



# 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 THE DRUG & COSMETIC ACT. 1940 & THE RULES THERE UNDER FORM-39(RULE 150-E(F)) FINISHED PRODUCT CERTIFICATE OF ANALYSIS

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<b>Product Name</b> : POXET-90 TABLET	<b>A.R. No.</b> : FPE230397
<b>Packing</b> : 10x10 TAB	<b>Release Dt.</b> : 14-03-2024
<b>Generic Name</b> : DAPOXETINE TABLETS 90MG	<b>T.R. Slip No.</b> : FGTEST2300699
<b>Product Code</b> : POXE03	<b>T.R. Slip Dt.</b> : 14-03-2024
<b>Batch No.</b> : SE-1060	<b>Specification No.</b> : SPC/FP/POXE03/06
<b>Actual Batch Size</b> : 50,000.00 TAB	<b>Specification Dt.</b> : 11-05-2023
<b>Sample Size</b> : 1.00 Strip	<b>STP No.</b> : MOA/FP/POXE03/06
<b>Released Qty.</b> : 49,700.00 TAB	<b>Mfg. Lic. No.</b> : GUJ/DRUG/25/1428
<b>Mfg. Dt.</b> : 02/24	<b>Location</b> : SANTEJ
<b>Exp. Dt.</b> : 01/26	<b>Company</b> : SUNRISE
<b>Test As per</b> : IHS	

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	3.6871 GM	3.7060 GM $\pm$ 7.5 %
3.00	AVERAGE WEIGHT (TABLET)	184.36 MG	185.3 MG $\pm$ 7.5 %
4.00	UNIFORMITY OF WEIGHT	COMPLIES	AVG. WEIGHT OF TAB $\pm$ 7.5 % NOT MORE THAN 2 OF INDIVIDUAL TABLET WEIGHTS DEVIATE FROM THE AVERAGE WEIGHT $\pm$ 7.5 % AND NONE DEVIATE FROM THE AVERAGE WEIGHT $\pm$ 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	3.67 MM	3.75 $\pm$ 0.2 MM
7.00	DISINTEGRATION TIME	02 MIN 06 SEC	NMT 30 MINUTES
8.00	RELATED SUBSTANCES	NOT DETECTED NOT DETECTED	OTHER IMPURITY : NOT MORE THAN 1.0 % TOTAL IMPURITIES : NOT MORE THAN 2.0 %
9.00	DISSOLUTION	AVG : 87.70 % MIN : 82.02 % MAX : 98.40 %	NOT LESS THAN 70 % (D)
10.00	ASSAY		EACH FILM COATED TABLET CONTAINS : DAPOXETINE HCL EQ. TO DAPOXETINE 90.0 MG

Analysis By

Checked By

Approved BY

CHETAN  
QC-EXECUTIVE

MAYUR  
SR. QC-EXECUTIVE

JASMITA  
QA & QC MANAGER

FgAnlCert04\_REN07



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## QUALITY CONTROL DEPARTMENT

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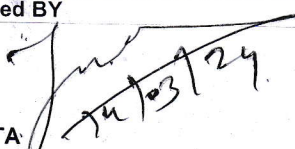
THE DRUG & COSMETIC ACT. 1940 & THE RULES THERE UNDER FORM-39(RULE 150-E(F))

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Sr. No.	Test	Result	Specification
		90.40 MG 100.45 %	[ LIMIT : 81.0 MG TO 99.0 MG ] [ BET : 90.0 % TO 110.0 % ]
11.00	UNIFORMITY OF CONTENT	AVG : 100.44 % MIN : 97.42 % MAX : 103.30 %	BY WEIGHT VARIATION : 85.0 % TO 115.0 %

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

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