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-CTO02-000801 / 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.

Remarks: APPROVED (Sample Conforms to above Specification)

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