

CLOPIDOGREL HYDROGEN SULFATE (FORM-I) - EP

PRODUCT CODE: 151369	CAS N°: 120202-66-6	ANALYSIS N°: 323/21
MANUFACTURER BATCH: AAOH018601	CERTIFICATE ID: 33.553	
SUPPLIER BATCH: ----	MANUFACTURING DATE: 02/09/2021	
METAPH BATCH: 0171221	RETEST DATE: 01/09/2026	

ATTRIBUTES	SHOULD BE	IS
Appearance	White or almost white powder	White powder
Solubility	Freely soluble in water and in methanol, practically insoluble in cyclohexane	Complies (*)
Identification A	Complies	Complies
Identification B	Complies	Complies
Identification D	Complies	Complies
Specific optical rotation	+54.0 / +58.0	+56.0
Appearance of solution	Clear and not more intensely coloured than ref. sol. Y6	Complies
Enantiomeric purity		
Impurity C	= < 0.5 %	0.19 %
Related substances		
Impurity B	= < 0.3 %	< 0.05 %
Impurity A	= < 0.2 %	< 0.05 %
Unspecified impurities	= < 0.10 %	0.06 % (RT = 23.83 min)
Total impurities	= < 0.5 %	0.06 %
Water	= < 0.5 %	0.12 %
Sulfated ash	= < 0.1 %	0.06 %
Assay	99.0 - 101.0 %	99.6 %
Particle size		(*)
D (10 %)	For information	15 µm
D (50 %)	For information	69 µm
D (90 %)	For information	129 µm

COMPLIES WITH

European Pharmacopoeia 10.0

REMARKS

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.

(*) Data adapted from the certificate of analysis of the manufacturer.

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.

STORAGE

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

Analysis date: 23/03/2022
 Signature: Ferran Gonzalez de Rivera Riera (QA/QP)
 Conclusion: Complies
 Original certificate available upon request

Manufacturer: 40000908

