



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 10 TABLETS	A.R. No.	: KLFG230499
Packing	: 50x10 TAB	Rel. Dt.	: 04-12-2023
Generic Name	: PREDNISOLONE TABLET IP 10 MG	T.R. Slip No.	: KLFG230499
Product Code	: PRED09	T.R. Slip Dt.	: 04-12-2023
Batch No.	: KH113	Analysis Date	: 04-12-2023
Actual Batch Size	: 400000(TAB(800 BOX))	Specification No.:	SP/FG/PRED09
Packing Batch Size	: 400000 TAB	Specification Dt	: 04-12-2023
Sample Size	: 100.00(TAB	STP No.	: SOP/003
Released Qty	: 400000.00(TAB(800 BOX))	Location	: SANAND
	Test As Per : IP	Make	: KLPL
Marks :			

Sr.	Test	Result	Specification
1	DESCRIPTION	White colour uncoated round flat tablet with break line on one side	White colour uncoated round flat tablet with break line on one side
2	IDENTIFICATION	Complies	Complies
1	RELATED SUBSTANCE	Complies	Complies
3	UNIFORMITY OF WEIGHT	Weight of 20 tablets : 3.006 gm Avg.Wt. of tablet : 150.3 mg	Weight of 20 tablets: About 3.000 gm Avg. Wt. of tablet : About 150.0 mg ($\pm 7.5\%$)
4	FRIABILITY	0.22 %	NMT 1.0%
5	HARDNESS	3.5 Kg/cm ²	NLT 2.0 Kg/cm ²
6	DIAMETER	7.2 mm	7.1 $\pm$ 0.2 mm
7	THICKNESS	2.86 mm	3.0 $\pm$ 0.2 mm
1	DISINTEGRATION TIME	05 min 03 sec	NMT 15 min
8	UNIFORMITY OF CONTENTS	Complies max - 100.61 % min - 99.82 %	Bet'n 85% to 115%
9	DISSOLUTION	Complies Mean - 90.68 %	NLT 70 %
10	ASSAY	1) 100.30 %	1) Prednisolone IP - 10 mg [Limit : Bet'n 90% to 110%]
13	PACKING STYLE	Complies	50 X 10 Tablets Blister Packing

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

@Patel.