

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	: PREDNIHEAL 40 TABLETS	A.R. No.	: KLFG240397
Packing	: 50x10 TAB	Rel. Dt.	: 28-10-2024
Generic Name	: PREDNISOLONE TABLETS IP 40 MG	T.R. Slip No.	: KLFG240397
Product Code	: PRED11	T.R. Slip Dt.	: 28-10-2024
Batch No.	: HK027	Analysis Date	: 28-10-2024
Actual Batch Size	: 20000(TAB(400 BOX))	Specification No.	: SP/BULK/PRED11
Packing Batch Size	: 200000 TAB	Specification Dt	: 31-12-2023
Sample Size	: 100.00(TAB)	STP No.	: SOP/003
Released Qty	: 200000.00(TAB(400 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: 5.664 gm Avg. Wt. of tablet: 283.2 mg	Weight of 20 tablets: About 5.600 gm Avg. Wt. of tablet: About 280.0 mg ($\pm 5.0\%$)
4	FRIABILITY	0.25 %	NMT 1.0%
5	HARDNESS	4.0 Kg/cm ²	NLT 2.0 Kg/cm ²
6	DIAMETER	9.57 mm	9.6 $\pm$ 0.2 mm
7	THICKNESS	3.68 mm	3.7 $\pm$ 0.2 mm
1	DISINTEGRATION TIME	03 min 05 sec	NMT 15 min
8	RELATED SUBSTANCE	Complies	Complies
9	DISSOLUTION	Complies Mean - 91.86 %	NLT 70 %
10	ASSAY	100.15 %	Prednisolone IP - 40 MG (Limit : Bet'n 90% to 110%)
11	PACKING STYLE	Complies	Blister Packig 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

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[Signature]