



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 240837

Product:	FAMOTIDINE
Lot:	240837
Expiry date:	15/11/2026
Reference:	Cumple PhEur11.4
Synonyms:	
Formule:	C ₈ H ₁₅ N ₇ O ₂ S ₃
Poids moléculaire:	337,43 g/mol

Assay	Result	Specification	
Impurity B	0,06 %	<= 0,15 %	
Impurity C	< 0,05 %	<= 0,3 %	
Impurity A	< 0,05 %	<= 0,15 %	
Appearance of solution	Conform		
Impurity G	< 0,05 %	<= 0,15 %	
Elemental impurities	Conform		#
Unspecified Impurities	0,06 %	<= 0,10 %	
Identification	Conform	Test PhEur	
Impurity D	< 0,05 %	<= 0,3 %	
Organoleptic properties	Conform		
Impurity F	< 0,05 %	<= 0,15 %	
Sulphated ashes	0,01 %	<= 0,1%	
Residual solvent: acetone	< 5000 ppm	<= 5000 ppm	#
Assay (on anhydrous)	99,5 %	98,5-101,5%	
Residual solvent: Isopropanol	< 5000 ppm	<= 5000 ppm	#
Related substances (HPLC)	Conform		
Total impurities	0,12 %	<= 0,8 %	
Loss on drying	0,09 %	<= 0,5 %	
Residual solvent: Methanol	< 3000 ppm	<= 3000 ppm	#

Organoleptic characteristics: White or yellowish-white, crystalline powder or crystals. Very slightly sol. in water, freely solub. in glacial acetic acid, very slightly sol. in anhydrous EtOH, pract. insol. in ethyl acetate. It dissolves in dil. mineral ac.

Conservation: In tightly closed containers. Protect from light.

Date of analysis: 15/05/2024

Judgement:
APPROVED

Responsible: M. Mesa

Technical director: Montserrat Enrique

Manufacturer: F01003 ERCROS, S.A.

Manufacturer batch: F 483

Produit	Nom	Capacité	Lot
1144063	FAMOTIDINA	5 g	240837-E-1
1144063	FAMOTIDINA	5 g	240837-E-2
1144066	FAMOTIDINA	50 g	240837-I-1
1144066	FAMOTIDINA	50 g	240837-I-2
1144066	FAMOTIDINA	50 g	240837-I-3
1144070	FAMOTIDINA	1 Kg	240837-P-1
1144070	FAMOTIDINA	1 Kg	240837-P-2
1144070	FAMOTIDINA	1 Kg	240837-P-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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