



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 230002

Product:	SODIUM FUSIDATE
Lot:	230002
Expiry date:	19/09/2025
Reference:	Cumple PhEur11.0
Synonyms:	
Formula:	C ₃₁ H ₄₇ NaO ₆
Molecular weight:	538,69 g/mol

Assay	Result	Specification	
Impurity L	ND	<= 0,5 %	=
Impurity K	< 0,05 %	<= 0,2 %	=
Impurity N	ND	<= 0,2 %	=
Impurity M	< 1,0 %	<= 1,0 %	=
Total impurities	< 2,0 %	<= 2,0 %	=
Unspecified Impurities	<0,05 %	<= 0,10 %	=
Residual solvent: Methanol	< 3000 ppm	<= 3000 ppm	#
Residual solvent: acetone	< 5000 ppm	<= 5000 ppm	#
Impurity A	ND	<= 0,3 %	=
Impurity C	ND	<= 0,2 %	=
Impurity B	ND	<= 0,4 %	=
Impurity F	ND	<= 0,2 %	=
Impurity D	ND	<= 0,2 %	=
Impurity I	ND	<= 0,2 %	=
Impurity G	< 0,7 %	<= 0,7 %	=
Appearance of solution	Conform		=
Organoleptic properties	Conform		
Related substances (HPLC)	Conform		=
pH aqueous solution 1,25%	8,3	7,5-9,0	=
Assay	99,8 %	97,5-101,0%	
Water	0,31 %	<= 2,0 %	
STORE IN REFRIGERATOR (2-8°C)			
Identification	Conform (A,B)		
Residual solvent: Methyl isobutyl ketone	< 5000 ppm	<= 5000 ppm	#
Residual solvent: xylene	< 2170 ppm	<= 2170 ppm	#

Organoleptic characteristics:

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

Date of analysis: 08/02/2023

Judgement:
APPROVED

Responsible: M. Mesa

Technical director: Montserrat Enrique

Manufacturer: F01003 ERCROS, S.A.

Manufacturer batch: FST910

Product	Name	Capacity	Batch
1112031	FUSIDATO SODICO	5 g	230002-E-1
1112032	FUSIDATO SODICO	10 g	230002-F-1
1821775	ACOFAR ALMOHADILLA ELECTRICA CONFORT LUMBAR		230002

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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