

Certificate of analysis

Product:	CLOPIDOGREL HYDROGEN SULFATE (FORM II)		
Batch number:	2507033.1877	Manuf. Batch number:	CM20380325
Manufacturing date:	Mar-2025	Expiry date:	Feb-2030
Quality:	EP 01/2017:2531 corrected 10.0		

Test	Requirement	Result	Unit	Standard remark	Control by
Characters					
Appearance	White or almost white powder	Complies			AC Man
Solubility	Freely soluble in methanol, practically insoluble in cyclohexane	Complies			AC Man
Identification					
Specific optical rotation	+54.0 – +58.0	+56.7	°	On anhydrous basis	AC Man
Infrared absorption	The infrared absorption spectrum of the sample shall be concordant with that of Clopidogrel Hydrogen Sulfate standard infrared absorption spectrum	Complies			AC Man
HPLC	The retention time of the major peak of the sample solution corresponds to that of the standard solution, as obtained from Enantiometric purity by HPLC	Complies			AC Man
Sulfate	It responds to the test for sulfates	Complies			AC Man
Test					
Appearance of solution	Solution should be clear and colour is not more than reference solution Y6	Complies			AC Man
Water content	≤ 0.50	0.12	% w/w	KFR	AC Man
Sulfated ash	≤ 0.10	0.05	% w/w		AC Man
Polymorphic identification	The PXRD pattern of the sample should exhibit, the presence of peak at 2-theta values of Clopidogrel hydrogen sulfate Ph.Eur, (Form-II) are at about 12.9°, 18.5° and 21.6° ±0.2° 2-theta	Complies		PXRD, In House	AC Man
Para Formaldehyde content	≤ 5	Not applicable	ppm	HPLC; In House	AC Man
Related substances				HPLC	
Impurity A	≤ 0.15	0.01	%		AC Man
Impurity B	≤ 0.15	BDL	%	LOD=0.004%	AC Man
Highest individual Unspecified impurity	≤ 0.10	0.05	%		AC Man
Total impurities	≤ 0.50	0.16	%		AC Man

AC Man = Analysis performed by Manufacturer | AL = Analysis performed by authorized Laboratory
Guaranteed traceability available at Ofipharma

Drenthweg 25, 9561 AZ, Ter Apel, The Netherlands		T: +31 599 745 390	F: +31 599 582 734	E: info@ofipharma.com	
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Test	Requirement	Result	Unit	Standard remark	Control by
Enantiomeric purity				HPLC	
Impurity C	≤ 0.15	0.06	%		AC Man
Assay					
Potentiometry	99.0 – 101.0	99.8	% w/w	On anhydrous basis	AC Man
HPLC	99.0 – 101.0	N/A	% w/w	On anhydrous basis; In house	AC Man
Residual solvents				GC; In house	
Methanol	≤ 3000	81	ppm		AC Man
Acetone	≤ 5000	865	ppm		AC Man
Dichloromethane	≤ 600	BDL	ppm	LOD=16.99 ppm	AC Man
Cyclohexane	≤ 3880	BQL	ppm	LOQ=6.26 ppm	AC Man
Toluene	≤ 890	BQL	ppm	LOQ=3.18 ppm	AC Man
Mesityl oxide				GC; In house	
Content	≤ 200	BQL	ppm	LOQ=44.22 ppm	AC Man

Storage condition: Store protected from light and at controlled room temperature between 20°C and 25°C (excursions allowed between 15°C and 30°C)

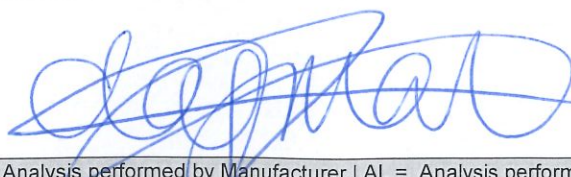
Other data	Requirement	Result	Standard remark
TSE/BSE-statement	No contamination with TSE/BSE-risk materials	Conform	Data producer
Metallic Residues	Conform CHMP/ICH/353369/2013	Conform	Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform	Data producer
Nitrosamine statement	(EMA/369136/2020)	Conform	Data producer
CEP	Available on request R1-CEP 2015-331 - Rev 00	Conform	Data producer

Manufacturer: MSN Organics Private Limited (IN)

Production, expiry/retest date conform primary packaging. I hereby confirm that the above mentioned results are in compliance with the referred Pharmacopoeia and are authentic and accurate.

Conclusion: Approved

Quality Assurance



21 JUL 2025
D. Pals, MSc

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