

漯河南街村药业集团制药有限公司

LUOHE NANJIECUN PHARMACEUTICAL GROUP PHARMACY CO., LTD

ADD:NO.7, RENMIN ROAD (EAST), LUOHE CITY, HENAN PROVINCE, P.R.CHINA.



CERTIFICATE OF ANALYSIS

PRODUCT:	RIFABUTIN	QUANTITY:	15KGS
BATCH NO.:	RFB080403	MFG. DATE:	03/03/2008
PACKING:	5KGS/TIN	EXP. DATE:	03/02/2012
FOUNDATION:	USP27	DATE OF REPORT:	03/02/2008
Sr No.	Items	Specifications	Observation
01	Appearance	Red-violet amorphous powder	Complies
02	Identification		
	(A) Infra-red absorption	Concordant with reference Spectrum	complies
	(B) HPLC	Retention time of major peak in Assay preparation corresponds to that of the standard preparation.	Complies
03	Limit of N-Iso Butylpiperidone	NMT 0.5%	Complies
04	Chromatographic Purity		
	a) Each individual impurity at about RRT 0.5,0.6,0.8 and1.4 with respect to Rifabutin	NMT1.0%	0.04%, 0.17% 0.05%, 0.07%
	b) Each other individual	NMT 0.5%	Complies
	c) Total Impurity	NMT 3.0%	1.8%
05	Assay (C46H62N4O11)		
	On anhydrous basis	95.0% to 102.0%	99.5%
<p>This is certified that we, the undersigned, have inspected the quality of above mentioned goods as manufacturer and found the result as following:</p> <p>Conclusion is up to the Standard of USP27</p>			

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Approved by:

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Checked by:

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Analysed by:

李会荣