

## CENTURION REMEDIES PVT. LTD.

: 01/06/2022

: 31/05/2025

G-5, INDUSTRIAL ESTATE, GORWA, VADODARA-390016 REG.OFF.: G-5,INDUSTRIAL ESTATE,GORWA,VADODARA-390016

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

Mfg. Dt.

Exp. Dt.

Mfg. Lic No. : G/25/1325

Test Packing: 10X10 TAB

Test As Per : IP

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**Product Name** 

: CENFORCE 100

Packing

: 10x10 TAB

Generic Name

: SILDENAFIL CITRATE TABLETS IP 100 MG

**Product Code** Batch No.

Sample Size

: TC-126DOME

**Actual Batch Size** 

: TC-1260294 : 400000 TAB

: 50.000 TAB

Released Qty : 400000.000 TAB (4000 CAR)

Remarks: pass

A.R. No. : F/0615-A/22-23

Rel. Dt.

: 16-06-2022

T.R. Slip No.

: CPT220660

T.R. Slip Dt.

: 16-06-2022 : 16-06-2022

**Analysis Date** 

Specification No.: CRFS/TC-

126DOME/2223

Specification Dt.: 06-05-2022

STP No.

: STP/TC-126DOME/AS

PER IP

Location

Make

: GORWA01 : CENTURION

Test	Result	Specification
DESCRIPTION	A light blue colored, diamond shaped, biconvex, film coated tablet, engraved with "100" on both sides.	A light blue colored, diamond shaped, biconvex, film coated tablet, engraved with "100" on both sides.
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.
the same of the sa	530.2mg	530.45 mg ± 5.0 % of avg. weight
UNIFORMITY OF WEIGHT	H.L.: + 1.22 % L.L.: - 1.85 %	Within ± 5.0 % of avg. weight
THICKNESS	4.95 mm	4.90 mm ± 0.4 mm
DISINTEGRATION TIME	07 Minutes 22 Seconds in Water Medium at 37 °C	NMT 30 Minutes in water medium at 37 °C
DISSOLUTION	96.36 %	
RELATED SUBSTANCES	Complies	NLT 70.00 %(D) Must Complies as per IP
9 ASSAY BY HPLC	99.88 %	Each Film Coated Tablet Contains: Sildenafil Citrate IP Eq. to Sildenafil100 mg [Limit: 90.00 % to 110.00 %]
	DESCRIPTION  IDENTIFICATION BY HPLC  AVERAGE WEIGHT OF TABLETS  UNIFORMITY OF WEIGHT  THICKNESS  DISINTEGRATION TIME  DISSOLUTION  RELATED SUBSTANCES	DESCRIPTION  A light blue colored, diamond shaped, biconvex, film coated tablet, engraved with "100" on both sides.  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.  AVERAGE WEIGHT OF TABLETS  530.2mg  UNIFORMITY OF WEIGHT  H.L.: + 1.22 %  L.L.: - 1.85 %  THICKNESS  DISINTEGRATION TIME  07 Minutes 22 Seconds in Water Medium at 37 °C  DISSOLUTION  96.36 %  RELATED SUBSTANCES  ASSAY BY HPLC

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

**QC CHEMIST** 

SWAPNESH MISTRY HEAD QC

Checked By

DIGMĂ PATEL ASSISTANT MANAGER Q.A

Approved By