



# SUNRISE REMEDIES PVT LTD

BLOCK NO.2244, OPP. SHAH ALLOYS LTD, AT-SANTEJ,  
 TAL.:KALOL- District : GANDHINAGAR State : GUJARAT -382721  
 Phone(O) :2764 286719 E-Mail:-accounts@sunriseremedies.in

REG.OFF.: 104, SAHJANAND COMPLEX,,NR. THALTEJ CROSS ROAD,,S.G.HIGHWAY,,AHMEDABAD-380059

## QUALITY CONTROL DEPARTMENT

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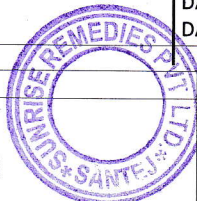
THE DRUG & COSMETIC ACT. 1940 & THE RULES THERE UNDER FORM-39(RULE 150-E(F))

## FINISHED PRODUCT CERTIFICATE OF ANALYSIS

<b>Product Name</b> : POXET-60 TABLET	<b>A.R. No.</b> : FPST230238
<b>Packing</b> : 10x10 TAB	<b>Release Dt.</b> : 09-03-2024
<b>Generic Name</b> : DAPOXETINE TABLETS IP 60MG	<b>T.R. Slip No.</b> : FGTEST2300682
	<b>T.R. Slip Dt.</b> : 09-03-2024
<b>Product Code</b> : POXE05	<b>Specification No.</b> : SPC/FP/POXE05/00
<b>Batch No.</b> : ST-4481	<b>Specification Dt.</b> : 03-10-2023
<b>Actual Batch Size</b> : 2,00,000.00 TAB	<b>STP No.</b> : MOA/FP/POXE05/00
<b>Sample Size</b> : 1.00 Strip	<b>Mfg. Lic. No.</b> : G/25/1428
<b>Released Qty.</b> : 1,99,000.00 TAB	<b>Location</b> : SANTEJ
	<b>Company</b> : SUNRISE
<b>Mfg. Dt.</b> : 02/24	
<b>Exp. Dt.</b> : 01/26	
<b>Test As per</b> : IP	

Sr. No.	Test	Result	Specification
1.00	DESCRIPTION	BLUE COLOURED ROUND SHAPED FILM COATED BICONVEX TABLET WITH BOTH SIDE PLAIN.	BLUE COLOURED ROUND SHAPED FILM COATED BICONVEX TABLET WITH BOTH SIDE PLAIN.
2.00	WEIGHT OF 20 TABLETS	3.7269 GM	3.6800 GM ± 7.5 %
3.00	AVERAGE WEIGHT (TABLET)	186.35 MG	184.0 MG ± 7.5 %
4.00	UNIFORMITY OF WEIGHT	COMPLIES	AVG. WEIGHT OF TAB ± 7.5 % NOT MORE THAN 2 OF INDIVIDUAL TABLET WEIGHTS DEVIATE FROM THE AVERAGE WEIGHT ± 7.5 % AND NONE DEVIATE FROM THE AVERAGE WEIGHT ± 10.0 %
5.00	IDENTIFICATION	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 SHALL CORRESPOND TO THE PEAK IN THE CHROMATOGRAM OBTAINED WITH THE REFERENCE SOLUTION.
6.00	THICKNESS	3.77 MM	3.9 ± 0.3 MM
7.00	DISINTEGRATION TIME	02 MIN 08 SEC	NOT MORE THAN 30 MINUTES
8.00	RELATED SUBSTANCES	NOT DETECTED	OTHER IMPURITY : NOT MORE THAN 1.0 %
		NOT DETECTED	TOTAL IMPURITIES : NOT MORE THAN 2.0 %
9.00	DISSOLUTION	AVG : 92.21 % MIN : 90.28 % MAX : 94.95 %	NOT LESS THAN 70 % (D)
10.00	ASSAY	59.42 MG	EACH FILM COATED TABLET CONTAINS : DAPOXETINE HCL IP EQ. TO DAPOXETINE 60.0 MG

<b>Analysis By</b> CHETAN QC-EXECUTIVE 09/03/24	<b>Checked By</b> MAYUR SR. QC-EXECUTIVE 09/03/24	<b>Approved BY</b> JASMITA QA & QC MANAGER 09/03/24
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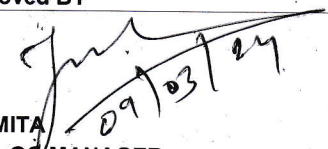
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<b>Test As per</b> : IP	

Sr. No.	Test	Result	Specification
		99.04 %	[ LIMIT : 54.0 MG TO 66.0 MG ] [ BET : 90.0 % TO 110.0 % ]
11.00	UNIFORMITY OF CONTENT	AVG : 99.03 % MIN : 93.91 % MAX : 102.57 %	BY WEIGHT VARIATION : 85.0 % TO 115.0 %

Conclusion : The above sample complies as per IP. "This computer generated certificate of analysis is valid without signature"

<b>Analysis By</b>	<b>Checked By</b>	<b>Approved BY</b>
 CHETAN QC-EXECUTIVE	 MAYUR SR. QC-EXECUTIVE	 JASMITA QA & QC MANAGER

