OFIPHARMA

Certificate of analysis

Product:	**CLOPIDOGREL HYDROGEN SULFATE (FORM II)**		
Batch number:	**2103067.1877**	**Manuf. Batch number:**	**CM20141220**
Manufacturing date:	Dec-2020	**Expiry date:**	Nov-2025
Quality:	EP 01/2020:2531		

Test	Requirement	Result	Unit	Standard remark	Control by
Characters					
Appearance	White or almost white powder	White powder			AC Man
Solubility	Freely soluble in methanol, practically insoluble in cyclohexane	Complies			AC Man
Identification					
Specific optical rotation	54.0 – 58.0	55.7	°	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 form 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	0.22	% w/w	KFR	AC Man
Sulfated ash	≤ 0.10	0.05	% w/w		AC Man
Polymorhic identification	The PXRD pattern of the sample should match with the PXRD pattern of Clopidogrel bisulfate Form II	Complies		PXRD	AC Man
Enantiomeric purity				**HPLC**	
Impurity C	≤ 0.15	BQL	%	LOQ=0.0089%	AC Man
Related substances				**HPLC**	
Impurity A	≤ 0.15	0.02	%		AC Man
Impurity B	≤ 0.15	0.03	%		AC Man
Highest individual Unspecified impurity	≤ 0.10	0.03	%		AC Man
Total impurities	≤ 0.50	0.18	%		AC Man

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

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Test	Requirement	Result	Unit	Standard remark	Control by
Assay					
Potentiometry	99.0 – 101.0	99.9	% w/w	On anhydrous basis	AC Man
Residual solvents				**GC**	
Methanol	≤ 3000	171	ppm		AC Man
Acetone	≤ 5000	1080	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	BDL	ppm	LOD=3.18 ppm	AC Man

*BQL: Below Quantification Limit, BDL: Below detection limit, LOD: Limit of detection, LOQ: Limit of quantification

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
CEP	Available on request | R0-CEP 2015-331-Rev 02	Conform	Data producer

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

13 APR 2021

J. Furda, BSc