



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 242096

Product:	TRIMETOPRIM
Lot:	242096
Expiry date:	30/01/2029
Reference:	Cumple PhEur11.5
Synonyms:	Trimetoprima.
Formula:	C ₁₄ H ₁₈ N ₄ O ₃
Molecular weight:	290,3 g/mol

Assay	Result	Specification	
Identification	Conform (C)	Test PhEur (C)	
Organoleptic properties	Conform	PhEur	
Appearance of solution	Conform		
Related substances (HPLC)	Conform		
Elemental impurities	Conform	Test PhEur	#
Impurity K	< 5 ppm	<= 5 ppm	
Loss on drying	0,01 %	<= 1,0 %	
Sulphated ashes	0,04 %	<= 0,1%	
Assay	100,4 %	99,0 - 101,0 %	
Unspecified Impurities	< 0,05 %	<= 0,10 %	
Total impurities	< 0,05 %	<= 0,2 %	
Residual solvents	Conform	Test PhEur	#
Nitrosamine impurities	Conform	Test PhEur	#

Organoleptic characteristics: White or yellowish-white powder. Very slightly soluble in water, slightly soluble in ethanol (96 per cent), practically insoluble in heptane.

Conservation: In tightly closed containers. Protect from light.

Date of analysis: 29/11/2024

Judgement:
APPROVED

Responsible: B. Chia

Technical director: Montserrat Enrique

Manufacturer: F00182 SHOUGUANG FUKANG PHARMACEUTICAL CO., LTD

Manufacturer batch: A-20112402004

Product	Name	Capacity	Batch
1100070	TRIMETOPRIM	25 kg	242096-T-2
1100070	TRIMETOPRIM	25 kg	242096-T-3
1187056	TRIMETOPRIM	1 kg	242096-P-1
1200279	TRIMETOPRIM	100 g	242096-J-1

1200279	TRIMETOPRIM	100 g	242096-J-2
1200279	TRIMETOPRIM	100 g	242096-J-3

This certificate is not initialled as it is computer processed, it is validated with the originals available at Acofarma.

Original manufacturer's certificate available on request.

(#) Parameter controlled by the manufacturer

(=) UE certificate

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