



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 10 TABLETS	A.R. No.	: KLFG240231
Packing	: 50x10 TAB	Rel. Dt.	: 27-07-2024
Generic Name	: PREDNISOLONE TABLET IP 10 MG	T.R. Slip No.	: KLFG240231
Product Code	: PRED09	T.R. Slip Dt.	: 27-07-2024
Batch No.	: HK016	Analysis Date	: 27-07-2024
Actual Batch Size	: 800000(TAB(1600 BOX)	Specification No.:	SP/FG/PRED09
Packing Batch Size	: 800000 TAB	Specification Dt	: 04-12-2023
Sample Size	: 100.000 TAB	STP No.	: SOP/003
Released Qty	: 800000.00(TAB (1600 BOX)	Location	: SANAND
Remarks :	Test As Per : IP	Make	: KLPL

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: 3.034 gm Avg. WL of tablet : 151.7 mg	Weight of 20 tablets: About 3.000 gm Avg. WL of tablet : About 150.0 mg ($\pm 7.5\%$)
4	FRIABILITY	0.16 %	NMT 1.0%
5	HARDNESS	3.5 Kg/cm ²	NLT 2.0 Kg/cm ²
6	DIAMETER	7.19 mm	7.1 $\pm$ 0.2 mm
7	THICKNESS	2.9 mm	3.0 $\pm$ 0.2 mm
1	DISINTEGRATION TIME	05 min 17 sec	NMT 15 min
8	UNIFORMITY OF CONTENTS	Complies max - 100.79 % min - 99.32 %	Be'tn 85% to 115%
9	DISSOLUTION	Complies Mean - 91.66 %	NLT 70 %
10	ASSAY	1) 100.21 %	1) Prednisolone IP - 10 mg [Limit : Be'tn 90% to 110%]
13	PACKING STYLE	Complies	50 X 10 Tablets Blister Packing

Conclusion : The above sample complies as per IP

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 result given above. "This computer generated certificate of analysis is valid without signature"

Analysis By

Q.A./Q.C. Incharge