



Kentreck Laboratories Pvt. Ltd.

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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.	: KLFG230552
Packing	: 50x10 TAB	Rel. Dt.	: 30-12-2023
Generic Name	: PREDNISOLONE TABLET IP 20 MG	T.R. Slip No.	: KLFG230552
Product Code	: PRED10	Mfg. Dt.	: 12/2023
Batch No.	: KH117	Exp. Dt.	: 11/2025
Actual Batch Size	: 300000 TAB (600 BOX)	Test Packing:	: 100 TAB
Packing Batch Size	: 300000 TAB	Analysis Date	: 30-12-2023
Sample Size	: 100.000 TAB	Specification No.:	: SP/FG/PRED10
Released Qty	: 300000.000 TAB (600 BOX)	Specification Dt.	: 30-12-2023
Remarks :	Test As Per : IP	STP No.	: SOP/003
		Location	: SANAND
		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 : 5.558 gm Avg. Wt. of tablet : 277.9 mg	Weight of 20 tablets : About 5.600 gm Avg. Wt. of tablet : About 280.0 mg ($\pm 5.0\%$)
4	FRIABILITY	0.22 %	NMT 1.0%
5	HARDNESS	3.0 Kg/cm ²	NLT 2.0 Kg/cm ²
6	DIAMETER	9.64 mm.	9.6 $\pm$ 0.2 mm
7	THICKNESS	3.67 mm.	3.7 $\pm$ 0.2 mm
1	DISINTEGRATION TIME	04 min 26 sec	NMT 15 min
8	RELATED SUBSTANCE	Complies	Complies
9	DISSOLUTION	Complies Mean - 89.68 %	NLT 70 %
10	ASSAY	100.14 %	Prednisolone IP - 5 MG (Limit : Befn 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