



Kentreck Laboratories Pvt. Ltd.

56, AJANTA INDUSTRIAL ESTATE, P.O VASNA IYAVA, SANAND-382170
REG.OFF.: ADMIN OFF- 207, ANAND MANGAL COMPLEX, BH.OMKAR HOUSE, C.G.ROAD, NAVRANGPURA, AHMEDABAD-380008
Fax : 26463107 C.I.No. : U24231GJ1989PTC012216

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 40 TABLETS
Packing : 50x10 TAB
Generic Name : PREDNISOLONE TABLETS IP 40 MG

Product Code : PRED11
Batch No. : KH118
Actual Batch Size : 20000(TAB(400 BOX))
Packing Batch Size : 200000 TAB
Sample Size : 100.00(TAB
Released Qty : 200000.00(TAB (400 BOX))

Mfg. Dt. : 12/2023
Exp. Dt. : 11/2025
Test Packing : 100 TAB

Test As Per : IP

Remarks :

A.R. No. : KLFG230554
Rel. Dt. : 31-12-2023
T.R. Slip No. : KLFG230554
T.R. Slip Dt. : 31-12-2023
Analysis Date : 31-12-2023
Specification No. : SP/BULK/PRED11

Specification Dt : 31-12-2023
STP No. : SOP/003

Location : SANAND
Make : KLPL

Sr.	Test	Result	Specification
1	DESCRIPTION	White colour uncoated round biconvex tablet.	White colour uncoated round biconvex tablet.
2	IDENTIFICATION	Complies	Complies
1	RELATED SUBSTANCE	Complies	Complies
3	UNIFORMITY OF WEIGHT	Weight of 20 tablets : 5.582 gm Avg. Wt. of tablet : 279.1 mg	Weight of 20 tablets: About 5.600 gm Avg. Wt. of tablet : About 280.0 mg ($\pm 5.0\%$)
4	FRIABILITY	0.22 %	NMT 1.0%
5	HARDNESS	3.0 Kg/cm ²	NLT 2.0 Kg/cm ²
6	DIAMETER	9.6 mm	9.6 $\pm$ 0.2 mm
7	THICKNESS	3.61 mm	3.7 $\pm$ 0.2 mm
1	DISINTEGRATION TIME	03 min 41 sec	NMT 15 min
8	RELATED SUBSTANCE	Complies	Complies
9	DISSOLUTION	Complies Mean - 90.17 %	NLT 70 %
10	ASSAY	100.13 %	Prednisolone IP - 5 MG (Limit : Betn 90% to 110%)
11	PACKING STYLE	Complies	Blister Packig 50 X10 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

Eptel

Blister