

Factory : Dr.Reddy's Laboratories Ltd., CTO Unit-II Plot No. 110 & 111, Sri Venkateswara Co-operative Industrial Estate, Bollaram,
Jinnaram Mandal, Medak District, Andhra Pradesh, INDIA Ph. : 08456 - 279463 & 279466

CERTIFICATE OF ANALYSIS

Product	: KETOROLAC TROMETHAMINE	Customer name	: Farmaceutica Paraguaya S.A.
Batch No.	: ABHH003814	Date of Manufacture	: JULY 2014
Batch Quantity	: 232.740 Kg	Expiry Date	: JUNE 2019
A.R.No.	: 40000770992	Date Analysed	: 15.08.2014
Reference	: USP / In-house	Specification No.	: S-08-KM-USP/07
Storage	: 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.		

Sl.No.	TEST	RESULT	SPECIFICATION
1.0	Description	Off-white crystalline powder	White to off-white crystalline powder.
2.0	Solubility	Complies	Freely soluble in water and in methanol; slightly soluble in alcohol, in dehydrated alcohol, in tetrahydrofuran; practically insoluble in acetone, in dichloromethane, in toluene, in ethyl acetate, in dioxane, in hexane, in butyl alcohol, and in acetonitrile.
3.0	Identification		
3.1	IR absorption spectrum	Matches with 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	UV absorption spectrum	Matches with working standard.	The Ultra violet absorption spectrum of the test and standard solution exhibit maxima and minima at 318 and 242 nm.
3.3	Tromethamine test	Complies	To meet the test.
4.0	Melting point	167°C	Between 165°C and 170°C with decomposition.
5.0	pH (1%w/v aqueous solution)	5.90	Between 5.7 and 6.7
6.0	Loss on drying (Dry it in Vacuum at 60°C for 3 hrs.)	0.3%w/w	Not more than 0.5%w/w
7.0	Residue on ignition	0.05%w/w	Not more than 0.1%w/w
8.0	Heavy metals	Less than 0.001%w/w	Not more than 0.001 %w/w
9.0	Residual solvents by GC		
9.1	Methanol	Less than LOQ (LOQ=9 ppm)	Not more than 500 ppm
9.2	Acetone	359 ppm	Not more than 1000 ppm

The product CONFORMS to above specifications.

Compiled by: *[Signature]*
Date: *16/08/14*

Checked by: *[Signature]*
Date: *16/08/14*

Head, Quality Control: *[Signature]*
Date: *18/08/14*



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Batch Quantity	: 232.740 Kg.	Expiry Date	: JUNE 2019
A.R.No.	: 40000770992	Date Analysed	: 15.08.2014
Reference	: USP / In-house	Specification No.	: S-03-KM-USP/07
Storage	: 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.		
Sl.No.	TEST	RESULT	SPECIFICATION
10.0	Chromatographic purity		
10.1	Ketorolac 1-keio analog	0.01%	Not more than 0.1%
10.2	Ketorolac 1-hydroxy analog	Not detected	Not more than 0.1%
10.3	Impurity at RRT about 0.54	0.04%	Not more than 0.1%
10.4	Impurity at RRT about 0.66	Not detected	Not more than 0.1%
10.5	Any other individual unknown impurity	0.01%	Not more than 0.1%
10.6	Sum of all impurities	0.1%	Not more than 1.0%
11.0	Assay (on dried basis)	100.6%w/w	Not less than 98.5% and not more than 101.5%w/w.
*12.0	Colour (3% and 10%w/v aqueous solution at 430 nm)	0.0561 0.1665	2% solution Absorption is NMT 0.10 10% solution Absorption is NMT 0.2
*13.0	Density		
	Bulk density	0.20 g/mL	Between 0.10 and 0.30 g/mL
	Tapped density	0.33 g/mL	Between 0.25 and 0.50 g/mL
*14.0	Particle size distribution		
	On 40 ASTM	Nil	Retainers should be nil.
	On 60 ASTM	Nil	Retainers not more than 5%

* In-house Specifications-12)S-KMIH-002/00, 13)S-KMIH-006/00 and 14)S-KMIH-005/00.

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