

MSN ORGANICS PRIVATE LIMITED

Factory:Sy.No.224/A, Bibinagar (Village), Bibinagar (Mandal), Yadadri Bhuvanagiri (District)
Telangana. India. Phone: +91-40-38265290 Fax : +91-40-38265299 Pincode : 508 126

CERTIFICATE OF ANALYSIS

Product Name : CLOPIDOGREL HYDROGEN SULFATE Ph.Eur., (FORM-II)				
Batch Number : CM20380325		Customer name : OFIPHARMA BV		
Batch Quantity : 243.600 Kg		Date of Mfg. : March-2025		
A.R.Number : FP250301		Date of Analysis : 17.04.2025		
Reference : Ph.Eur.,		Re-test date : February-2030		
Specification No. : QC-FPCM2-EP-0001-009				
Storage Conditions:Preserve in well closed containers and store at controlled room temperature i.e. between 20°C and 25°C. Protected from light (excursions are allowed between 15°C and 30°C)				
S.No	TEST	RESULT	SPECIFICATION	METHOD REFERENCE
Ph.Eur.,				
1.0	Appearance	White powder	White or almost white powder	Ph.Eur.,
2.0	Solubility	Complies	Freely soluble in methanol, Practically insoluble in cyclohexane	Ph.Eur.,
3.0	Identification by			
3.1	Specific optical rotation (On anhydrous basis)	(+) 56.7°	(+) 54.0° and (+) 58.0°	Ph.Eur.,
3.2	Infrared absorption	Complies	The infrared absorption spectrum of the sample shall be concordant with that of Clopidogrel Hydrogen Sulfate standard infrared absorption spectrum.	Ph.Eur.,
3.3	HPLC	Complies	The retention time of the major peak of the sample solution corresponds to that of the standard solution, as obtained from Enantiomeric purity by HPLC.	Ph.Eur.,
3.4	Sulfate	Complies	It responds to the test for sulfates	Ph.Eur.,
4.0	Appearance of solution	Complies	Solution should be clear solution and colour is not more than reference solution Y6.	Ph.Eur.,
5.0	Water content by KFR	0.12% w/w	Not more than 0.50% w/w	Ph.Eur.,
6.0	Sulfated ash	0.05% w/w	Not more than 0.10% w/w	Ph.Eur.,
7.0	Related substances by HPLC			
7.1	Impurity-A	0.01%	Not more than 0.15%	Ph.Eur.,
7.2	Impurity-B	BDL(LOD=0.004%)	Not more than 0.15%	
7.3	Highest individual Unspecified impurity	0.05%	Not more than 0.10%	
7.4	Total impurities	0.16%	Not more than 0.50%	
8.0	Enantiomeric purity by HPLC			
8.1	Impurity-C	0.06%	Not more than 0.15%	Ph.Eur.,
9.0	Assay by Potentiometry (On anhydrous basis)	99.8%w/w	Not less than 99.0% w/w and Not more than 101.0% w/w	Ph.Eur.,

The product CONFORMS to above specifications

F-CQC-0306-001-15/10/2024

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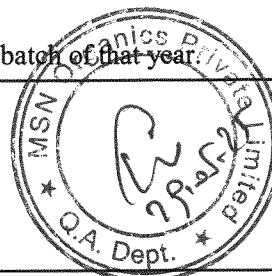
S.No	TEST	RESULT	SPECIFICATION	METHOD REFERENCE
In house				
10.0	Assay by HPLC (On anhydrous basis)	Not applicable	Not less than 99.0% w/w and Not more than 101.0% w/w	In house
11.0	Residual solvents by GC			In house
11.1	Methanol	81 ppm	Not more than 3000 ppm	
11.2	Acetone	865 ppm	Not more than 5000 ppm	
11.3	Dichloromethane	BDL(LOD=16.99 ppm)	Not more than 600 ppm	
11.4	Cyclohexane	BQL(LOQ=6.26 ppm)	Not more than 3880 ppm	
11.5	Toluene	BDL(LOD=3.18 ppm)	Not more than 890 ppm	
12.0	Mesityl oxide content by GC			In house
12.1	Mesityl oxide	BQL(LOQ=44.22 ppm)	Not more than 200 ppm	
13.0	Polymorphic identification by PXRD [#]	Complies	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.	In house
14.0	Para Formaldehyde content by HPLC	Not applicable	Not more than 5 ppm	In house

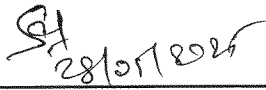
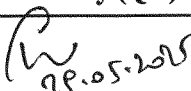
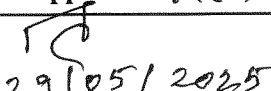
Note -1 : Test No.10.0 Will perform only for stability samples and the batches intended for stability study, If batch not belongs to stability in the Result column shall Report as 'NA' (Not Applicable).

Note -2 : Test No.14.0 Will carried out for First batch of the year, and Every 10th batch of that year

The product CONFORMS to above specifications

Note: # Test Performed at external Laboratory



--	Compiled by (QC)	Checked by (QA)	Approved by (QA)
Sign & Date	 28/05/2025	 29.05.2025	 29/05/2025
Name & Designation	S. Praveen R. Reddy Pr. Manager	G.N. Vajravelu Sr. Manager	M. Ram Lakshmi Asst Manager