

SUNRISE REMEDIES PVT LTD



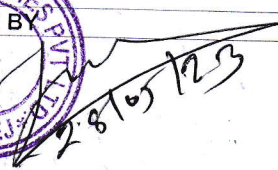
BLOCK NO.2244, OPP. SHAH ALLOYS LTD, AT-SANTEJ,
TAL.:KALOL- District : GANDHINAGAR State : GUJARAT -382721
Phone(O) :2764 286719 E-Mail:-accounts@sunriseremedies.in
REG.OFF.: 104, SAHJANAND COMPLEX,,NR. THALTEJ CROSS ROAD,,S.G.HIGHWAY,,AHMEDABAD-380059

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

Product Name : POXET-30 TABLET	A.R. No. : FPE230044
Packing : 10x10 TAB	Release Dt. : 28-05-2023
Generic Name : DAPOXETINE HCL TABLETS 30MG	T.R. Slip No. : FGTEST2300082
Product Code : POXE02	T.R. Slip Dt. : 28-05-2023
Batch No. : SE-0766	Specification No. : SPC/FP/POXE02/06
Actual Batch Size : 50,000.000 TAB	Specification Dt. : 11-05-2023
Sample Size : 60.00 Strip	STP No. : MOA/FP/POXE02/06
Released Qty. : 49,920.000 TAB	Mfg. Lic. No. : GUJ/DRUG/25/1428
Mfg. Dt. : 05/23	Location : SANTEJ
Exp. Dt. : 04/25	Company : SUNRISE
Test As per : IHS	

Sr. No.	Test	Result	Specification
1.00	DESCRIPTION	BLUE COLORED ROUND SHAPED FILM COATED BICONVEX TABLET WITH BOTH SIDE PLAIN.	BLUE COLORED ROUND SHAPED FILM COATED BICONVEX TABLET WITH BOTH SIDE PLAIN.
2.00	WEIGHT OF 20 TABLETS	3.8034 GM	3.7020 GM ± 7.5 %
3.00	AVERAGE WEIGHT	190.17 MG	185.1 MG ± 7.5 %
4.00	UNIFORMITY OF WEIGHT	COMPLIES	AV. WEIGHT OF TAB ± 7.5% NOT MORE THAN 2 OF INDIVIDUAL TABLETS WEIGHTS SHALL DEVIATE FROM AV. WT. ± 7.5% AND NONE SHALL DEVIATE FROM AV. WT. ± 10%
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 ± 0.2 MM
7.00	DISINTEGRATION TIME	01 MIN 26 SEC	NMT 30 MINUTES
8.00	DISSOLUTION	MIN : 91.21 % MAX : 98.14 % AVG : 94.75 %	NLT 70% (D)
9.00	RELATED SUBSTANCES	NOT DETECTED	OTHER IMPURITY : NOT MORE THAN 1.0 % TOTAL IMPURITIES : NOT MORE THAN 2.0 %
10.00	ASSAY	29.57 MG 98.57 %	EACH FILM COATED TABLET CONTAINS : DAPOXETINE HCL EQ. TO DAPOXETINE 30.0 MG [LIMIT : 27.0 MG TO 33.0 MG] [BET : 90.0 % TO 110.0 %]

Conclusion : The above sample complies as per IHS

Analysis By	Checked By	Approved By
 DHAVAL 28/05/23 Q.C.OFFICER	 MAYUR 28/05/23 QC-EXECUTIVE	 JASMITA 28/05/23 QA & QC MANAGER

