15\%$	Complies
	Disregard limit $\leq 1\%$	Complies
Sulphate	27.0%-31.0%	28.8%
Loss on drying	$\leq 8\%$	4.7%
Sulphated ash	$\leq 1.0\%$	0.2%
Microbiological Enumeration	TAMC $\leq 1000\text{CFU/g(EP 5.1.4)}$	20
	TYMC $\leq 100\text{CFU/g(EP 5.1.4)}$	< 10
Assay	$\geq 680\text{ IU./mg(DRY)}$	687 IU./mg(DRY) 655 IU./mg(MOIST)
Conclusion: The product meets the requirements of EP7.0		

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:2013/12/25 AND "BATCH PRODUCTION RECORD CHECKED AND APPROVED."

YICHANG SANXIA PHARMACEUTICAL CO., LTD.
宜昌三峡制药有限公司

YICHANG SANXIA PHARMACEUTICAL CO., LTD.

FAGRON IBÉRICA, S.A.U
Corresponde al lote de Fagron:

L12090046

Director Técnico S.