CENTURION LABORATORIES PVT. LTD.

P-2, SAVLI BIO-TECH PARK,AT MANJUSAR,TAL-SAVLI,VADODARA-391775
REG.OFF.: P-2, SAVLI BIO-TECH PARK,AT MANJUSAR,TAL-SAVLI,VADODARA-391775
Phone : 2282061,2281074 Fax : 2280436 C.I.No. : U73100GJ2006PTC049620
Email : ceo@centurionlaboratories.in

QUALITY CONTROL DEPARTMENT

THE DRUG & COSMETIC ACT. 1940 & THE RULES THEREUNDER

FINISHED PRODUCT CERTIFICATE OF ANALYSIS

Product Name	: VIDALISTA 60	**A.R. No.**	: **FAR/240676**
Packing	: 10x10 TAB	**Rel. Dt.**	: 17-06-2024
Generic Name	: TADALAFIL TABLETS USP 60 MG	**T.R. Slip No.**	: CMFT240259
Product Code	: V-82	**T.R. Slip Dt.**	: 09-06-2024
Batch No.	: V-82005	**Analysis Date**	: 09-06-2024
Actual Batch Size	: 1212000TAB	**Specification No.**	: FPS/V-82
Mfg. Dt.	: MAY-2024	**Specification Dt.**	: 24-11-2023
Exp. Dt.	: APR-2027	**STP No.**	: FPS/V-82
Test Packing	: 60 TAB	**Location**	: MANJUSAR
Mfg. Lic No.	: G/25/2025	**Make**	: CLPL
Sample Size	: 60.000TAB		
Released Qty	: 1212000.000TAB (12120 CRTN)	**Test As Per**	: USP

Remarks :

Sr.	Test	Result	Specification
1	Description	A light yellow colored, oval shaped, biconvex, film coated tablets, plain on both side.	A light yellow colored, oval shaped, biconvex, film coated tablets, plain on both side.
2	Identification By HPLC	The retention time of the major peak of the sample solution corresponds to that of the standard solution, as obtained in the assay.	The retention time of the major peak of the sample solution corresponds to that of the standard solution, as obtained in the assay.
1	Identification By IR	The infrared absorption spectrum of the residue is concordant with the reference spectrum of Tadalafil.	The infrared absorption spectrum of the residue is concordant with the reference spectrum of Tadalafil.
3	Weight of 20 Tablets	6.5971 g	6.592 g ± 3.0 %
4	Average weight of 20 tablets	329.86 mg	329.60 mg ± 3.0 %
5	Uniformity Of Weight	Min: -1.47% Max: +1.29%	Within ± 5.0 % of Avg. weight.
6	Thickness	Min: 4.75mm Max: 4.94mm	4.90mm ± 0.2mm
7	Height	Min: 12.51mm Max: 12.66mm	12.6 mm ± 0.1mm
8	Width	Min: 7.01mm Max: 7.14mm	7.10 mm ± 0.1mm
9	Disintegration Time	Min: 5:20 min Max: 5:58 min	NMT 30 min.
10	Dissolution	1) After 10 min: Min: 45.51% Max: 48.41% 2) After 30 min: Min: 96.19% Max: 99.75%	1) NLT 40% (Q) of the labeled amount Of tadalafil is dissolved in 10 min. 2) NLT 80% (Q) of the labeled Amount of tadalafil is dissolved in 30 min.
11	Uniformity of Dosage Units	4.97	1. Acceptance Value (10 Dosage Unit) < L1 % ,where L1=15. 2. Acceptance Value (30 Dosage Unit) < L1 % and No individual content of any dosage unit is less than (1-L2 *0.01) M nor more than (1+ L2 * 0.01) M , where L2= 25.

Conclusion : The above sample complies as per USP

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
17Jun24 PATEL BRIJESH TRAINEE CHEMIST	17Jun24	for 17June24

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Sample Size	: 60.000TAB	**Specification Dt.**	: 24-11-2023
Released Qty	: 1212000.000TAB (12120 CRTN)	**STP No.**	: FPS/V-82
Remarks :		**Location**	: MANJUSAR
		Make	: CLPL

Mfg. Dt. : MAY-2024
Exp. Dt. : APR-2027
Test Packing : 60 TAB
Mfg. Lic No. : G/25/2025
Test As Per : USP

Sr.	Test	Result	Specification
12	Organic impurities	1) Individual impurities: Not Detected 2) Total impurities: Not Detected 3) Reporting level for impurities: Not Detected	1) Individual impurities: NMT 0.2% 2) Total impurities: NMT 0.3% 3) Reporting level for impurities: 0.05%
13	Assay	Tadanafil: 58.94mg 98.23%	Each Film coated tablet contains: Tadanafil USP 60 mg 90.0 % to 110.0% (i.e.54 mg to 66 mg)

Conclusion : The above sample complies as per USP
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
B 17Jun24 PATEL BRIJESH TRAINEE CHEMIST	17Jun24	For 17June24

BRIJESH24 17-06-24 09:25 AM