

# 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

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

|                                                                   |                                             |
|-------------------------------------------------------------------|---------------------------------------------|
| <b>Product Name</b> : DULATA-40 TABLET                            | <b>A.R. No.</b> : FPST230201                |
| <b>Packing</b> : 20x10 TAB                                        | <b>Release Dt.</b> : 10-02-2024             |
| <b>Generic Name</b> : DULOXETINE GASTRO RESISTANT TABLETS IP 40MG | <b>T.R. Slip No.</b> : FGTEST2300620        |
|                                                                   | <b>T.R. Slip Dt.</b> : 10-02-2024           |
| <b>Product Code</b> : DULA06                                      | <b>Specification No.</b> : SPC/DULA06/01/02 |
| <b>Batch No.</b> : ST-4431                                        | <b>Specification Dt.</b> : 12-09-2022       |
| <b>Actual Batch Size</b> : 1,00,000.00 TAB                        | <b>STP No.</b> : SPC/DULA06/01/02           |
| <b>Sample Size</b> : 1.00 Strip                                   | <b>Mfg. Lic. No.</b> : G/25/1428            |
| <b>Released Qty.</b> : 99,000.00 TAB                              | <b>Location</b> : SANTEJ                    |
|                                                                   | <b>Company</b> : SUNRISE                    |
| <b>Mfg. Dt.</b> : 01/24                                           |                                             |
| <b>Exp. Dt.</b> : 12/25                                           |                                             |
| <b>Test As per</b> : IP                                           |                                             |

| 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    | 4.34878 GM                                                                                                                                                             | 4.4300 GM $\pm$ 7.5 %                                                                                                                                                             |
| 3.00    | AVERAGE WEIGHT (TABLET) | 217.439 MG                                                                                                                                                             | 221.5 MG $\pm$ 7.5 %                                                                                                                                                              |
| 4.00    | UNIFORMITY OF WEIGHT    | COMPLIES                                                                                                                                                               | AVG. WEIGHT OF TAB $\pm$ 7.5 %<br>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 07 MIN 07 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 : 1.91 %<br>MIN : 0.78 %<br>MAX : 2.91 %<br><br>AVG : 81.79 %<br>MIN : 77.94 %<br>MAX : 85.05 %                                                                    | IN ACID STAGE :<br>[ LIMIT : NMT 10 % ]<br><br>IN BUFFER STAGE :<br>[ LIMIT : NLT 70 % (D) ]                                                                                      |

Analysis By

Checked By

Approved BY

CHETAN  
QC-EXECUTIVE

MAYUR  
SR. QC-EXECUTIVE

JASMITA  
QA & QC MANAGER

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