

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

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FINISHED PRODUCT CERTIFICATE OF ANALYSIS

Product Name : LDN- 4.5	A.R. No. : F/3163/2324
Packing : 3x10 CAP	Rel. Dt. : 25-01-2024
Generic Name : NALTREXONE HYDROCHLORIDE CAPSULES 4.5 MG	T.R. Slip No. : CHPAP23220
Product Code : CL-93HEALI	T.R. Slip Dt. : 24-01-2024
Batch No. : CL-930002	Analysis Date : 24-01-2024
Actual Batch Size : 102000 CAP	Specification No. : CRFS/CL-93HEALI/2122
Mfg. Dt. : JAN-2024	Specification Dt : 25-05-2021
Exp. Dt. : DEC-2026	STP No. : STP/CL-93HEALI/ASPERIHS
Test Packing : 3X10 CAP	Location : GORWA01
Mfg. Lic No. : G/25A/5141-A	Make : HEALING
Sample Size : 50.000 CAP	
Released Qty : 102000.000 CAP (3400 C.COV)	Test As Per : IH
Remarks : pass	

Sr.	Test	Result	Specification
1	DESCRIPTION	A White/White, size "2" hard gelatin capsule conating white coloured powder.	A White/White, size "2" hard gelatin capsule conating white coloured powder.
2	AVERAGE NET CONTENT OF CAPSULES	297.68 mg	295.00 mg $\pm$ 5.0 % of avg.net weight
3	UNIFORMITY OF WEIGHT	H.L. +2.93% L.L. - 2.48%	Within $\pm$ 7.5 % of average net weight
4	DISINTEGRATION TIME	06 Minute 55 Second in Water Medium at 37°C	NMT 30 Minutes in water medium at 37°C
5	UNIFORMITY OF CONTENT	MAX : 102.85 % MIN : 99.25 % AVG : 101.16 %	85 % TO 115 %
6	ASSAY	96.12 %	Each hard gelatin capsule conatins: Naltrexone Hydrochloride USP 4.5 mg [Limit :90.0% to 110.0%]

Conclusion : The above sample complies as per IH
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	Checked By	Approved By
 YASHPAL JAMADAR TRAINEE OFFICER	 ASMITA QUALITY HEAD	 VANI PATEL QA HEAD

NIKITA2023 29-01-24 03:44 PM

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