



Kentreck Laboratories Pvt. Ltd.

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QUALITY CONTROL DEPARTMENT

THE DRUG & COSMETIC ACT, 1940 & THE RULES THERE UNDER FORM-39(RULE 150-E(F))

FINISHED PRODUCT CERTIFICATE OF ANALYSIS

Product Name : LEVOHEAL 250 TABLETS
Packing : 10x10 TAB
Generic Name : LEVOFLOXACIN, TABLET I.P 250 MG

Product Code : LEVO25
Batch No. : KH143
Actual Batch Size : 100000 TAB (1000 BOX)
Packing Batch Size : 100000 TAB
Sample Size : 100.000 TAB
Released Qty : 100000.00 TAB (1000 BOX)

Mfg. Dt. : 03/2024
Exp. Dt. : 02/2026
Test Packing : 100 TAB

Test As Per : IP

A.R. No. : KLFG240011
Rel. Dt. : 08-04-2024
T.R. Slip No. : KLFG240011
T.R. Slip Dt. : 08-04-2024
Analysis Date : 08-04-2024
Specification No. : SP/FG/LEVO25
Specification Dt : 03-11-2023
STP No. : SOP/003
Location : SANAND
Make : KLPL

Remarks :

Sr.	Test	Result	Specification
1	DESCRIPTION	Light orange colour film coated round biconvex tablet.	Light orange colour film coated round biconvex tablet.
2	IDENTIFICATION	Complies	Complies as per IP
3	UNIFORMITY OF WEIGHT	Weight of 20 tablets : 6.254 gm Avg. Wt. of tablet : 312.7 mg	Weight of 20 tablets: About 6.000 gm Avg. Wt. of tablet : About 300.0 mg ($\pm 5\%$)
4	DIAMETER	9.62 mm	9.6 ± 0.2 mm
5	THICKNESS	4.02 mm	4.2 ± 0.2 mm
6	DISINTEGRATION TIME	05 min 58 sec	NMT 30 min
7	RELATED SUBSTANCE	Complies	Complies as per IP
8	DISSOLUTION	Complies Mean - 89.32 %	NLT 70 %
9	ASSAY	100.10 %	Levofloxacin Hemihydrate IP Eq. to Levofloxacin - 250 mg [Limit : Bet'n 90 % to 110%]
10	PACKING STYLE	Complies	Blister Packing 10 X 10 Tablets

Conclusion : The above sample complies as per IP

In the Opinion of the undersigned the sample referred to above is of Standard quality as defined in the Act and the Rules made thereunder for the result given above. "This computer generated certificate of analysis is valid without signature"

Analysis By

Q.A./Q.C. Incharge