



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 212258

Product:	DICLOFENAC SODIUM
Lot:	212258
Expiry date:	31/12/2025
Reference:	Cumple PhEur10.4
Synonyms:	
Formula:	C ₁₄ H ₁₀ Cl ₂ NNaO ₂
Molecular weight:	318,1 g/mol

Assay	Result	Specification	
Identification	Conform (A,D)	Test RFE/Ph. Eur.	
Organoleptic properties	Conform	RFE/Ph. Eur.	
Melting point	279 °C	Approx. 280°C	
Appearance of solution	Conform		
Related substances (HPLC)	Conform	Test RFE/Ph. Eur.	
Elemental impurities	Conform		#
Loss on drying	0,12 %	<= 0,5%	
	100,0 %	99,0 - 101, 0 %	
Impurity A	<= 0,05 %	<= 0,2 %	
Impurity F	NDT	<= 0,15 %	
Unspecified Impurities	<= 0,05 %	<= 0,10 %	
Total impurities	<= 0,05 %	<= 0,4 %	
Residual solvent: Toluene	<= 890 ppm	<= 890 ppm	#
Residual solvent: Isopropanol	<= 5000 ppm	<= 5000 ppm	#
Residual solvent: Methanol	<= 3000 ppm	<= 3000 ppm	#

Organoleptic characteristics: White or slightly yellowish, slightly hygroscopic, crystalline powder. Sparingly soluble in water, freely soluble in methanol, soluble in ethanol (96 per cent), slightly soluble in acetone.
Conservation: In tightly closed containers. Protect from light.

Date of analysis: 13/05/2021

Judgement:
APPROVED

Responsible: M. Mesa

Technical director: Montserrat Enrique

Manufacturer: F00417 AARTI DRUGS LTD.

Manufacturer batch: DFS-11010016

Product	Name	Capacity	Batch
1103664	DICLOFENACO SODICO (INACTIVO)	100 g	212258-J-1
1103664	DICLOFENACO SODICO (INACTIVO)	100 g	212258-J-2

1103669	DICLOFENACO SODICO (INACTIVO)	250 g	212258-N-1
1103669	DICLOFENACO SODICO (INACTIVO)	250 g	212258-N-2
1103669	DICLOFENACO SODICO (INACTIVO)	250 g	212258-N-3
1103670	DICLOFENACO SODICO	5 kg	212258-Q-1
1400060	DICLOFENACO SODICO (INACTIVO)	25 g	212258-G-1
1400060	DICLOFENACO SODICO (INACTIVO)	25 g	212258-G-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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