



## TECHNICAL DATA SHEET

009905-TDS-ENG-2023

DICLOFENAC DIETILAMINA (BRIT. PH.)		
DESCRIPTION DCI: DICLOFENAC DIETHYLAMINE		DESCRIPTION DOE: DICLOFENACO DIETILAMINA
CAS Nº: 78213-16-8	EC Nº: 616-599-2	AEMPS CODE: 745DO
MOL. WEIGHT: 369.28	MOL. FORMULA: C <sub>18</sub> H <sub>22</sub> Cl <sub>2</sub> N <sub>2</sub> O <sub>2</sub>	ARTICLE CODE: 009905

ATTRIBUTES	SHOULD BE
Appearance	White to light beige, crystalline powder
Solubility	Sparingly soluble in water and in acetone, freely soluble in ethanol (96 %) and in methanol; practically insoluble in 1M NaOH
Identification	Complies
Acidity or alkalinity	
pH (1%)	6.4 - 8.4
Clarity and colour of solution	
Absorbance 440 nm	=< 0.05
Related substances	
Unspecified impurities	=< 0.2 %
Total impurities	=< 0.5 %
Loss on drying	=< 0.5 %
Sulfated ash	=< 0.1 %
Assay	99.0 - 101.0 %

### COMPLIES WITH

British Pharmacopoeia 2023

### STORAGE

Keep the container tightly closed and store it in a cool, dry, well-ventilated area.

### REMARKS

Diclofenac Diethylamine is subjected to the requirements of the ICH Q3D "Elemental Impurities" guideline and the requirements of guides EMA/CHMP/ICH/82260/2006.

Absence of N-nitrosamines impurities has been ensured after a risk evaluation according to ICH Q9, ICH M7 and in accordance with guidelines EMA/428592/2019 Rev 2 and EMA/189634/2019.

Certificates of residual solvents, allergens, non-GMO and BSE-TSE, among others, are available upon request.

All methods of analysis are validated by official pharmacopoeias or are validated by internal methods of the manufacturer, which can be obtained at specific request. The above information does not exempt from the obligation to identify the product before use.