

A/C OF HEALING PHARMA INDIA PVT LTD
QUALITY CONTROL DEPARTMENT
THE DRUG & COSMETIC ACT. 1940 & THE RULES THEREUNDER




Page 1 of 1

FINISHED PRODUCT CERTIFICATE OF ANALYSIS

Product Name : PREGAFOX 300 Packing : 10x15 CAP Generic Name : PREGABALIN CAPSULES IP 300 MG	A.R. No. : F/3031/2324 Rel. Dt. : 11-01-2024 T.R. Slip No. : CHPAP23205 T.R. Slip Dt. : 11-01-2024 Analysis Date : 11-01-2024 Specification No. : CRFS/CP-195HEAL/24
Product Code : CP-195HEAL Batch No. : CP-1950001 Actual Batch Size : 228000 CAP	Mfg. Dt. : DEC-2023 Exp. Dt. : NOV-2026 Test Packing : 10X15 CAP Mfg. Lic No. : G/25A/5141-A
Sample Size : 50.000 CAP Released Qty : 228000.000 CAP (1520 CAR)	Test As Per : IP
Remarks : pass	
Specification Dt : 04-01-2024 STP No. : STP/CP-195HEAL/AS PER IP Location : GORWA01 Make : HEALING	

Sr.	Test	Result	Specification
1	DESCRIPTION	A Red/white coloured, Hard Gelatin size "0" hard gelatin capsules, containing White coloured Powder.	A Red/white coloured, Hard Gelatin size "0" hard gelatin capsules, containing White coloured Powder.
2	IDENTIFICATION	Complies	Must Complies as per IP
1	IDENTIFICATION BY HPLC	The retention time of the major peak in the chromatogram of the assay preparation corresponds to that in the chromatogram of std. preparation, as obtained in the assay	The retention time of the major peak in the chromatogram of the assay preparation corresponds to that in the chromatogram of std. preparation, as obtained in the assay
3	AVERAGE WEIGHT	400.25 mg	400 mg \pm 7.5% of avg. weight
4	UNIFORMITY OF WEIGHT	H.L. : 1.44 % L.L. : -1.66 %	Within \pm 7.5% of avg. weight
5	DISINTEGRATION TIME	12 Min. 45 Sec. in Water Medium at 37°C	NMT 30 Min.
6	DISSOLUTION	92.62 %	NLT 70.0% (Q)
7	RELATED SUBSTANCES	complies	Must complies as per IP
8	ASSAY BY HPLC	101.01 %	Each Hard Gelatin Capsule Contains: Pregabalin IP.....300.0 mg [Limit :90.0 % to 110.0 %]

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"

Prepared By  PATELJIGAR QC CHEMIST	Checked By  ASMITA QUALITY HEAD	Approved By  VANI PATEL QA HEAD
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AYDIP123 05-02-24 04:44 PM

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