



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 : TADARISE-20 TABLET | A.R. No. : FPST240078 |
| Packing : 10x10 TAB | Release Dt. : 27-06-2024 |
| Generic Name : TADALAFIL TABLETS IP 20 MG | T.R. Slip No. : FGTEST2400207 |
| Product Code : TADA55 | T.R. Slip Dt. : 27-06-2024 |
| Batch No. : ST-4589 | Specification No. : SPC/FP/TADA55/00 |
| Actual Batch Size : 2,50,000.00 TAB | Specification Dt. : 15-10-2022 |
| Sample Size : 1.00 Strip | STP No. : MOA/FP/TADA55/00 |
| Released Qty. : 2,49,000.00 TAB | Mfg. Lic. No. : GUJ/DRUG/25/1428 |
| Mfg. Dt. : 06/24 | Location : SANTEJ |
| Exp. Dt. : 05/27 | Company : SUNRISE |
| Test As per : IP | |

| Sr. No. | Test | Result | Specification |
|---------|-------------------------|---|--|
| 1.00 | DESCRIPTION | GOLDEN YELLOW COLORED FILM COATED BICONVEX ALMOND SHAPED TABLET WITH BOTH SIDE PLAIN. | GOLDEN YELLOW COLORED FILM COATED BICONVEX ALMOND SHAPED TABLET WITH BOTH SIDE PLAIN. |
| 2.00 | WEIGHT OF 20 TABLETS | 6.8696 GM | 6.8680 GM ± 5 % |
| 3.00 | AVERAGE WEIGHT (TABLET) | 343.48 MG | 343.4 MG ± 5 % |
| 4.00 | UNIFORMITY OF WEIGHT | COMPLIES | AVG. WEIGHT OF TAB ± 5% NOT MORE THAN 2 OF INDIVIDUAL TABLET WEIGHTS DEVIATE FROM THE AVERAGE WEIGHT ± 5.0 % AND NONE DEVIATE FROM THE AVERAGE WEIGHT ± 10.0 % |
| 5.00 | DISINTEGRATION TIME | 06 MIN 16 SEC | NOT MORE THAN 30 MINUTES |
| 6.00 | THICKNESS | 3.93 MM | 4.2 ± 0.3 MM |
| 7.00 | IDENTIFICATION | IN THE ASSAY, THE PRINCIPAL PEAK IN THE CHROMATOGRAM OBTAINED WITH THE TEST SOLUTION CORRESPONDS TO THE PEAK IN T | 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 (A) |
| 8.00 | DISSOLUTION | 10 MIN : AVG : 50.46 % 30 MIN : AVG : 93.15 % | 10 MIN : NMT 40 % (Q) 30 MIN : NMT 80 % (Q) |
| 9.00 | UNIFORMITY OF CONTENT | AVG : 97.94 % MIN : 95.02 % MAX : 100.98 % | BY CONTENT UNIFORMITY : 85.0 % TO 115.0 % |
| 10.00 | RELATED SUBSTANCES | NOT DETECTED | OTHER IMPURITY : NMT 0.2 % |

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| Analysis By JANAK PATIDAR SR.QC-OFFICER | Checked By CHETAN QC-EXECUTIVE | Approved BY MAYUR SR. QC-EXECUTIVE |
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| Sr. No. | Test | Result | Specification |
|---------|-------|---|--|
| 11.00 | ASSAY | NOT DETECTED 19.63 MG 98.15 % | TOTAL IMPURITY : NMT 0.3 % EACH FILM COATED TABLET CONTAINS: TADALAFIL IP 20.0 MG [LIMIT : 18.0 MG TO 22.0 MG] [BET : 90.0 % TO 110.0 %] |

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

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