

# 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-380005  
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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

<b>Product Name</b> : PREDNIHEAL 5 TABLETS <b>Packing</b> : 50x10 TAB <b>Generic Name</b> : PREDNISOLONE TABLETS IP 5 MG  <b>Product Code</b> : PRED08 <b>Batch No.</b> : KH126 <b>Actual Batch Size</b> : 50000(TAB(1000 BOX)) <b>Packing Batch Size</b> : 500000 TAB <b>Sample Size</b> : 100.00(TAB) <b>Released Qty</b> : 500000.00(TAB(1000 BOX))  Remarks :	<b>A.R. No.</b> : KLFG230615  <b>Rel. Dt.</b> : 29-01-2024 <b>T.R. Slip No.</b> : KLFG230615 <b>T.R. Slip Dt.</b> : 29-01-2024 <b>Analysis Date</b> : 29-01-2024 <b>Specification No.</b> : SP/FG/PRED08  <b>Specification Dt</b> : 01-12-2023 <b>STP No.</b> : SOP/003  <b>Location</b> : SANAND <b>Make</b> : KLPL
<b>Mfg. Dt.</b> : 01/2024 <b>Exp. Dt.</b> : 12/2025 <b>Test Packing</b> : 100 TAB  <b>Test As Per</b> : IP	

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. Wt. of tablet : 150.1 mg	Weight of 20 tablets: About 3.000 gm Avg. Wt. of tablet : About 150.0 mg (± 7.5%)
4	FRIABILITY	0.20 %	NMT 1.0%
5	HARDNESS	3.5 Kg/cm <sup>2</sup>	NLT 2.0 Kg/cm <sup>2</sup>
6	DIAMETER	7.15 mm	7.1 ± 0.2 mm
7	THICKNESS	2.84 mm	3.0 ± 0.2 mm
1	DISINTEGRATION TIME	04 min 02 sec	NMT 15 min
8	RELATED SUBSTANCE	Complies	Complies
9	UNIFORMITY OF CONTENTS	Complies max - 100.88 % min - 99.65 %	Bet'n 85% to 115%
10	DISSOLUTION	Complies Mean - 91.06 %	NLT 70 %
11	ASSAY	100.21 %	Prednisolone IP - 5 MG [Limit : Bet'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)*  
Zpatel

*(Signature)*