

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 EAST RENMIN ROAD LUOHE HENAN, P.R.CHINA



CERTIFICATE OF ANALYSIS

Product:	Rifamycin S	Packing:	25kg/Drum
Batch No.:	0712120(M)	Weight:	500kg
Foundation:	《QNYZ09.01-04》	Expiry Date:	06/2010
MFG Date:	12/24/2007	Date Of Report:	12/30/2007

Items	Specifications	Results
Description	A Yellow to orange crystalline powder	Passed
Solubility	Freely soluble in acetone,insoluble in water	Conform
Identification		
IR spectrum	IR spectrum of the test substance is concordant to that of the reference standard spectrum	Positive
Loss On Drying	Not more than 10.0%	7.5%
Sulphated	Not more than 1.0%	0.07%
Related substances (by HPLC)		
a. Desacetyl Rifamycin S	Not more than 1.0%	0.6%
b. Total impurity	Not more than 3.0%	1.7%
Purity (by HPLC)	Not less than 97.0%	98.3%
Assay (as is basis)		
(by UV)	Not less than 88.0%	93.7%

This is certified that we, the undersigned, have inspected the quality of above-mentioned goods as manufacturer and found the result as following:

Conclusion is up to the Standard of 《QNYZ09.01-04》

Approved by:



Rechecked by:



Tested by:



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 EAST RENMIN ROAD LUOHE HENAN, P.R.CHINA



CERTIFICATE OF ANALYSIS

Product:	Rifamycin S	Packing:	25kg/Drum
Batch No.:	0712121(M)	Weight:	500kg
Foundation:	《QNYZ09.01-04》	Expiry Date:	06/2010
MFG Date:	12/24/2007	Date Of Report:	12/30/2007

Items	Specifications	Results
Description	A Yellow to orange crystalline powder	Passed
Solubility	Freely soluble in acetone,insoluble in water	Conform
Identification		
IR spectrum	IR spectrum of the test substance is concordant to that of the reference standard spectrum	Positive
Loss On Drying	Not more than 10.0%	7.4%
Sulphated	Not more than 1.0%	0.05%
Related substances (by HPLC)		
a. Desacetyl Rifamycin S	Not more than 1.0%	0.6%
b. Total impurity	Not more than 3.0%	1.7%
Purity (by HPLC)	Not less than 97.0%	98.3%
Assay (as is basis)		
(by UV)	Not less than 88.0%	92.5%

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Conclusion is up to the Standard of 《QNYZ09.01-04》

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LUOHE NANJIECUN PHARMACEUTICAL GROUP PHARMACY CO.,LTD

ADD: NO. 7 EAST RENMIN ROAD LUOHE HENAN, P.R.CHINA



CERTIFICATE OF ANALYSIS

Product:	Rifamycin S	Packing:	25kg/Drum
Batch No.:	0712122(M)	Weight:	500kg
Foundation:	《QNYZ09.01-04》	Expiry Date:	06/2010
MFG Date:	12/25/2007	Date Of Report:	12/31/2007

Items	Specifications	Results
Description	A Yellow to orange crystalline powder	Passed
Solubility	Freely soluble in acetone, insoluble in water	Conform
Identification IR spectrum	IR spectrum of the test substance is concordant to that of the reference standard spectrum	Positive
Loss On Drying	Not more than 10.0%	7.5%
Sulphated	Not more than 1.0%	0.07%
Related substances (by HPLC)		
a. Desacetyl Rifamycin S	Not more than 1.0%	0.6%
b. Total impurity	Not more than 3.0%	1.4%
Purity (by HPLC)	Not less than 97.0%	98.6%
Assay (as is basis) (by UV)	Not less than 88.0%	92.5%

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