

CENTURION REMEDIES PVT. LTD.

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

Mfg. Dt.

Exp. Dt.

Page 1 of 1

Product Name

: VILITRA 20 TABLETS

Packing

: 10x10 TAB

Generic Name

: VARDENAFIL TABLETS 20MG

Product Code Batch No.

: TV-39

: TV-390020

Actual Batch Size : 300150 TAB (3001 CAR)

Packing Batch Size: 300150 TAB

Sample Size Released Qty

Remarks : PASS

: 50.000 TAB

: 300150,000 TAB (3001 CAR)

Mfg. Lic No. : G/25/1325

Test As Per: IH

Test Packing: 10X10 TAB

: AUG-2020

: JUL-2023

A.R. No.

: F/0851/2021

Rel. Dt.

: 28-08-2020

T.R. Slip No.

: CPT200718

T.R. Slip Dt.

: 27-08-2020

Analysis Date

: 27-08-2020

Specification No.: CRFS/TV-39/1819

Specification Dt. : 20-11-2018

STP No.

STP/TV-39/AS PER II

Location Make

: GORWA01 * CENTURION

		: CENTURION
Test	Result	Specification
DESCRIPTION	A Yellow colored, round shaped, biconvex, film coated tablet, engraved with "20" on one side and plain on other side.	A Yellow colored, round shaped, biconvex, film coated tablet, engraved with " 20 " on one side and plain on other side.
	Complies	Must complies as per IHS.
	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.
	111.2 mg	108.15 mg ± 5.0% of avg. weight
UNIFORMITY OF WEIGHT	Complies. H.L= +2.15% L.L= -2.54%	Within ± 7.5% of the avg.weight
DIAMETER	6.46 mm	6.40 mm ± 0.2mm
THICKNESS	3.25 mm	3.20 mm ± 0.2 mm
DISINTEGRATION TIME	5 Minutes 15 secs in : Water Medium at 37°c	NMT 30 Minutes
ASSAY BY HPLC	99.97 %	Each Film Coated Tablet contains : Vardenafil Hydrochloride Eq.to Vardenafil 20 mg [LIMIT : 90.0% to 110.0%]
	DESCRIPTION IDENTIFICATION 1 BY HPLC AVERAGE WEIGHT OF TABLETS UNIFORMITY OF WEIGHT DIAMETER THICKNESS DISINTEGRATION TIME	DESCRIPTION A Yellow colored, round shaped, biconvex, film coated tablet, engraved with " 20 " on one side and plain on other side. IDENTIFICATION Complies 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. AVERAGE WEIGHT OF TABLETS UNIFORMITY OF WEIGHT Complies. H.L= +2.15% L.L= -2.54% DIAMETER THICKNESS J.25 mm DISINTEGRATION TIME 5 Minutes 15 secs in : Water Medium at 37°c

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"

DARPAN PATEL QC OFFICER

Prepared By

ASMITA Q.C IN CHARGE Approved By

PENDRA QÁ HEAD

DARPAN1 17-09-20 02:33 PM

EGANI CERTO