

Dr. Reddy's Laboratories Ltd.
Chemical Technical operations-Unit II
Plot No. 1, 75A, 75B, 105, 110, 111 & 112,
Sri Venkateswara Co-operative Industrial Estate,
Bollaram, Jinnaram Mandal, Sangareddy District,
Telangana-502325.
Ph:08458283500

Dr.Reddy's

CERTIFICATE OF ANALYSIS

Product Name: KETOROLAC TROMETHAMINE

Material Code	200000391	Customer Name	Adium Pharma S.A.
Batch No.	ABMH010162	Date of manufacture	08/2019
Batch Quantity	229.300 KG	Expiry Date	07/2024
A..R. No.	1002FP19003054	Date Of Analysis	31-08-2019
Reference	USP / In-house	SpecificationNumber	SP-CT002-000801 / 2.0

S. No.	TEST	SPECIFICATION	RESULT
1	Description	White to off-white crystalline powder.	Off-white crystalline powder
2	Solubility		
2.1	In water	Freely soluble in water	Freely soluble in water
2.2	In methanol	Freely soluble in methanol	Freely soluble in methanol
2.3	In alcohol	Slightly soluble in alcohol.	Slightly soluble in alcohol
2.4	In dehydrated alcohol	Slightly soluble in dehydrated alcohol.	Slightly soluble in dehydrated alcohol.
2.5	In tetrahydrofuran	Slightly soluble in tetrahydrofuran.	Slightly soluble in tetrahydrofuran
2.6	In acetone	Practically insoluble in acetone.	Practically insoluble in acetone.
2.7	In dichloromethane	Practically insoluble in dichloromethane.	Practically insoluble in dichloromethane
2.8	In toluene	Practically insoluble in toluene.	Practically insoluble in toluene
2.9	In ethyl acetate	Practically insoluble in ethyl acetate.	Practically insoluble in ethyl acetate
2.10	In dioxane	Practically insoluble in dioxane.	Practically insoluble in dioxane
2.11	In hexane	Practically insoluble in hexane.	Practically insoluble in hexane
2.12	In butyl alcohol	Practically insoluble in butyl alcohol.	Practically insoluble in butyl alcohol
2.13	In acetonitrile	Practically insoluble in acetonitrile.	Practically insoluble in acetonitrile
3	Identification		
3.1	IR. absorption spectrum	The infrared absorption spectrum exhibits maxima only at the same wavelengths as that of similar preparation of Ketorolac Tromethamine working Standard.	The infrared absorption spectrum exhibits maxima only at the same wavelengths as that of similar preparation of Ketorolac Tromethamine working Standard.
3.2	HPLC	The retention time of the major peak of the sample solution corresponds to that of the standard solution as obtained in the Assay	The retention time of the major peak of the sample solution corresponds to that of the standard solution as obtained in the Assay
3.3	Tromethamine test	To meet the test.	Complies
4	Melting Point	Between 165°C and 170°C with decomposition	169.4 °C
5	pH(1 % w/v aqueous solution)	Between 5.7 and 6.7	6.1
6	Loss on drying (Dry it in Vacuum at 60°C for 3 hrs.)	Not more than 0.5 %w/w	0.2 %w/w
7	Residue on ignition	Not more than 0.1 %w/w	0.0 % w/w

Remarks: APPROVED (Sample Conforms to above Specification)

Prepared By	Reviewed By	Approved By
Ananth Kumar.T(Team Leader)	Venkata Reddy.K(Team Leader)	PVSSN.Raju(Team Leader)
18-10-2019 12:19	18-10-2019 12:38	18-10-2019 12:47
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8	Residual solvents by GC		
8.1	Methanol	Not more than 500 ppm	Less than LOQ (LOQ : 9ppm)
8.2	Acetone	Not more than 1000 ppm	402 ppm
9	Chromatographic purity		
9.1	Ketorolac 1-keto analog	Not more than 0.1 %	Not Detected
9.2	Ketorolac 1-hydroxy analog	Not more than 0.1 %	Not Detected
9.3	Impurity at RRT about 0.54	Not more than 0.1 %	Not detected
9.4	Impurity at RRT about 0.66	Not more than 0.1 %	Not detected
9.5	Any other individual unknown impurity	Not more than 0.1 %	0.05 %
9.6	Sum of all impurities	Not more than 1.0 %	0.0 %
10	Assay (on dried basis)	Not less than 98.5 %w/w and Not more than 101.5 %w/w.	99.7 % w/w
11	Colour (3% and 10%w/v aqueous solution at 430 nm))*S-08-KM-IH-02*		
11.1	Colour (3%w/v aqueous solution at 430 nm)	3 % solution Absorption is NMT 0.10	0.04
11.2	Colour (10%w/v aqueous solution at 430 nm)	10 % solution Absorption is NMT 0.2	0.1
12	Particle size distribution *S-08-KM-IH-05*		
12.1	On 40 ASTM	Retainers should be Nil	0 %
12.2	On 60 ASTM	Retainers not more than 5%	0 %
13	Bulk density and Tapped density *S-08-KM-IH-06*		
13.1	Bulk density	Between 0.10 and 0.30 g/mL	0.18 g/mL
13.2	Tapped density	Between 0.25 and 0.50 g/mL	0.34 g/mL

Additional Comments if Any: Storage Conditions: Preserve in tight, light-resistant containers. Store at control room temperature 20 to 25°C.(Excursions allowed between 15°C and 30°C). Packing condition: Material is packed in a clear poly bag and tie with nylon strap. Keep this in black poly bag and tie with nylon strap. Keep this in HDPE container.

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