MSN
MSN Organics Private Limited
Factory:Sy.No.224/A, Bibinagar (Village), Bibinagar (Mandal), Yadadri Bhuvanagiri (District)
Telangana. India. Phone: +91-8685-399999 Fax : +91-8685-399985 Pincode : 508 126

CERTIFICATE OF ANALYSIS

Product	: **CLOPIDOGREL HYDROGEN SULFATE Ph.Eur., (FORM-II)**		
Batch No.	: CM20100222	Customer name	: **OFIPHARMA BV**
Batch Quantity	: 245.200 Kg	Mfg.Date	: February-2022
A.R.No.	: FP220077	Date of Analysis	: 26.02.2022
Reference	: Ph.Eur.,	Expiry date	: January-2027
		Specification No.	: QC-FPCM2-EP-01/06

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
1.0	Description	White Powder	White or almost white powder
2.0	Solubility	Complies	Freely soluble in methanol, Practically insoluble in cyclohexane
3.0	Identification by		
3.1	Specific optical rotation (On anhydrous basis)	(+) 56.3°	(+) 54.0° and (+) 58.0°
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.
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.
3.4	Sulfate	Complies	It responds to the test for sulfates
4.0	Appearance of solution	Complies	Solution should be clear solution and colour is not more than reference solution Y6.
5.0	Water content by KFR	0.21% w/w	Not more than 0.50 % w/w
6.0	Sulfated ash	0.06% w/w	Not more than 0.10% w/w
7.0	Related substances by HPLC		
7.1	Impurity-A	0.01%	Not more than 0.15%
7.2	Impurity-B	0.02%	Not more than 0.15%
7.3	Highest individual Unspecified impurity	0.03%	Not more than 0.10%
7.4	Total impurities	0.14%	Not more than 0.50%
8.0	Enantiomeric purity by HPLC		
8.1	Impurity-C	BQL(LOQ=0.0089%)	Not more than 0.15%

The product conforms to above specifications

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S.No	TEST	RESULT	SPECIFICATION
9.0	Assay by Potentiometry (On anhydrous basis)	99.9%w/w	Not less than 99.0% w/w and Not more than 101.0% w/w
10.0	Assay by HPLC (On anhydrous basis)	99.2%w/w	Not less than 99.0% w/w and Not more than 101.0% w/w
11.0	Residual solvents by GC		
11.1	Methanol	BDL(LOD=11.12ppm)	Not more than 3000 ppm
11.2	Acetone	550ppm	Not more than 5000 ppm
11.3	Dichloromethane	BDL(LOD=16.99ppm)	Not more than 600 ppm
11.4	Cyclohexane	BQL(LOQ=6.26ppm)	Not more than 3880 ppm
11.5	Toluene	BDL(LOD=3.18ppm)	Not more than 890 ppm
12.0	Mesityl oxide content by GC		
12.1	Mesityl oxide	BDL(LOD=13.40ppm)	Not more than 200 ppm
13.0	Polymorphic identification by PXRD	Complies	The PXRD pattern of the sample should match with the PXRD pattern of Clopidogrel bisulfate Form-II
14.0	Para Formaldehyde content by HPLC	BQL(LOQ=1.2ppm)	Not more than 5 ppm

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.

MSN Organics Private Limited ★ QC Dept. ★ 26.02.22

The product conforms to above specifications

Compiled by QC		**Reviewed by QC**		**Approved by QA**	
Date	26/02/2022	**Date**	26/02/2022	**Date**	26/02/2022
Name	S. praveen Kumar	**Name**	S. Sravanthi	**Name**	P. Swetha kumari
Designation/ QC	Jr. Manager	**Designation/ QC**	Dy. Manager	**Designation/ QA**	Asst. manager