

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	A.R. No. : F/0272/2425
Packing : 10x6 TAB	Rel. Dt. : 06-05-2024
Generic Name : SILDENAFIL CITRATE & TADALAFIL TABLETS	T.R. Slip No. : CHPAP24032
Product Code : TT-104HEAL	T.R. Slip Dt. : 02-05-2024
Batch No. : TT-1040005	Analysis Date : 06-05-2024
Actual Batch Size : 121000 TAB	Specification No. : CRFS/TT-104HEAL/2425
Mfg. Dt. : APR-2024	Specification Dt. : 02-05-2024
Exp. Dt. : MAR-2027	STP No. : STP/TT-104HEAL/AS PER IH
Test Packing : 10X6 TAB	Location : GORWA01
Mfg. Lic No. : G/25A/5141-A	Make : HEALING
Sample Size : 50.000 TAB	
Released Qty : 121000.000 TAB (2016 CAR)	
Test As Per : IH	
Remarks : pass	

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 sildenafil, 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 sildenafil, as obtained in the Assay.
3	AVERAGE WEIGHT OF TABLETS	427.38 mg	426.50 mg $\pm$ 5.0 % of avg. weight
4	UNIFORMITY OF WEIGHT	H.L.=+1.69 % L.L=-1.47 %	Within $\pm$ 5.0% of avg. weight
5	THICKNESS	4.08 mm	4.00 mm $\pm$ 0.3mm
6	HEIGHT	10.24 mm	10.20 mm $\pm$ 0.2 mm
7	DISINTEGRATION TIME	06 minutes 22 seconds in Water Medium at 37°C	NMT 30 Minute Water Medium at 37°C
8	ASSAY BY HPLC	1) 98.78 % 2) 104.85 %	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%]

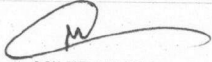
Conclusion : The above sample complies as per IH

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

Checked By

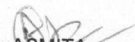
Approved By



MIHIR VARIA
JR. QC OFFICER



MANISHA
EXECUTIVE



ASMITA
QUALITY HEAD

SURBHI 20-05-24 04:29 PM

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