



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
Packing : 50x10 TAB
Generic Name : PREDNISOLONE TABLETS IP 5 MG

Product Code : PRED08
Batch No. : KH145
Actual Batch Size : 50000(TAB(1000 BOX))
Packing Batch Size : 500000 TAB
Sample Size : 100.00(TAB
Released Qty : 500000.00(TAB(1000 BOX))

Mfg. Dt. : 03/2024
Exp. Dt. : 02/2026
Test Packing : 100 TAB

Test As Per : IP

A.R. No. : KLFG240007
Rel. Dt. : 07-04-2024
T.R. Slip No. : KLFG240007
T.R. Slip Dt. : 07-04-2024
Analysis Date : 07-04-2024
Specification No. : SP/FG/PRED08
Specification Dt : 01-12-2023
STP No. : SOP/003
Location : SANAND
Make : KLPL

Remarks :

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 : 2.990 gm Avg.Wt. of tablet : 149.5 mg	Weight of 20 tablets: About 3.000 gm Avg. Wt. of tablet : About 150.0 mg ($\pm 7.5\%$)
4	FRIABILITY	0.23 %	NMT 1.0%
5	HARDNESS	3.5 Kg/cm ²	NLT 2.0 Kg/cm ²
6	DIAMETER	7.15 mm	7.1 $\pm$ 0.2 mm
7	THICKNESS	2.91 mm	3.0 $\pm$ 0.2 mm
1	DISINTEGRATION TIME	03 min 58 sec	NMT 15 min
8	RELATED SUBSTANCE	Complies	Complies
9	UNIFORMITY OF CONTENTS	Complies max - 100.95 % min - 99.10 %	Be'tn 85% to 115%
10	DISSOLUTION	Complies Mean - 92.97 %	NLT 70 %
11	ASSAY	100.20 %	Prednisolone IP - 5 MG [Limit : Be'tn 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

@Patel

[Signature]