

CERTIFICATE OF ANALYSIS

Product name: Purimox® (amoxicillin trihydrate, powder)
 Product code: 6.36.21.00
 Active Ingredient: Amoxicillin
 Batch/Lot number: 3F52544
 Batch size: 550.00 kg
 Date of Manufacture: December/2012
 Date of release: 13/December/2012
 Retest/expiry date: November/2017
 Pharmacopoeia quality: Complies with the latest editions of USP, FEUM

Parameter:	Specification:	Result:
Assay HPLC	Min. 82.8 %	86.7 %
as such	Min. 95.0 %	99.8 %
On dry basis	White to off-white crystalline powder	conforms
Appearance	Conforms with test	conforms
Identification	3.5 - 5.5	5.0
pH		
Appearance of solution	Not more opalescent than ref. susp. 2	conforms
in HCl	Not more opalescent than ref. susp. 2	conforms
in NH ₄ OH	+290 to +315 °	304 °
Optical Rotation *	NMT 1.0 %	0.1 %
Sulphated ash *	11.5 - 14.5 %	13.1 %
Water	Crystalline	crystalline
Crystallinity *		
Related impurities		
amoxicilloic acid	NMT 1.0 %	0.02 %
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amoxicillin dimer	NMT 1.0 %	0.02 %
amoxicillin trimer	NMT 1.0 %	0.02 %
amoxicillin dimer (open)	NMT 1.0 %	0.02 %
2-(S)-piperazine-2,5-dione	NMT 1.0 %	0.02 %
2-(R)-piperazine-2,5-dione	NMT 1.0 %	0.02 %
6-aminopenicillanic acid	NMT 0.5 %	0.02 %
p-hydroxyphenylglycine	NMT 1.0 %	0.02 %
p-OH-phenylglycylamoxicillin	NMT 1.0 %	0.02 %
Any unspecified individual impurity	NMT 1.0 %	0.02 %
Total impurities	NMT 5.0 %	0.3 %
Total Plate Count	Max. 250 UFC/g	6 UFC/g
Yeasts & Moulds	Max. 100 UFC/g	0 UFC/g
E. Coli	0 UFC/10gr	0 UFC/10g

*Checked at regular intervals

N,N-Dimethylaniline is not used in the manufacturing process of this substance or present on any of the raw materials.

Manufactured by:

Planta Síntesis, Camino a Guanajuato S/N, Ramos Arizpe, Coahuila, México CP 25900.

Date of issue: 24/12/12

Quality Assurance Department

Q.F.B. José F. Areozola M.