

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:	RIFAMPICIN	QUANTITY:	500KG
BATCH NO.:	20210112	MFG.DATE:	01/15/2021
PACKING:	25KG/DRUM	EXP.DATE:	01/14/2025
FOUNDATION:	BP2020	DATE OF REPORT:	01/28/2021

Sr No.	Items	Specifications	Observation
01	Appearance	Reddish-brown or brownish-red, crystalline powder.	Reddish-brown, crystalline powder.
02	Solubility	Slightly soluble in water, soluble in methanol, slightly soluble in acetone and in ethanol.	Conform
03	Identification		
	1) UV absorption	The ratio of absorption at 334nm to that at 475nm is about 1.75;	Conform
	2) IR spectrum	Conforms with reference spectrum;	Conform
	3) Colour reaction	The colour changes from orange-yellow to violet-red and no precipitate is formed.	Conform
04	pH	4.5~6.5	5.8
05	Related Substances		
	1) Rifampicin Quinone	Not more than 1.5%	0.1%
	2) Any other impurity	Not more than 1.0%	0.7%
	3) Sum of impurities other than Rifampicin Quinone	Not more than 3.5%	1.5%
06	Loss on Drying	Maximum 1.0%	0.2%
07	Sulfated Ash	Maximum 0.1%	0.08%
08	Residual Solvents		
	1) Acetone	Maximum 5000ppm	Conform
	2) 1-Butanol	Maximum 5000ppm	Conform
	3) Ethyl acetate	Maximum 5000ppm	Conform
	4) Butyl acetate	Maximum 5000ppm	Conform
	5) N,N-Dimethylformamide	Maximum 880ppm	Conform
09	Assay	It contains 97.0%~102.0% of C ₄₃ H ₅₈ N ₄ O ₁₂ , calculated on dried basis.	99.8%

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 BP2020

Approved by:



Checked by:



Analysed by:

