

# ELIKEM PHARMACEUTICALS PRIVATE LIMITED

PLOT NO : 816/1, RAKANPUR IND. AREA, RAKANPUR

TA : KALOL, DIST : GANDHINAGAR - 382721, GUJARAT, INDIA



ELIKEM

Pharmaceuticals Private Limited

## 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

|                                                                      |                                     |
|----------------------------------------------------------------------|-------------------------------------|
| <b>Product Name</b> : TRYPTICAN 25 TABLETS.                          | <b>A.R. No.</b> : FP-20896          |
| <b>Packing</b> : 10 Tab                                              | <b>Rel. Dt.</b> : 06-02-2024        |
| <b>Generic Name</b> : AMITRIPTYLINE HYDROCHLORIDE TABLETS I.P. 25 MG | <b>T.R. Slip No.</b> : HPTR230046   |
| <b>Product Code</b> : 8TRYP02                                        | <b>T.R. Slip Dt.</b> : 05-02-2024   |
| <b>Batch No.</b> : 17601                                             | <b>Analysis Date</b> :              |
| <b>Actual Batch Size</b> : 2,00,000 Tab                              | <b>Mfg. Lic. No.</b> : G/25A/5729-A |
| <b>Mfg. Dt.</b> : 02-02-2024                                         | <b>Sample Size</b> : 50.000 Tab     |
| <b>Exp. Dt.</b> : 31-01-2027                                         | <b>Released Qty.</b> : 2,00,000 Tab |
| <b>Test As per</b> : IP                                              | <b>Location</b> : RAKANPUR          |
|                                                                      | <b>Company</b> : HEALING            |

| Sr.   | Test                                | Result                                                                                      | Specification                                                                               |
|-------|-------------------------------------|---------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------|
| 1.00  | DESCRIPTION                         | RED COLOUR ROUND FLAT BICONVEX FILM-COATED TABLET, ONE SIDE BREAKLINE AND OTHER SIDE PLAIN. | RED COLOUR ROUND FLAT BICONVEX FILM-COATED TABLET, ONE SIDE BREAKLINE AND OTHER SIDE PLAIN. |
| 2.00  | AVG. WEIGHT OF TABLETS              | 0.1220 GM                                                                                   | +/- 7.5% OF 0.1200 GM                                                                       |
| 3.00  | UNIFORMITY OF WEIGHT                | COMPLIES                                                                                    | +/-7.5% OF AVG. WT                                                                          |
| 4.00  | DISINTEGRATION TIME                 | 10 MINT                                                                                     | NMT 30 MINT                                                                                 |
| 5.00  | THICKNESS                           | 2.10 MM                                                                                     | 2.00 MM TO 3.00 MM                                                                          |
| 6.00  | HARDNESS                            | 3.5 KG/CM2                                                                                  | NLT 3.0 KG/CM2                                                                              |
| 7.00  | IDENTIFICATION                      | A, B -COMPLIES                                                                              | COMPLIES AS PER IP                                                                          |
| 8.00  | RELATED SUBSTANCE                   | TLC- COMPLIES                                                                               | COMPLIES AS PER IP                                                                          |
| 9.00  | DISSOLUTION                         | 81.52% TO 85.69%                                                                            | NLT 75%                                                                                     |
| 10.00 | ASSAY-EACH FILM-COATED TABLET CONTS | 24.932 MG                                                                                   | AMITRIPTYLINE HCL I.P.....25 MG<br>LIMIT:- 90% TO 110%                                      |
|       |                                     |                                                                                             |                                                                                             |

Conclusion : The above sample complies as per IP

Prepared By  
MUNAFHUSAIN  
Q.C. CHEMIST  
06-Feb-2024 11:20

Note : "Report is computer generated,does not required signature"

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