



# CENTURION REMEDIES PVT. LTD.

G-5/6, H-10 & F-19, INDUSTRIAL ESTATE ,,GORWA,,VADODARA-390016  
REG.OFF.: G-5/6, H-10 & F-19, INDUSTRIAL ESTATE ,,GORWA,,VADODARA-390016  
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## A/C OF FORTUNE HEALTH CARE QUALITY CONTROL DEPARTMENT

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THE DRUG & COSMETIC ACT. 1940 & THE RULES THEREUNDER

### FINISHED PRODUCT CERTIFICATE OF ANALYSIS

<b>Product Name</b> : DURATIA 30 TABLET	<b>A.R. No.</b> : F/2217-A/2223
<b>Packing</b> : 10x10 TAB	<b>Rel. Dt.</b> : 08-02-2023
<b>Generic Name</b> : DAPOXETINE TABLET 30MG	<b>T.R. Slip No.</b> : CFPAP22075
<b>Product Code</b> : TD-69FORTU	<b>T.R. Slip Dt.</b> : 08-02-2023
<b>Batch No.</b> : TD-690007	<b>Analysis Date</b> : 08-02-2023
<b>Actual Batch Size</b> : 30000 TAB	<b>Specification No.</b> : CRFS/TD-69/2021
<b>Mfg. Dt.</b> : JAN-2023	<b>Specification Dt.</b> : 03-11-2020
<b>Exp. Dt.</b> : DEC-2025	<b>STP No.</b> : STP/TD-69/IHS
<b>Test Packing</b> : 10X10 TAB	<b>Location</b> : GORWA01
<b>Mfg. Lic No.</b> : G/25-A/3167-A	<b>Make</b> : FORTUNE
<b>Sample Size</b> : 50.000 TAB	
<b>Released Qty</b> : 30000.000 TAB (300 CAR)	<b>Test As Per</b> : IH
<b>Remarks</b> : pass	

Sr.	Test	Result	Specification
1	DESCRIPTION	A green coloured, round shaped, biconvex, film coated Tablet, plain on both sides	A green coloured, round shaped, biconvex, film coated Tablet, plain on both sides
2	IDENTIFICATION	Complies	Must comply as per IHS.
1	BY HPLC	In the Assay, the principal peak in the chromatogram obtained with the test solution corresponds 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	106.5 mg	108.15 mg $\pm$ 5.0% of avg. weight
4	UNIFORMITY OF WEIGHT	H.L.=+ 2.57 % L.L.=-2.04 %	Within $\pm$ 7.5% of the avg. weight
5	THICKNESS	3.34 mm	3.30 mm $\pm$ 0.2 mm
6	DIAMETER	6.12 mm	6.10 mm $\pm$ 0.2mm
7	DISINTEGRATION TIME	11 Min. 38 Sec. in Water : Medium at 37°C	NMT 30 Min. in Water : Medium at 37°C
8	ASSAY BY HPLC	97.18 %	Each Film Coated Tablet Contains: Dapoxetine hydrochloride Eq. to Dapoxetine 30 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"

<b>Prepared By</b>  YASH SHARMA QC OFFICER	<b>Checked By</b>  ASMITA MANAGER QC	<b>Approved By</b>  CHEXA PATEL QA OFFICER
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