



SUNRISE REMEDIES PVT LTD

BLOCK NO.2244, OPP. SHAH ALLOYS LTD, AT-SANTEJ,

TAL.:KALOL- District : GANDHINAGAR State : GUJARAT -382721

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

Product Name	: DULATA-40 TABLET	A.R. No.	: FPST240121
Packing	: 20x10 TAB	Release Dt.	: 23-08-2024
Generic Name	: DULOXETINE GASTRO RESISTANT TABLETS IP 40MG	T.R. Slip No.	: FGTEST2400341
		T.R. Slip Dt.	: 23-08-2024
Product Code	: DULA06	Specification No.	: SPC/DULA06/01/02
Batch No.	: ST-4620	Specification Dt.	: 12-09-2022
Actual Batch Size	: 1,00,000.00 TAB	STP No.	: SPC/DULA06/01/02
Sample Size	: 1.00 Strip	Mfg. Lic. No.	: G/25/1428
Released Qty.	: 99,000.00 TAB	Location	: SANTEJ
		Company	: SUNRISE

Sr. No.	Test	Result	Specification
1.00	DESCRIPTION	WHITE COLORED ROUND SHAPED BICONVEX ENTERIC COATED GASTRO RESISTANT TABLET WITH BOTH SIDE PLAIN.	WHITE COLORED ROUND SHAPED BICONVEX ENTERIC COATED GASTRO RESISTANT TABLET WITH BOTH SIDE PLAIN.
2.00	WEIGHT OF 20 TABLETS	4.3331 GM	4.4300 GM $\pm$ 7.5 %
3.00	AVERAGE WEIGHT (TABLET)	216.65 MG	221.5 MG $\pm$ 7.5 %
4.00	UNIFORMITY OF WEIGHT	COMPLIES	AVG. WEIGHT OF TAB $\pm$ 7.5 % NOT MORE THAN 2 OF INDIVIDUAL TABLETS WEIGHTS DEVIATE FROM THE AVERAGE WEIGHT $\pm$ 7.5 % AND NONE DEVIATE FROM THE AVERAGE WEIGHT $\pm$ 10.0 %
5.00	DISINTEGRATION TIME	TABLET REMAINS INTACT FOR 2.0 HOURS IN 0.1 M HCL AND 03 MIN 54 SEC IN PHOSPHATE BUFFER pH 6.8.	TABLET SHALL REMAIN INTACT FOR 2.0 HOURS IN 0.1 M HCL AND NOT MORE THAN 60.0 MIN IN PHOSPHATE BUFFER pH 6.8.
6.00	THICKNESS	3.81 MM	3.9 $\pm$ 0.2 MM
7.00	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.
8.00	DISSOLUTION	AVG : 1.80 % MIN : 0.98 % MAX : 4.42 % AVG : 92.93 % MIN : 90.82 % MAX : 97.74 %	IN ACID STAGE : [LIMIT : NMT 10 %] IN BUFFER STAGE : [LIMIT : NLT 70 % (D)]

Analysis By

Checked By

Approved BY

CHETAN
QC-EXECUTIVE

MAYUR
SR. QC-EXECUTIVE

JASMITA
QA & QC MANAGER

