



# Kentreck Laboratories Pvt. Ltd.

56, AJANTA INDUSTRIAL ESTATE., P.O VASNA IYAVA, SANAND-382170

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## 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. : KLFG230491
Packing : 50x10 TAB	Rel. Dt. : 01-12-2023
Generic Name : PREDNISOLONE TABLETS IP 5 MG	T.R. Slip No. : KLFG230491
Product Code : PRED08	T.R. Slip Dt. : 01-12-2023
Batch No. : KH112	Analysis Date : 01-12-2023
Actual Batch Size : 50000(TAB(1000 BOX))	Specification No. : SP/FG/PRED08
Packing Batch Size : 500000 TAB	Specification Dt : 01-12-2023
Sample Size : 100.00C TAB	STP No. : SOP/003
Released Qty : 500000.00(TAB(1000 BOX))	Location : SANAND
Test As Per : IP	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 one side
2	IDENTIFICATION	Complies	Complies
1	RELATED SUBSTANCE	Complies	Complies
3	UNIFORMITY OF WEIGHT	Weight of 20 tablets : 3.008 gm Avg.Wt. of tablet : 150.4 mg	Weight of 20 tablets: About 3.000 gm Avg. Wt. of tablet : About 150.0 mg (± 7.5%)
4	FRIABILITY	0.21 %	NMT 1.0%
5	HARDNESS	3.5 Kg/cm <sup>2</sup>	NLT 2.0 Kg/cm <sup>2</sup>
6	DIAMETER	7.18 mm	7.1 ± 0.2 mm
7	THICKNESS	2.87 mm	3.0 ± 0.2 mm
1	DISINTEGRATION TIME	05 min 12 sec	NMT 15 min
8	RELATED SUBSTANCE	Complies	Complies
9	UNIFORMITY OF CONTENTS	Complies max - 100.62 % min - 100.00 %	Be'n 85% to 115%
10	DISSOLUTION	Complies Mean - 90.70 %	NLT 70 %
11	ASSAY	100.14 %	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

*zpatel*

*[Signature]*