



## ANALYSIS CERTIFICATE

**Lot/Analysis/Analysis N°: 240440**

Product:	SODIUM FUSIDATE
Lot:	240440
Expiry date:	05/08/2026
Reference:	Cumple PhEur11.3
Synonyms:	
Formula:	C <sub>31</sub> H <sub>47</sub> NaO <sub>6</sub>
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%	8,3	7,5-9,0	=
Related substances (HPLC)	Conform		=
Water	0,37 %	<= 2,0 %	
Assay	100,1 %	97,5-101,0%	
STORE IN REFRIGERATOR (2-8°C)			
Impurity A	ND	<= 0,3 %	=
Impurity B	ND	<= 0,4 %	=
Impurity C	ND	<= 0,2 %	=
Impurity D	ND	<= 0,2 %	=
Impurity F	ND	<= 0,2 %	=
Impurity G	0,07 %	<= 0,7 %	=
Impurity I	ND	<= 0,2 %	=
Impurity K	0,04 %	<= 0,2 %	=
Impurity L	ND	<= 0,5 %	=
Impurity M	0,54 %	<= 1,0 %	=
Impurity N	ND	<= 0,2 %	=
Unspecified Impurities	< 0,05 %	<= 0,10 %	=
Total impurities	0,70%	<= 2,0 %	=
Residual solvent: acetone	< 500 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)

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Date of analysis: 13/03/2024

Judgement:  
APPROVED

Responsible: M. Mesa

Technical director: Montserrat Enrique

Manufacturer: F01003 ERCROS, S.A.

Manufacturer batch: FST 952

Product	Name	Capacity	Batch
1112031	FUSIDATO SODICO	5 g	240440-E-1
1112031	FUSIDATO SODICO	5 g	240440-E-2
1112031	FUSIDATO SODICO	5 g	240440-E-3
1112032	FUSIDATO SODICO	10 g	240440-F-1
1112032	FUSIDATO SODICO	10 g	240440-F-2
1112032	FUSIDATO SODICO	10 g	240440-F-3
1112032	FUSIDATO SODICO	10 g	240440-F-4

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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