

SYMED LABS LIMITED

UNIT-II, Plot No.25/B, Phase-III, IDA, Jeedimetla (V), Quthbullapur (M),
Medchal-Malkajgiri District – 500 055, Telangana State, INDIA. Tel: + 91 40231913376/09124
URL: <http://www.symedlabs.com>, CIN: U24231TG1998PLC029961



Certificate of Analysis

Product	: KETOROLAC	Reference	: USP
Batch No.	: 2KTM0330624	Batch Quantity	: 207.75 Kg
Date of Manufacture	: Jun - 2024	Date of analysis	: 10/07/2024
Expiry date	: May - 2029	A.R. No.	: 02FP24001645
Storage conditions	: Preserve in tight light resistant containers. Store at 25°C, excursions permitted between 15 & 30°C		

S.No	Test	Specification	Results
1. ✓	Description	A white to off white crystalline powder	An off White crystalline powder ✓
2. ✓	Solubility	Freely soluble in water and in methanol, slightly soluble in alcohol, in dehydrated alcohol and in Tetrahydrofuran, practically insoluble in acetone, in dichloromethane, in toluene, in Ethyl acetate, in Dioxane, in hexane, in butyl alcohol and in Acetonitrile	Complies ✓
3. ✓	Identification	A) IR: The Infrared absorption spectrum of the finely ground sample in KBr dispersion compressed into a disc should exhibit maxima only at the same wave lengths as that of a similar preparation of Working Standard. B) HPLC: The retention time of the major peak of the sample solution corresponds to that of the standard solution, as obtained in the assay. C) Tromethamine Test by TLC: Should comply the requirements of the TLC for tromethamine.	Matches with the spectrum of standard ✓ Matches with the retention time of standard ✓ Complies ✓
4. ✓	Melting Range	Between 165 °C and 170 °C (with decomposition)	165.8°C to 166.8°C ✓
5. ✓	pH (1 in 100 Sol'n)	Between 5.7 and 6.7	5.874 ✓
6. ✓	Loss on Drying	Not more than 0.50%w/w	0.31 %w/w ✓
7. ✓	Residue on Ignition	Not more than 0.10%w/w	0.04 %w/w ✓
*8. ✓	Colour and clarity of solution		
	Colour of solution (3.0%w/v aqueous solution)	Not more than 0.10 abs	0.05 abs ✗
	Absorbance at 430nm		
	Clarity of solution (3.0%w/v aqueous solution)	Should be clear, free from fibrous particulate matter. Should not show any crystallization, sedimentation or creaming within 72hours	Complies ✗
9. ✓	Assay by HPLC (on dried basis)	Not less than 98.5% w/w and not more than 101.5% w/w	100.0 %w/w ✓
10.	Chromatographic Purity by HPLC	Ketorolac 1-keto analog : Not more than 0.10% ✓	Not detected (LOQ= 0.0100%)
		Ketorolac 1-hydroxy analog : Not more than 0.10% ✓	Not detected (LOQ= 0.0102%)

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S.No	Test	Specification	Results
0.5		Impurity C at RRT 0.54 : Not more than 0.10% {(1RS)-6-benzoyl-2,3-dihydro-1H-pyrrolizine-1-carboxylic acid}	Not detected (LOQ= 0.0281%)
		Impurity D at RRT 0.66 : Not more than 0.10% {(1RS)-5-benzoyl-1-methoxy-2,3-dihydro-1H-pyrrolizine-carboxylic acid}	Not detected (LOQ= 0.0103%)
		Impurity F at RRT 0.59 : Not more than 0.10% {(1RS)-7-benzoyl-2,3-dihydro-1H-pyrrolizine-1-carboxylic acid}	Not detected (LOQ= 0.0315%)
		Impurity H at RRT 1.49 : Not more than 0.10% {Methyl (1RS)-5-benzoyl-2,3-dihydro-1H-pyrrolizine-1-carboxylate}	Not detected (LOQ= 0.0201%)
		Impurity I at RRT 1.66 : Not more than 0.10% {Phenyl(2,3-dihydro-1H-pyrrolizin-5-yl) methanone}	Not detected (LOQ= 0.0202%)
		Individual unspecified impurity : Not more than 0.10%	0.04 %
		Total impurities : Not more than 1.0%	0.07 %
*11. ✓	Residual Solvents by GC	Methanol : Not more than 500 ppm	Not detected (LOQ= 105 ppm)
		Acetone : Not more than 1000 ppm	131 ppm
		Toluene : Not more than 500 ppm	Not detected (LOQ= 53 ppm)
12. ✓	Microbial test limit		
	a) Total Aerobic microbial count	Not more than 1000 cfu/g	Less than 10 cfu/g
	b) Total combined yeast and moulds count	Not more than 100 cfu/g	Less than 10 cfu/g

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S.No	Test	Specification	Results
	c) Test for specified micro organisms		
	i) Bile tolerant gram negative bacteria	Should be absent	Absent
	ii) Pseudomonas aeruginosa	Should be absent	Absent
	iii) Staphylococcus aureus	Should be absent	Absent
	iv) Escherichia coli	Should be absent	Absent
	v) Salmonella Species	Should be absent	Absent
	vi) Candida albicans	Should be absent	Absent
13. ✓	Bacterial endotoxins	Should be ≤ 5.8 EU/mg	Less than 5.8 EU/mg

The product **conforms** to the above specifications.

*In house test.

LOQ= Limit of Quantitation.

Approved Signatory (QC)

Name : T.Usha Rani

Designation : Sr.Supervisor

Date

16.07.2024

Authorized signatory (QA)

Name : Y.Prameela Jyothi

Designation: Asst.Manager

Date

16/07/2024

STANDARISASI CERTIFICATE OF ANALYSIS API PRODUK

No	Nama Bahan	Manufaktur	Referensi pada CoA Manufacturer saat ini	Referensi pada CoA yang diusulkan	Penyesuaian Parameter			Nomor SPBB	Keterangan
					Parameter yang Dihilangkan	Parameter yang Ditambah	Parameter yang direvisi		
1	Ketorolac	Symed Labs Limited	USP	USP47/ FI VI	Identifikasi D (Nanomam) Colour and clarity of solution Impurity F, H, dan I Residual Solvent	Logam berat (FI VI) Cemaran senyawa organik yang mudah menguap (FI VI) Logam berat (FI VI)	Individual specific impurity, NMT 0.5% Impurity C dan D (NMT 0.5%)		Update SPBB Penyesuaian CoA dari Manufacturer

Diperiksa Oleh

ALAN 23/10 24
Koordinator QC

[Signature] 23/10 24
Koordinator TS

[Signature] 23/10 24
Koordinator QA

Disetujui Oleh,

[Signature] 23/10 24
Manager QA