



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 251897

Product:	SODIUM FUSIDATE
Lot:	251897
Expiry date:	21/04/2028
Reference:	Cumple PhEur11.8
Synonyms:	
Formula:	C ₃₁ H ₄₇ NaO ₆
Molecular weight:	538,69 g/mol

Assay	Result	Specification	
Identification	Conform (A,B)		
Organoleptic properties	Conform		
Appearance of solution	Conform		
pH aqueous solution 1,25%	8,4	7,5-9,0	
Related substances (HPLC)	Conform		
Water	0,54 %	<= 2,0 %	
Assay	99,8 %	97,5-101,0%	
STORE IN REFRIGERATOR (2-8°C)			
Impurity A	< 0,05 %	<= 0,3 %	
Impurity B	< 0,05 %	<= 0,4 %	
Impurity C	< 0,05 %	<= 0,2 %	
Impurity D	< 0,05 %	<= 0,2 %	
Impurity F	< 0,05 %	<= 0,2 %	
Impurity G	0,08 %	<= 0,7 %	
Impurity I	< 0,05 %	<= 0,2 %	
Impurity K	< 0,05 %	<= 0,2 %	
Impurity L	0,06 %	<= 0,5 %	
Impurity M	0,40 %	<= 1,0 %	
Impurity N	< 0,05 %	<= 0,2 %	
Unspecified Impurities	0,05 %	<= 0,10 %	
Total impurities	0,59 %	<= 2,0 %	
Residual solvent: acetone	< 5000 ppm	<= 5000 ppm	#
Residual solvent: Methanol	< 3000 ppm	<= 3000 ppm	#
Residual solvent: Methyl isobutyl ketone	< 5000 ppm	<= 5000 ppm	#
Residual solvent: xylene	< 2170 ppm	<= 2170 ppm	#
Elemental impurities	Conform	Test PhEur	#
Nitrosamine impurities	Conform	Test PhEur	#

Organoleptic characteristics:

Conservation: In tightly closed containers. Protect from light. FRIDGE (2-8°C)

Date of analysis: 20/10/2025

Judgement:
APPROVED

Responsible: B.Chia

Technical director: Montserrat Enrique

Manufacturer: F01003 ERCROS, S.A.

Manufacturer batch: FST 1029

Product	Name	Capacity	Batch
1112031	FUSIDATO SODICO	5 g	251897-E-1
1112031	FUSIDATO SODICO	5 g	251897-E-2
1112032	FUSIDATO SODICO	10 g	251897-F-1
1112032	FUSIDATO SODICO	10 g	251897-F-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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