



TECHNICAL DATA SHEET

151369-TDS-ENG-2021

CLOPIDOGREL HYDROGEN SULFATE (FORM-I) - EP		
DESCRIPTION DCI: CLOPIDOGREL HYDROGEN SULFATE		DESCRIPTION DOE: CLOPIDOGREL HIDROGENO SULFATO
CAS N°: 120202-66-6	EC N°: 686-767-8	AEMPS CODE: ---
MOL. WEIGHT: 419.89	MOL. FORMULA: C16H18ClNO6S2	ARTICLE CODE: 151369

ATTRIBUTES	SHOULD BE
Appearance	White or almost white powder
Solubility	Freely soluble in water and in methanol, practically insoluble in cyclohexane
Identification A	Complies
Identification B	Complies
Identification D	Complies
Specific optical rotation	+54.0 / +58.0
Appearance of solution	Clear and not more intensely coloured than ref. sol. Y6
Enantiomeric purity	
Impurity C	= < 0.5 %
Related substances	
Impurity B	= < 0.3 %
Impurity A	= < 0.2 %
Unspecified impurities	= < 0.10 %
Total impurities	= < 0.5 %
Water	= < 0.5 %
Sulfated ash	= < 0.1 %
Assay	99.0 - 101.0 %
Particle size	
D (10 %)	For information
D (50 %)	For information
D (90 %)	For information

COMPLIES WITH

European Pharmacopoeia 10.0

STORAGE

Keep the container tightly closed between 2 and 8 °C. Protect from light.

REMARKS

It shows polymorphism (5.9).

Clopidogrel Hydrogen Sulfate 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.