



UNIZA LIFECARE PRIVATE LIMITED

OLD S.R NO 404,SR.NO 919 KADI-DETROJ ROAD BALASAR KADI - 382715

QUALITY CONTROL DEPARTMENT

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FINISHED PRODUCT CERTIFICATE OF ANALYSIS

Product Name	: KETROHEAL DT 10	A.R. No.	: 7/4/0437
Packing	: 15 Tab	Release Dt.	: 06-07-2024
Generic Name	: KETOROLAC TROMETHAMINE DISPERSIBLE TABLETS 10 MG	T.R. Slip No.	: ULPPTR24250096
		T.R. Slip Dt.	: 29-06-2024
Product Code	: 700102	Mfg. Dt. :	06/24
Batch No.	: 40423	Exp. Dt. :	05/26
Actual Batch Size	: 760,000.0000 Tab	Test As per :	IHS
Sample Size	: 300.000 Tab	Specification No. :	FPS/TAB/0096/00
Released Qty.	: 754,999.9950 Tab	STP No.	: UNF/MOA/0112/00
		Mfg. Lic. No.	: G/25/2489
		Location	: KADI
		Company	: UNIZALIFE

Sr. No.	Test	Result	Specification
1.00	Description	White to off white colored, round shaped, plain on both sides, uncoated dispersible tablets.	White to off white colored, round shaped, plain on both sides, uncoated dispersible tablets.
2.00	Identification (By UV)	Complies	Maxima at about 322 nm.
3.00	Average weight	181.83 mg	180.00 mg $\pm$ 7.5 %
4.00	Uniformity of weight (By content uniformity)	Complies	The requirements for dosage uniformity are met if the acceptance value of the first 10 dosage units is less than or equal to L1%. If the acceptance value is greater than L1%, test the next 20 units and calculate the acceptance value. The requirements are met if the final acceptance value of the 30 dosage units is less than or equal to L1%, and no individual content of any dosage unit is less than $(1 - L2 \times 0.01) M$ or more than $(1 + L2 \times 0.01) M$ as specified in the Calculation of Acceptance Value under Content Uniformity or under Weight Variation. Unless otherwise specified in the individual monograph, L1 is 15.0 and L2 is 25.0.
5.00	Thickness	Min:3.49 mm, Max:3.55 mm	3.50 mm $\pm$ 0.5 mm
6.00	Diameter	Min:8.00 mm, Max:8.05 mm	8.00 mm $\pm$ 0.5 mm
7.00	Hardness	Min:4.65 Kp, Max:5.01 Kp	NLT 3 kp
8.00	Friability	0.29 % w/w	NMT 1.0 % w/w
9.00	Disintegration Test	00 Min 29 Sec	Not more than 15 min
10.00	Assay	.	.
10.10	Each uncoated tablet contains	.	.
10.20	Ketorolac Tromethamine 10 mg	10.2361 mg/Tab	Between 90.0 % to 110.0 % of the label claim.

Prepared By	Checked By	Approved By
JAYENDRA PATEL QC EXECUTIVE	RAKESHBHAI PATEL ASSIS. MANAGER	RAJENDRA QC MANAGER



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Sr. No.	Test	Result	Specification
		102.36 %	
11.00	Microbial Contamination	.	.
11.10	Total aerobic microbial count	Less than 10 cfu/g	Not more than 1000 CFU/g.
11.20	Total yeast and mould count	Less than 10 cfu/g	Not more than 100 CFU/g.
11.30	E.Coli	Absent	Should be absent
11.40	Salmonella	Absent	Should be absent
11.50	Pseudomonas aeruginosa	Absent	Should be absent
11.60	Staphylococcus aureus	Absent	Should be absent

Conclusion : The above sample complies as per IHS. "This computer generated certificate of analysis is valid without signature"

Prepared By	Checked By	Approved By
JAYENDRA PATEL QC EXECUTIVE	RAKESHBHAI PATEL ASSIS. MANAGER	RAJENDRA QC MANAGER