CTO
Unit: I
Dr.Reddy's
Address: Plot No. 137,138, 145 & 146 S. V. Co-op. Industrial Estate, Bollaram village,
Jinnaram Mandal, Sangareddy Dist. Telangana state.INDIA . Ph. : 08458 - 280600 & Fax Number : 08458-279623.

CERTIFICATE OF ANALYSIS

CEP Number : R1-CEP-2012-059-Rev-00

Product : CLOPIDOGREL HYDROGEN SULPHATE (Form-1)		**Customer Name**	**: Galenicum Health , S.L.**
Batch No.	: AAOH002762	Date of Manufacture	: February 2021
Batch Quantity	: 99.000 Kg	Retest Date	: January 2026
Analytical Report No.	: 1001FP21000531	Date of Analysis	: 21/02/2021
Reference	: **Ph.Eur**	Specification No	: SP-CTO01-000896 (6.0)

Storage : Store at 2 to 8°C in well closed containers.

S.No.	Test	Result	Specification
1.0	CHARACTERS		
1.1	Appearance	Off-white powder	White to Cream powder.
1.2	Solubility	Freely soluble in methanol and practically insoluble in Cyclohexane.	Freely soluble in methanol and practically insoluble in Cyclohexane.
2.0	Identification		
2.1	IR-Spectrum	Matches with working standard	IR absorption spectrum of test sample should corresponds to that of Clopidogrel bisulphate Form-1 working standard.
2.2	Test for Sulfate	Positive	Solution should respond to the test for sulfate.
2.3	HPLC	Matches with working standard	The retention time of major peak in test preparation should corresponds to that of the major peak obtained with Standard preparation in the Related substances by HPLC Method-2.
3.0	Specific Optical rotation(On anhydrous basis at 20°C in methanol medium)	+56.2°	Should be between +54.0° and +58.0°
4.0	Appearance of solution	The solution is clear (2.2.1) and less intensely coloured than reference solution Y6 (2.2.2, method-1).	The solution is clear (2.2.1) and not more intensely coloured than reference solution Y6 (2.2.2, method-1).
5.0	Water By KF	0.02% w/w	Not more than 0.50 %w/w
6.0	Sulphated ash	0.03%w/w	Not more than 0.10 %w/w
7.0	Related Substances By HPLC		
7.1	Method-1:		
7.1.1	Impurity A	0.04%	Not more than 0.15 %
7.1.2	Impurity B	Less than LOQ (0.0108%)	Not more than 0.30 %
7.1.3	Any other impurity	0.04%	Not more than 0.10 %
7.1.4	Total impurities (Excluding impurity C of method-2)	0.09%	Not more than 0.50 %

The product CONFORMS to above specifications.

Compiled by :	**Checked by :**	**Approved by :**
Date : 27/02/2021	**Date :** 27/02/2021	**Date :** 27/02/2021

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Storage : Store at 2 to 8°C in well closed containers.

S.No.	Test	Result	Specification
7.2	Method-2:		
7.2.1	Impurity C	Less than LOQ (0.03025%)	Not more than 0.15 %
8.0	Assay by HPLC (On anhydrous basis)	99.5 %w/w	Not less than 99.0 %w/w and Not more than 101.0 %w/w
9.0	XRD(Identification by XRD)	Matches with working standard	The sample XRD pattern should match with that of standard XRD pattern of Clopidogrel bisulphate Form-1 working standard
10.0	Residual solvents by GC		
10.1	Methanol	135 ppm	Not more than 3000 ppm
10.2	Acetone	Not detected	Not more than 5000 ppm
10.3	Dichloro methane	Not detected	Not more than 600 ppm
10.4	2-Butanol	1348 ppm	Not more than 5000 ppm
10.5	Cyclohexane	64 ppm	Not more than 3880 ppm
10.6	Toluene	Less than LOQ (8 ppm)	Not more than 890 ppm
10.7	1-Butane (2-Butanol Degradants)	37 ppm	Not more than 450 ppm
10.8	Trans & Cis Isomers of 2-Butene	361 ppm	Not more than 3500 ppm
10.9	Di 2-Butyl ether and 2-Butyl-n-butyl ether	254 ppm	Not more than 700 ppm
11.0	Acetic acid and Dimethyl Formamide by HPLC		
11.1	Acetic acid by HPLC	Not detected	Not more than 5000 ppm
11.2	Dimethyl formamide by HPLC	Not detected	Not more than 880 ppm
*12.0	Particle size by Malvern		
12.1	10 % of the particles	13 µm	For information
12.2	50 % of the particles	63 µm	For information
12.3	90 % of the particles	117 µm	For information

The product CONFORMS to above specifications.

*In-house tests

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