



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 210044

Product:	KETOPROFEN
Lot:	210044
Expiry date:	01/09/2025
Reference:	Cumple PhEur10.3
Synonyms:	
Formule:	C16H14O3
Poids moléculaire:	254,29 g/mol

Assay	Result	Specification	
Identification	Conform (C)	Test PhEur (C)	
Organoleptic properties	Conform	PhEur	
Appearance of the solution, 10% in acetone	Conform	Test RFE/Ph. Eur.	=
Related substances (HPLC)	Conform	Test PhEur	=
Heavy metals	<= 10 ppm	<= 10 ppm	=
Loss on drying (60°C)	0,11 %	<=0,5%	
Sulphated ashes	0,008 %	<= 0,1%	=
Assay	100,0 %	99,0-100,5%	
Impurity A	<= 0,2 %	<= 0,2 %	=
Impurity B	0,05 %	<= 0,2 %	=
Impurity C	<= 0,2 %	<= 0,2 %	=
Impurity D	<= 0,2 %	<= 0,2 %	=
Impurity E	<= 0,2 %	<= 0,2 %	=
Impurity F	<= 0,2 %	<= 0,2 %	=
Unspecified Impurities	<= 0,10 %	<= 0,10 %	=
Total impurities (other than A and C)	<= 0,4 %	<= 0,4 %	=
Residual solvent: acetone	<= 250 ppm	<= 250 ppm	#
Residual solvent: Toluene	<= 250 ppm	<= 250 ppm	#
Residual solvent: Benzene	<= 2 ppm	<= 2 ppm	#

Organoleptic characteristics: White or almost white, crystalline powder. Practically insoluble in water, freely soluble in acetone, in ethanol (96 per cent) and in methylene chloride.

Conservation: In tightly closed containers. Protect from light.

Date of analysis: 09/03/2021

Judgement:
APPROVED

Responsible: M. Mesa

Technical director: Montserrat Enrique

Manufacturer: F00152 COSMA, S.p.A.

Manufacturer batch: 202000755

Produit	Nom	Capacité	Lot
1155226	KETOPROFENO (INACTIVO)	10 g	210044-F-1
1155226	KETOPROFENO (INACTIVO)	10 g	210044-F-2
1155229	KETOPROFENO (INACTIVO)	100 g	210044-J-1
1155232	KETOPROFENO (INACTIVO)	1 kg	210044-P-1
1155232	KETOPROFENO (INACTIVO)	1 kg	210044-P-2

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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