



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 241536

Product:	TRIMETOPRIM
Lot:	241536
Expiry date:	30/12/2027
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	1 ppm	<= 5 ppm	#
Loss on drying	0,02%	<= 1,0 %	
Sulphated ashes	0,01%	<= 0,1%	
Assay	99,6 %	99,0 - 101,0 %	
Unspecified Impurities	0,08%	<= 0,10 %	
Total impurities	0,08 %	<= 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: 31/07/2024

Judgement:
APPROVED

Responsible: B.Chia

Technical director: Montserrat Enrique

Manufacturer: F00182 SHOUGUANG FUKANG PHARMACEUTICAL CO., LTD

Manufacturer batch: A-20112301026

Product	Name	Capacity	Batch
1100070	TRIMETOPRIM	25 kg	241536-T-1
1187056	TRIMETOPRIM	1 kg	241536-P-1
1200279	TRIMETOPRIM	100 g	241536-J-1

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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