

METAPHARMACEUTICAL

22/11/2021

Dr. Reddy's Laboratories Ltd.
Chemical Technical operations-Unit I
Plot No. 137, 138, 145 & 146
Sri Venkateswara Co-operative Industrial Estate,
Bollaram, Jinnaram Mandal, Sangareddy District,
Telangana-502325.

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Dr.Reddy's



CERTIFICATE OF ANALYSIS

Product Name: CLOPIDOGREL HYDROGEN SULPHATE (Form-1)

Batch No.	AAOH018601	Customer Name	Galenicum Health,S.L.(VIR)
Batch Quantity	77.700 KG	Date of Manufacture	02-09-2021
A.R. No.	1001FP21003875	Retest Date	01-09-2026
Reference	Ph.Eur	Date of Analysis	22-11-2021
Storage condition	Store at 2 to 8°C in well closed containers.	Specification and MOA No.	SP-CTO01-000896 (7.0)

S. No.	TEST	SPECIFICATION	RESULT
1	Characters		
1.1	Appearance	White to Cream powder	Off white Powder
1.2	Solubility in Methanol	Freely soluble in methanol	Complies
1.3	Solubility in Cyclohexane	Practically insoluble in Cyclohexane	Complies
2	Identification		
2.1	IR-Spectrum	IR absorption spectrum of test sample should corresponds to that of Clopidogrel bisulphate Form-I working standard	Complies
2.2	Test for Sulfate	Solution should respond to the test for Sulfate	Complies
2.3	HPLC	The retention time of major peak in test preparation should corresponds to that of the major peak obtained with Standard preparation in the Related substance by HPLC Method-2	Complies
3	Specific optical rotation (on anhydrous basis at 20°C in methanol medium)	Should be between +54.0° and +58.0°	55.3 °
4	Appearance of solution	The Solution is clear (2.2.1) and not more intensely coloured than reference solution Y6 (2.2.2, Method-I)	Complies
5	Water by KF	Not more than 0.50 %w/w	0.10 %w/w
6	Sulphated Ash		
6.1	Sulphated ash	Not more than 0.10 %w/w	0.03 %w/w
7	Related Substances by HPLC		
7.1	Method-1		
7.1.1	Impurity A	Not more than 0.15 %	0.01 %
7.1.2	Impurity B	Not more than 0.30 %	0.01 %
7.1.3	Any other impurity	Not more than 0.10 %	0.03 %
7.1.4	Total impurities (Excluding impurity C of method-2)	Not more than 0.50 %	0.10 %
7.2	Method-2		
7.2.1	Impurity C	Not more than 0.5 %	0.03 %

Remarks: APPROVED (Sample Conforms to above Specification)

Prepared By	Reviewed By	Approved By
Surya Srinivasarao.Katakam(Lab Support Team)	G S V N.PUNNARAO(Team Leader)	Suresh.Kotapati(Team Leader)
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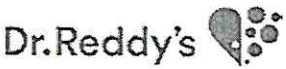
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Dr. Reddy's Laboratories Ltd. Chemical Technical operations-Unit I Plot No. 137, 138, 145 & 146 Sri Venkateswara Co-operative Industrial Estate, Bollaram, Jinnaram Mandal, Sangareddy District, Telangana-502325.			
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8	Assay by HPLC (On anhydrous basis)	Not less than 99.0 % w/w and Not more than 101.0 %w/w	99.6 % w/w
9	XRD (Identification by XRD)	XRD pattern of test sample should exhibit the 2-theta values at 9.2° ,10.9°, 11.5°,14.8°, 18.5°, 20.6° and 23.2° ± 0.2°	The Sample XRD Pattern have 2-Theta values at 9.2, 10.9, 11.5, 14.8, 18.5, 20.6, and 23.2 °
10	Residual solvents by GC		
10.1	Methanol	Not more than 3000 ppm	Not Detected
10.2	Acetone	Not more than 5000 ppm	Not Detected
10.3	Dichloromethane	Not more than 600 ppm	Not Detected
10.4	2-Butanol (Including Degradant 2-Butanone)	Not more than 5000 ppm	444 ppm
10.5	Cyclohexane	Not more than 3880 ppm	14 ppm
10.6	Toluene	Not more than 890 ppm	Less than LOQ (8 ppm)
10.7	1-Butene (2-Butanol Degradants)	Not more than 450 ppm	151 ppm
10.8	Trans & Cis isomers of 2-Butene (2-Butanol Degradants)	Not more than 3500 ppm	1396 ppm
10.9	Di 2-Butyl ether and 2-Butyl-n-butyl ether (2-Butanol Degradant)	Not more than 700 ppm	389 ppm
11	Acetic acid by HPLC Dimethyl formamide by HPLC		
11.1	Acetic acid by HPLC	Not more than 5000 ppm	Not Detected
11.2	Dimethyl formamide by HPLC	Not more than 880 ppm	Not Detected
12	Particle size by Malvern		
12.1	10% of the particles	For Information	15 µm
12.2	50% of the particles	For Information	69 µm
12.3	90% of the particles	For Information	129 µm

Additional Comments if Any: --

Remarks: APPROVED (Sample Conforms to above Specification)

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