

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

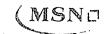
Specification No. : QC-FPCM2-EP-01/06

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)

	TEST	RESULT	SPECIFICATION			
1.0	Description					
1 1.0	Description	White Powder	White or almost white powder			
<sup>γ</sup> 2.0	Solubility	Complies	Freely soluble in methanol,			
2.0	Identification by	·	Practically insoluble in cyclohexane			
/ 3.0						
↑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 9 18 how			
7.0	Related substances by HP	PLC				
7.1	Impurity-A	0.01%	Not more than 0.1500 (272)			
7.2	Impurity-B	0.02%	Not more than 0.1890			
' / 3 1	Highest imdividual Unspecified impurity	0.03%	Not more than 0.19%			
7.4	Total impurities	0.14%	Not more than 0.50%			
8.0	Enantiomeric purity by HPLC					
	Impurity-C	BQL(LOQ=0.0089%)	Not more than 0.15%			

The product comforms to above specifications

F-QC-81/06-01.06.2021



MSN O rganics Private Limited

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## **CERTIFICATE OF ANALYSIS**

Product

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S.No	S.No TEST RESULT SPECIFICATION		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				
<sup>3</sup> 11.3	Dichloromethane	BDL(LOD=16.99ppm)	Not more than 600 ppm				
11.4	Cyclohexane	BQL(LOQ=6.26ppm)	Not more than 3880 ppm				
E11.5	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 ppino * 4				

Note -1: Test No.10.0 Will perform only for stability samples and the batches intended for stability study, It batches 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

The product conforms to above specifications

Compiled by QC	St	Reviewed by QC	Riavaulli	Approved by QA	Asuelte
Date 	26/08/2021	Date	26/02/2022	Date	26/02/2022
Name	S. pravesn Wonar	Name	S. Sravanthi	Name	P. Swelto burnos
Designation/ QC	50. Manager	Designation/ QC	DY. Manager	Designation/	Asst. managee

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