



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 5 TABLETS	A.R. No.	: KLFG240123
Packing	: 50x10 TAB	Rel. Dt.	: 03-06-2024
Generic Name	: PREDNISOLONE TABLETS IP 5 MG	T.R. Slip No.	: KLFG240123
Product Code	: PRED08	T.R. Slip Dt.	: 03-06-2024
Batch No.	: HK009	Analysis Date	: 03-06-2024
Actual Batch Size	: 65000(TAB(1300 BOX)	Specification No.	: SP/FG/PRED08
Packing Batch Size	: 650000 TAB	Specification Dt	: 01-12-2023
Sample Size	: 100.00(TAB	STP No.	: SOP/003
Released Qty	: 650000.00(TAB (1300 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: 3.002 gm Avg. WL of tablet : 150.1 mg	Weight of 20 tablets: About 3.000 gm Avg. WL of tablet : About 150.0 mg ($\pm 7.5\%$)
4	FRIABILITY	0.19 %	NMT 1.0%
5	HARDNESS	3.5 Kg/cm ²	NLT 2.0 Kg/cm ²
6	DIAMETER	7.17 mm	7.1 $\pm$ 0.2 mm
7	THICKNESS	2.89 mm	3.0 $\pm$ 0.2 mm
1	DISINTEGRATION TIME	03 min 32 sec	NMT 15 min
8	RELATED SUBSTANCE	Complies	Complies
9	UNIFORMITY OF CONTENTS	Complies max - 100.60 % min - 99.84 %	Be'n 85% to 115%
10	DISSOLUTION	Complies Mean - 90.83 %	NLT 70 %
11	ASSAY	100.07 %	Prednisolone IP - 5 MG [Limit : Be'n 90% to 110%]
12	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

[Signature]

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