



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 241867

Product:	FUROSEMIDE
Lot:	241867
Expiry date:	30/06/2029
Reference:	Cumple PhEur11.5
Synonyms:	Frusemida.
Formula:	C ₁₂ H ₁₁ ClN ₂ O ₅ S
Molecular weight:	330,74 g/mol

Assay	Result	Specification	
Assay	99,0%	98,5-101,0%	
Appearance of solution	Conform	Test PhEur	
Nitrosamine impurities	Conform	Test PhEur	#
Elemental impurities	Conform	Test PhEur	#
Impurity C	0,06 %	<= 0,2 %	
Impurity D	< 0,05 %	<= 0,15 %	
Unspecified Impurities	< 0,05 %	<= 0,10 %	
Identification	Conform (B)	Test PhEur (B)	
Total impurities	0,06 %	<= 0,5 %	
Organoleptic properties	Conform	PhEur	
Chlorides	<= 200 ppm	<= 200 ppm	
Sulphates	<= 300 ppm	<= 300 ppm	
Residual solvent: Methanol	< 3000 ppm	<= 3000 ppm	#
Residual solvent: Ethanol	< 5000 ppm	<= 5000 ppm	#
Related substances (HPLC)	Conform		
Residual solvent: Isopropanol	< 5000 ppm	<= 5000 ppm	#
Loss on drying	0,04 %	<= 0,5 %	
Residual solvent: Ethyl acetate	< 5000 ppm	<= 5000 ppm	#
Sulphated ashes	0,01 %	<= 0,1 %	
Residual solvent: methyl acetate	< 5000 ppm	<= 5000 ppm	#

Organoleptic characteristics: White or almost white, crystalline powder. Pract. insoluble in water, soluble in acetone, sparingly soluble in ethanol (96 %), pract. insoluble in methylene chloride. It dissolves in dilute solutions of alkali hydroxides

Conservation: In tightly closed containers. Protect from light.

Date of analysis: 15/10/2024

Responsible: B. Chia

Technical director: Montserrat Enrique

Judgement:
APPROVED

Manufacturer: F00397 MANGALAM DRUGS AND ORGANICS LTD. (Unit 1)

Manufacturer batch: FRU-1E-242033

Product	Name	Capacity	Batch
1145602	FUROSEMIDA	5 g	241867-E-1
1145602	FUROSEMIDA	5 g	241867-E-2
1145604	FUROSEMIDA	25 g	241867-G-1
1145604	FUROSEMIDA	25 g	241867-G-2
1145606	FUROSEMIDA	100 g	241867-J-1
1145606	FUROSEMIDA	100 g	241867-J-3
1145609	FUROSEMIDA	1 kg	241867-P-1
1370182	FUROSEMIDA (FLB)	100 g	241867-J-2
1370182	FUROSEMIDA (FLB)	100 g	241867-J-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

ACOFARMA DISTRIBUCIÓN, S.A.

C/ Llobregat, 20 - 08223 Terrassa (Barcelona)

Tel./ 93-736.00.88

www.acofarma.com

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