



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 241548

Product:	TETRACYCLINE HYDROCHLORIDE
Lot:	241548
Expiry date:	24/12/2027
Reference:	Cumple PhEur11.5
Synonyms:	
Formula:	C ₂₂ H ₂₄ N ₂ O ₈ ·HCl
Molecular weight:	480,9 g/mol

Assay	Result	Specification	
Identification	Conform (A,B,C)		
Organoleptic properties	Conform		
pH of the 1% water solution	2,6	1,8 - 2,8	
Related substances (HPLC)	Conform		
Specific rotation	-245	(-240) - (-255)	
Elemental impurities	Conform	Test PhEur	#
Loss on drying	0,46 %	<= 2,0 %	
Sulphated ashes	0,02 %	<= 0,5 %	
Bacterial endotoxins	NA	< 0,5 UI/mg	#
Assay (HPLC)	98,0 %	95,0-102,0%	
Impurity A	1,2 %	<= 3,0 %	
Impurity B	0,63 %	<= 1,5 %	
Impurity C	0,32 %	<= 0,5 %	
Impurity D	ND	<= 0,5 %	
Residual solvent: acetone	< 5000 ppm	<= 5000 ppm	#
Residual solvent: 1-Butanol	< 5000 ppm	<= 5000 ppm	#

Organoleptic characteristics: Yellow, crystalline powder. Soluble in water, slightly soluble in ethanol 96%, practically insoluble in acetone. It dissolves in solutions of alkali hydroxides and carbonates.

Conservation: In tightly closed containers. Protect from light.

Date of analysis: 20/08/2024

Judgement:
APPROVED

Responsible: B. Chia

Technical director: Montserrat Enrique

Manufacturer: F00039 NINGXIA QIYUAN PHARMACEUTICAL, CO. LTD

Manufacturer batch: 231225-63

Product	Name	Capacity	Batch
1184567	TETRACICLINA CLORHIDRATO	25 g	241548-G-1

1184567	TETRACICLINA CLORHIDRATO	25 g	241548-G-2
1184567	TETRACICLINA CLORHIDRATO	25 g	241548-G-3
1184569	TETRACICLINA CLORHIDRATO	100 g	241548-J-1
1184569	TETRACICLINA CLORHIDRATO	100 g	241548-J-3
1184569	TETRACICLINA CLORHIDRATO	100 g	241548-J-4
1184569	TETRACICLINA CLORHIDRATO	100 g	241548-J-5
1184572	TETRACICLINA CLORHIDRATO	1 kg	241548-P-1
1184572	TETRACICLINA CLORHIDRATO	1 kg	241548-P-2
1184572	TETRACICLINA CLORHIDRATO	1 kg	241548-P-3
1184572	TETRACICLINA CLORHIDRATO	1 kg	241548-P-4
1370045	TETRACICLINA CLORHIDRATO (FLB)	100 g	241548-J-2

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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