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CERTIFICATE OF ANALYSIS

Product Name:	Rifaximin		
CAS No.:	80621-81-4	Quantity	100kg
Rep Date	May.16.2014	Batch NO.	20140516
MFG. Date	May.16.2014	Expiry Date	May.15.2016

Item	Specifications	Results
Characters	Red-orange to dark,crystalline powder	Red-orange crystalline powder
PH	Take sample, add water into each 1 ml contains about 10mg of suspension, according to the determination should be 4.5~7.5	6.4
Identification 1) Chemical 2) HPLC 3) IR	Identification reaction for ferric chloride, A brownish-black colour is produced. The retention time of principal peak of substance being examined in the chromatogram obtained in the assay is identical with that of standard solution. The infrared absorption spectrum is concordant with reference spectrum of Rifaximin.	Confirm Confirm Confirm
Test 1)Crystallinity 2)Loss on drying 3)Related substance 4)Residue on ignition 5)Heavy metals 6)Solvent residue 7)Microbial limit tests Total microbial count Mould and yeast E.coli	Should meet the requirements. Not more than 4.5%. Individual impurity not more than 1.5%, Total impurities not more than 3.0%. Not more than 0.1%. Not more than 0.002%. Ethanol Not more than 0.5% Dichloromethane Not more than 0.06%	Confirm 1.7% Confirm Confirm 0.03% Confirm Confirm Not detected Confirm Confirm Confirm
Assay	Not less than 98% (anhydrous substance)	98.9%
Conclusion	The results conforms with Enterprise standards	

Analyst:Liya

Checker:Weichen


 Q.C. Director: Xuleilei


 Authorized Signature(s)