



Kentreck Laboratories Pvt. Ltd.

QUALITY CONTROL DEPARTMENT

Page 1 of 1

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	A.R. No.	: KLFG240124
Packing	: 10x10 TAB	Rel. Dt.	: 03-06-2024
Generic Name	: LEVOFLOXACIN TABLET I.P 250 MG	T.R. Slip No.	: KLFG240124
Product Code	: LEVO25	T.R. Slip Dt.	: 03-06-2024
Batch No.	: HK007	Analysis Date	: 03-06-2024
Actual Batch Size	: 10000(TAB(1000 BOX))	Specification No.:	SP/FG/LEVO25
Packing Batch Size	: 100000 TAB	Specification Dt	: 03-11-2023
Sample Size	: 100.00C TAB	STP No.	: SOP/003
Released Qty	: 100000.00C(TAB(1000 BOX))	Location	: SANAND
Remarks :	Test As Per : IP	Make	: KLPL

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 : 6.306 gm Avg. Wt. of tablet : 315.3 mg	Weight of 20 tablets: About 6.000 gm Avg. Wt. of tablet : About 300.0 mg ($\pm 5\%$)
4	DIAMETER	9.69 mm	9.6 ± 0.2 mm
5	THICKNESS	4.22 mm	4.2 ± 0.2 mm
6	DISINTEGRATION TIME	10 min 25 sec	NMT 30 min
7	RELATED SUBSTANCE	Complies	Complies as per IP
8	DISSOLUTION	Complies Mean - 90.22 %	NLT 70 %
9	ASSAY	100.25 %	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

D