

# 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

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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> : MALEGRA-100 ORAL JELLY (SEVEN FLAVOURS) | <b>A.R. No.</b> : FPE220186                 |
| <b>Packing</b> : 1X7 POUCH                                    | <b>Release Dt.</b> : 10-10-2022             |
| <b>Generic Name</b> : SILDENAFIL ORAL JELLY 100 MG            | <b>T.R. Slip No.</b> : FGTEST0457           |
|                                                               | <b>T.R. Slip Dt.</b> : 07-10-2022           |
| <b>Product Code</b> : MALE28                                  | <b>Specification No.</b> : SPC/FP/MALE28/02 |
| <b>Batch No.</b> : MJ1922                                     | <b>Specification Dt.</b> : 22-08-2021       |
| <b>Actual Batch Size</b> : 50,400.000 POUCH                   | <b>STP No.</b> : MOA/FP/MALE28/02           |
| <b>Sample Size</b> : 20.00 gms                                | <b>Mfg. Lic. No.</b> : GUJ/DRUG/25/1428     |
| <b>Released Qty.</b> : 50,260.000 POUCH                       | <b>Location</b> : SANTEJ                    |
|                                                               | <b>Company</b> : SUNRISE                    |

| Sr. No. | Test        | Result                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | Specification                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
|---------|-------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1.00    | DESCRIPTION | <p>MALEGRA -100 ORAL JELLY ( 7 FLAVOURS )</p> <p>1.0 BANANA FLAVOUR - LIGHT YELLOW COLOUR FLAVOURED JELLY.</p> <p>2.0 BUTTER SCOTCH FLAVOUR-LIGHT BROWN COLOUR FLAVOURED JELLY .</p> <p>3.0 MANGOFLAVOUR- YELLOW COLOUR FLAVOURED JELLY.</p> <p>4.0 ORANGE FLAVOUR- ORANGE COLOUR FLAVORED JELLY .</p> <p>5.0 PINEAPPLE FLAVOUR-YELLOW COLOUR FLAVOURED JELLY.</p> <p>6.0 RASPBERRY FLVOUR- LIGHT PINK COLOUR FLAVORED JELLY.</p> <p>7.0 STRAWBERRY FLAVOUR-PINK COLOUR FLAVOURED JELLY.</p> | <p>MALEGRA -100 ORAL JELLY ( 7 FLAVOURS )</p> <p>1.0 BANANA FLAVOUR - LIGHT YELLOW COLOUR FLAVOURED JELLY.</p> <p>2.0 BUTTER SCOTCH FLAVOUR-LIGHT BROWN COLOUR FLAVOURED JELLY .</p> <p>3.0 MANGOFLAVOUR- YELLOW COLOUR FLAVOURED JELLY.</p> <p>4.0 ORANGE FLAVOUR- ORANGE COLOUR FLAVORED JELLY .</p> <p>5.0 PINEAPPLE FLAVOUR-YELLOW COLOUR FLAVOURED JELLY.</p> <p>6.0 RASPBERRY FLVOUR- LIGHT PINK COLOUR FLAVORED JELLY.</p> <p>7.0 STRAWBERRY FLAVOUR-PINK COLOUR FLAVOURED JELLY.</p> |
| 2.00    | pH          | 1.0 BANANA FLAVOUR - 5.42                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | MALEGRA -100 ORAL JELLY<br>1.0 BANANA FLAVOUR -PH : (BET : 4.50 TO 6.00)                                                                                                                                                                                                                                                                                                                                                                                                                     |

|                                                                                                                             |                                                                                                                                                                                                                                     |
|-----------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Checked By</b>                                                                                                           | <b>Approved BY</b>                                                                                                                                                                                                                  |
| <br><b>HIMANSHU</b><br><b>Q.C.OFFICER</b> | <p>For, </p> <p><b>BHUMIKA</b><br/> <b>QC MANAGER</b></p>  |

