



Kentreck Laboratories Pvt. Ltd.

QUALITY CONTROL DEPARTMENT

Page 1 of 1

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
Packing : 50x10 TAB
Generic Name : PREDNISOLONE TABLET IP 10 MG

Product Code : PRED09
Batch No. : HK004
Actual Batch Size : 600000 TAB (1200 BOX)
Packing Batch Size : 600000 TAB
Sample Size : 100.00 TAB
Released Qty : 600000.00 TAB (1200 BOX)

Mfg. Dt. : 04/2024
Exp. Dt. : 03/2026
Test Packing : 100 TAB

Test As Per : IP

Remarks :

A.R. No. : KLFG240098
Rel. Dt. : 22-05-2024
T.R. Slip No. : KLFG240098
T.R. Slip Dt. : 22-05-2024
Analysis Date : 22-05-2024
Specification No. : SP/FG/PRED09
Specification Dt. : 04-12-2023
STP No. : SOP/003
Location : SANAND
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: 3.006 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	0.16 %	NMT 1.0%
5	HARDNESS	3.5 Kg/cm ²	NLT 2.0 Kg/cm ²
6	DIAMETER	7.18 mm	7.1 $\pm$ 0.2 mm
7	THICKNESS	3.03 mm	3.0 $\pm$ 0.2 mm
1	DISINTEGRATION TIME	05 min 03 sec	NMT 15 min
8	UNIFORMITY OF CONTENTS	Complies max - 100.49 % min - 99.87 %	Be't'n 85% to 115%
9	DISSOLUTION	Complies Mean - 91.34 %	NLT 70 %
10	ASSAY	1) 100.16 %	1) Prednisolone IP - 10 mg [Limit : Be't'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