

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 : TADASIVA
Packing : 10x6 TAB
Generic Name : SILDENAFIL CITRATE & TADALAFIL TABLETS

Product Code : TT-104HEAL
Batch No. : TT-1040004
Actual Batch Size : 150000 TAB

Mfg. Dt. : DEC-2023
Exp. Dt. : NOV-2026
Test Packing : 10X6 TAB

Mfg. Lic No. : G/25A/5141-A

Sample Size : 50.000 TAB
Released Qty : 150000.000 TAB (2500 CAR)

Test As Per : IH

Remarks : pass

A.R. No. : F/2858/2324

Rel. Dt. : 27-12-2023

T.R. Slip No. : CHPAP23193

T.R. Slip Dt. : 27-12-2023

Analysis Date : 27-12-2023

Specification No. : CRFS/TT-104HEAL/20-21

STP No. : STP/TT-104HEAL/AS
PER IH

Location : GORWA01

Make : HEALING

Sr.	Test	Result	Specification
1	DESCRIPTION	A red Coloured, square shaped, biconvex, film coated tablet with HP on one Side and Plain on other side.	A red Coloured, square shaped, biconvex, film coated tablet with HP on one Side and Plain on other side.
2	IDENTIFICATION	Complies	Must Complies as per IHS
1	BY HPLC	In the Assay, the principal peak in the chromatogram obtained with the test solution is correspond to the peak in the chromatogram obtained with the reference solution of tadalafil and dapoxetine, as obtained in the Assay.	In the Assay, the principal peak in the chromatogram obtained with the test solution should correspond to the peak in the chromatogram obtained with the reference solution of tadalafil and dapoxetine, as obtained in the Assay.
3	AVERAGE WEIGHT OF TABLETS	421.45 mg	426.50 mg $\pm$ 3.0 % of avg. weight
4	UNIFORMITY OF WEIGHT	H.L.=+2.20% L.L.=-2.36%	Within $\pm$ 5.0% of avg. weight
5	THICKNESS	4.08 mm	4.00 mm $\pm$ 0.3mm
6	HEIGHT	10.19 mm	10.20 mm $\pm$ 0.2 mm
7	DISINTEGRATION TIME	07 minutes 53 seconds in Water Medium at 37°C	NMT 30 Minute Water Medium at 37°C
8	ASSAY BY HPLC	1)98.58 % 2)98.75 %	Each Film Coated Tablet Contains : (1) Sildenafil Citrate Eq.to Sildenafil 100 mg [LIMIT : 90.0% to 110.0%] (2) Tadalafil 20 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

JAYDIP KANZARIYA
TRAINEE OFFICER

Checked By

ASMIDA
MANAGER QC

Approved By

VANI PATEL
QA HEAD

NIKITA2023 02-01-24 10:42 AM

FGANLCERTQA