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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> : MALEGRA-100 ORAL JELLY (SEVEN FLAVOURS) | <b>A.R. No.</b> : FPE220186                 |
| <b>Packing</b> : 1X7 POUCH                                    | <b>Release Dt.</b> : 10-10-2022             |
| <b>Generic Name</b> : SILDENAFIL ORAL JELLY 100 MG            | <b>T.R. Slip No.</b> : FGTEST0457           |
|                                                               | <b>T.R. Slip Dt.</b> : 07-10-2022           |
| <b>Product Code</b> : MALE28                                  | <b>Specification No.</b> : SPC/FP/MALE28/02 |
| <b>Batch No.</b> : MJ1922                                     | <b>Specification Dt.</b> : 22-08-2021       |
| <b>Actual Batch Size</b> : 50,400.000 POUCH                   | <b>STP No.</b> : MOA/FP/MALE28/02           |
| <b>Sample Size</b> : 20.00 gms                                | <b>Mfg. Lic. No.</b> : GUJ/DRUG/25/1428     |
| <b>Released Qty.</b> : 50,260.000 POUCH                       | <b>Location</b> : SANTEJ                    |
|                                                               | <b>Company</b> : SUNRISE                    |
| <b>Mfg. Dt.</b> : SEP/22                                      |                                             |
| <b>Exp. Dt.</b> : AUG/25                                      |                                             |
| <b>Test As per</b> : USP                                      |                                             |

| Sr. No. | Test             | Result                                | Specification                                           |
|---------|------------------|---------------------------------------|---------------------------------------------------------|
|         |                  | 2.0 BUTTER SCOTCH FLAVOUR - 5.50      | 2.0 : BUTTER SCOTCH FLAVOUR - PH : (BET : 4.50 TO 6.00) |
|         |                  | 3.0 MANGO FLAVOUR - 5.52              | 3.0: MANGO FLAVOUR - PH : (BET : 4.50 TO 6.00)          |
|         |                  | 4.0 ORANGE FLAVOUR - 5.31             | 4.0 : ORANGE FLAVOUR :PH : (BET : 4.50 TO 6.00)         |
|         |                  | 5.0 PINEAPPLE FLAVOUR - 5.73          | 5.0 : PINEAPPLE FLAVOUR - PH : (BET : 4.50 TO 6.00)     |
|         |                  | 6.0 RASPBERRY FLAVOUR - 5.73          | 6.0: RASPBERRY FLAVOUR - PH : (BET : 4.50 TO 6.00)      |
|         |                  | 7.0 STRAWBERRY FLAVOUR - 5.70         | 7.0:STRAWBERRY FLAVOUR - PH : (BET : 4.50 TO 6.00)      |
| 3.00    | WEIGHT VARIATION | 1.0 BANANA FLAVOUR : 5.0025 GM        | NOT LESS THAN 5.0 GMS                                   |
|         |                  | 2.0 BUTTER SCOTCH FLAVOUR : 5.0018 GM | 1.0 BANANA FLAVOUR                                      |
|         |                  | 3.0 MANGO FLAVOUR : 5.0014 GM         | 2.0 BUTTER SCOTCH FLAVOUR                               |
|         |                  | 4.0 ORANGE FLAVOUR : 5.0024 GM        | 3.0 MANGO FLAVOUR                                       |
|         |                  | 5.0 PINEAPPLE FLAVOUR : 5.0023 GM     | 4.0 ORANGE FLAVOUR                                      |
|         |                  | 6.0 RASPBERRY FLAVOUR : 5.0018 GM     | 5.0 PINEAPPLE FLAVOUR                                   |
|         |                  | 7.0 STRAWBERRY FLAVOUR : 5.0012 GM    | 6.0 RASPBERRY FLAVOUR                                   |
|         |                  |                                       | 7.0 STRAWBERRY FLAVOUR                                  |

|                                                                                                               |                                                                                                                   |
|---------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------|
| <b>Checked By</b>                                                                                             | <b>Approved BY</b>                                                                                                |
| <br>HIMANSHU<br>Q.C.OFFICER | F08, <br>BHUMIKA<br>QC MANAGER |



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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

