

QUALITY CONTROL DEPARTMENT
THE DRUG & COSMETIC ACT. 1940 & THE RULES THEREUNDER
FINISHED PRODUCT CERTIFICATE OF ANALYSIS

Product Name : VIDALISTA 20	A.R. No. : F/0777/2223
Packing : 10x10 TAB	Rel. Dt. : 08-07-2022
Generic Name : TADALAFIL TABLETS IP 20 MG (VIDALISTA-20)	T.R. Slip No. : CPT220804
Product Code : TV-62DOMES	T.R. Slip Dt. : 05-07-2022
Batch No. : TV-620094	Analysis Date : 05-07-2022
Actual Batch Size : 600000 TAB	Specification No. : CRFS/TV-62DOMES/2223
Mfg. Dt. : 06/2022	Specification Dt : 11-05-2022
Exp. Dt. : 11/2024	STP No. : STP/TV-62DOMES/AS PER IP
Test Packing : 10X10 TAB	Location : GORWA01
Mfg. Lic No. : G/1325	Make : CENTURION
Sample Size : 50.000 TAB	Test As Per : IP
Released Qty : 600000.000 TAB (6000 CAR)	
Remarks : pass	

Sr.	Test	Result	Specification
1	DESCRIPTION	Yellow colored, Drop shaped, biconvex, film coated tablets, Engraved with "20" on one side and "T" on other side.	Yellow colored, Drop shaped, biconvex, film coated tablets, Engraved with "20" on one side and "T" on other side.
2	IDENTIFICATION 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.	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.
3	AVERAGE WEIGHT OF TABLETS	312.41 mg	312 mg ± 5.0 % of avg. weight
4	UNIFORMITY OF WEIGHT	H.L.: +2.02 % L.L.: - 2.15 %	Within ± 5.00 % of Avg weight
5	THICKNESS	3.80 mm	3.90 mm ± 0.4 mm
6	HEIGHT	12.63 mm	12.60 mm ± 0.2 mm
7	DISINTEGRATION TIME	06 minutes 20 seconds in Water Medium at 37 °C	NMT 30 minutes in Water Medium at 37 °C
8	DISSOLUTION	1) 48.15 % 2) 95.29 %	1) After 10 Minutes (NLT 40.00 % (D)) 2) After 30 Minutes (NLT 80.00 % (D))
9	RELATED SUBSTANCES	Complies	Must comply as per IP
10	ASSAY BY HPLC	99.14%	Each film coated Tablet contains : Tadalafil IP 20 mg [Limit : 90.00 % to 110.00 %]

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 DISHA PATEL QC OFFICER	Checked By SWAPNESH MISTRY HEAD QC	Approved By DIGMA PATEL ASSISTANT MANAGER Q.A.
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