

Quality Control - Certificate of analysis Nr: **201806275**

Product
RIFAXIMIN

Batch
2018BJ7799

Analysis
20/11/2018

Expiry Date
06/2020

Analysis	Limits		unit of measure	Result
	min.	max		
CHARACTERS:				
APPEARANCE	Red-orange crystalline hygroscopic powder			Complies
IDENTIFICATION (IR,UV)	The same as standard			Complies
X-RAY POWDER DIFFRACTION	Complies with the polymorphic form Rifaximin α			Complies
SOLUBILITY	Practically insoluble in water, soluble in acetone and methanol			Complies
WATER		2.5	%	1.2
SPECIFIC OPTICAL ROTATION	420	460	°	448
RELATED SUBSTANCES:				
Sum of impurities D and H		0.5	%	0.34
Unspecified impurities		0.10	%	0.10
Total impurities		1.0	%	0.55
PARTICLE-SIZE DISTRIBUTION:				
Particle size ($\leq 100 \mu\text{m}$)	95.0			98.1
d (0.5)	10	40	micron	12
RESIDUAL ETHANOL		0.5	%	0.0
HEAVY METALS		≤ 20	ppm	Complies
SULPHATED ASH		0.1	%	0.0
ASSAY on dried basis	98.0	101.0	%	100.5

Note: SUPPLIER: FIS (VI)
SUPPLIER'S BATCH: 201806084008

APPROVED

Quality Control Manager
Dr. C. Trezza

[Signature] 02.05.2019