



Kentreck Laboratories Pvt. Ltd.

QUALITY CONTROL DEPARTMENT

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

FINISHED PRODUCT CERTIFICATE OF ANALYSIS

Product Name	: PREDNIHEAL 20 TABLETS	A.R. No.	: KLFG240301
Packing	: 50x10 TAB	Rel. Dt.	: 05-09-2024
Generic Name	: PREDNISOLONE TABLET IP 20 MG	T.R. Slip No.	: KLFG240301
Product Code	: PRED10	T.R. Slip Dt.	: 05-09-2024
Batch No.	: HK023	Analysis Date	: 05-09-2024
Actual Batch Size	: 400000(TAB(800 BOX))	Specification No.:	SP/FG/PRED10
Packing Batch Size	: 400000 TAB	Specification Dt	: 30-12-2023
Sample Size	: 100.00C TAB	STP No.	: SOP/003
Released Qty	: 400000.00C(TAB(800 BOX))	Location	: SANAND
Remarks :	Test As Per : IP	Make	: KLPL

Sr.	Test	Result	Specification
1	DESCRIPTION	White colour uncoated round biconvex tablet.	White colour uncoated round biconvex tablet.
2	IDENTIFICATION	Complies	Complies
1	RELATED SUBSTANCE	Complies	Complies
3	UNIFORMITY OF WEIGHT	Weight of 20 tablets: 5.674 gm Avg.Wt. of tablet: 283.7 mg	Weight of 20 tablets: About 5.600 gm Avg. Wt. of tablet : About 280.0 mg ($\pm 5.0\%$)
4	FRIABILITY	0.17 %	NMT 1.0%
5	HARDNESS	4.0 Kg/cm ²	NLT 2.0 Kg/cm ²
6	DIAMETER	9.65 mm	9.6 $\pm$ 0.2 mm
7	THICKNESS	3.63 mm	3.7 $\pm$ 0.2 mm
1	DISINTEGRATION TIME	03 min 56 sec	NMT 15 min
8	RELATED SUBSTANCE	Complies	Complies
9	DISSOLUTION	Complies Mean - 91.79 %	NLT 70 %
10	ASSAY	100.06 %	Prednisolone IP - 20 MG [Limit : Bet'n 90% to 110%]
11	PACKING STYLE	Complies	Blister Packing 50 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