



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 40 TABLETS	A.R. No. : KLFG240062
Packing : 50x10 TAB	Rel. Dt. : 04-05-2024
Generic Name : PREDNISOLONE TABLETS IP 40 MG	T.R. Slip No. : KLFG240062
Product Code : PRED11	T.R. Slip Dt. : 04-05-2024
Batch No. : HK003	Analysis Date : 04-05-2024
Actual Batch Size : 200000 TAB (400 BOX)	Specification No. : SP/BULK/PRED11
Packing Batch Size : 200000 TAB	Specification Dt. : 31-12-2023
Sample Size : 100.00C TAB	STP No. : SOP/003
Released Qty : 200000.00C TAB (400 BOX)	Location : SANAND
Test As Per : IP	Make : KLPL
Remarks :	

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: 5.570 gm Avg. Wt. of tablet : 278.5 mg	Weight of 20 tablets: About 5.600 gm Avg. Wt. of tablet : About 280.0 mg ($\pm 5.0\%$)
4	FRIABILITY	0.23 %	NMT 1.0%
5	HARDNESS	3.5 Kg/cm ²	NLT 2.0 Kg/cm ²
6	DIAMETER	9.58 mm	9.6 $\pm$ 0.2 mm
7	THICKNESS	3.61 mm	3.7 $\pm$ 0.2 mm
1	DISINTEGRATION TIME	05 min 58 sec	NMT 15 min
8	RELATED SUBSTANCE	Complies	Complies
9	DISSOLUTION	Complies Mean - 90.08 %	NLT 70 %
10	ASSAY	100.16 %	Prednisolone IP - 5 MG [Limit : Bet'n 90% to 110%]
11	PACKING STYLE	Complies	Blister Packg 50 X10 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