

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

Product Name : POXET-60 TABLET	A.R. No. : FPE220026
Packing : 10x10 TAB	Release Dt. : 27-04-2022
Generic Name : DAPOXETINE TABLET 60MG	T.R. Slip No. : FGTEST0064
	T.R. Slip Dt. : 27-04-2022
Product Code : POXE01	Specification No. : SPC/FP/POXE01/05
Batch No. : SE-0415	Specification Dt. : 03-04-2022
Actual Batch Size : 2,00,000.000 TAB	STP No. : MOA/FP/POXE01/05
Sample Size : 60.00 Tab	Mfg. Lic. No. : GUJ/DRUG/25/1428
Released Qty. : 1,99,380.000 TAB	Location : SANTEJ
	Company : SUNRISE
Mfg. Dt. : APR/22	
Exp. Dt. : MAR/24	
Test As per : IHS	

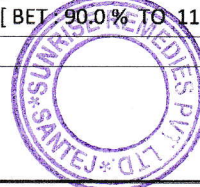
Sr. No.	Test	Result	Specification
1.00	DESCRIPTION	BLUE COLOURED ROUND SHAPED FILM COATED BICONVEX TABLET WITH BOTH SIDE PLAIN.	BLUE COLOURED ROUND SHAPED FILM COATED BICONVEX TABLET WITH BOTH SIDE PLAIN.
2.00	WEIGHT OF 20 TABLETS	3.7220 GM	3.6800 GM $\pm$ 7.5 %
3.00	AVERAGE WEIGHT (TABLET)	186.1 MG	184.0 MG $\pm$ 7.5 %
4.00	UNIFORMITY OF WEIGHT	COMPLIES	AV. 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	3.92 MM	3.9 $\pm$ 0.3 MM
7.00	DISINTEGRATION TIME	04 MIN 45 SEC	NMT 30 MINUTES
8.00	RELATED SUBSTANCES	NOT DETECTED	OTHER IMPURITY : NOT MORE THAN 1.0 % TOTAL IMPURITIES : NOT MORE THAN 2.0 %
9.00	DISSOLUTION	MIN : 95 % MAX : 97 % AVG : 96 %	NOT LESS THAN 70 % (D)
10.00	ASSAY	RESULT LABEL CLAIM 60.12 MG 60.0 MG 100.20 %	EACH FILM COATED TABLET CONTAINS : DAPOXETINE HCL EQ. TO DAPOXETINE 60.0 MG [LIMIT : 54.0 MG TO 66.0 MG] [BET : 90.0 % TO 110.0 %]

Checked By

Approved BY

NIDHI
Q.C.OFFICER

BHUMIKA
QC MANAGER



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

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Sr. No.	Test	Result	Specification

Conclusion : The above sample complies as per IHS

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