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|                                                               |                                             |
|---------------------------------------------------------------|---------------------------------------------|
| <b>Product Name</b> : MALEGRA-100 ORAL JELLY (SEVEN FLAVOURS) | <b>A.R. No.</b> : FPE220186                 |
| <b>Packing</b> : 1X7 POUCH                                    | <b>Release Dt.</b> : 10-10-2022             |
| <b>Generic Name</b> : SILDENAFIL ORAL JELLY 100 MG            | <b>T.R. Slip No.</b> : FGTEST0457           |
|                                                               | <b>T.R. Slip Dt.</b> : 07-10-2022           |
| <b>Product Code</b> : MALE28                                  | <b>Specification No.</b> : SPC/FP/MALE28/02 |
| <b>Batch No.</b> : MJ1922                                     | <b>Specification Dt.</b> : 22-08-2021       |
| <b>Actual Batch Size</b> : 50,400.000 POUCH                   | <b>STP No.</b> : MOA/FP/MALE28/02           |
| <b>Sample Size</b> : 20.00 gms                                | <b>Mfg. Lic. No.</b> : GUJ/DRUG/25/1428     |
| <b>Released Qty.</b> : 50,260.000 POUCH                       | <b>Location</b> : SANTEJ                    |
|                                                               | <b>Company</b> : SUNRISE                    |

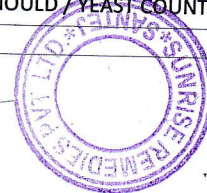
| Sr. No. | Test                    | Result                                          |                                                                                                      | Specification                                                                                                                              |
|---------|-------------------------|-------------------------------------------------|------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------|
| 4.00    | ASSAY                   | RESULT                                          | LABEL CLAIM                                                                                          | EACH 5 GM CONTAINS :<br>SILDENAFIL CITRATE EQ. TO<br>SILDENAFIL 100.0 MG<br>[ LIMIT : 90.0 MG TO 110.0 MG ]<br>[ BET : 90.0 % TO 110.0 % ] |
|         |                         | 1. 99.3 MG<br>99.3 %                            | 100.0 MG                                                                                             | 1.0 : BANANA FLAVOUR                                                                                                                       |
|         |                         | 2. 99.1 MG<br>99.1 %                            | 100.0 MG                                                                                             | 2.0 : BUTTER SCOTCH FLAVOUR                                                                                                                |
|         |                         | 3. 99.4 MG<br>99.4 %                            | 100.0 MG                                                                                             | 3.0 : MANGO FLAVOUR                                                                                                                        |
|         |                         | 4. 99.5 MG<br>99.5 %                            | 100.0 MG                                                                                             | 4.0 : ORANGE FLAVOUR                                                                                                                       |
|         |                         | 5. 100.4 MG<br>100.4 %                          | 100.0 MG                                                                                             | 5.0 : PINEAPPLE FLAVOUR                                                                                                                    |
|         |                         | 6. 100.1 MG<br>100.1 %                          | 100.0 MG                                                                                             | 6.0 : RASBERRY FLAVOUR                                                                                                                     |
|         |                         | 7. 100.0 MG<br>100.0 %                          | 100.0 MG                                                                                             | 7.0 : STRAWBERRY FLAVOUR                                                                                                                   |
| 5.00    | MICROBIAL CONTAMINATION | 1. BANANA FLAVOUR<br><br>10 CFU/G<br>< 10 CFU/G | 1.0 : BANANA FLAVOUR<br><br>TOTAL BACTERIAL COUNT : 10^2 CFU/GM<br>MOULD / YEAST COUNT : 10^1 CFU/GM |                                                                                                                                            |

Checked By

Approved BY

HIMANSHU  
Q.C.OFFICER

BHUMIKA  
QC MANAGER



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| <b>Product Name</b> : MALEGRA-100 ORAL JELLY (SEVEN FLAVOURS) | <b>A.R. No.</b> : FPE220186                 |
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|                                                               | <b>T.R. Slip Dt.</b> : 07-10-2022           |
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| <b>Batch No.</b> : MJ1922                                     | <b>Specification Dt.</b> : 22-08-2021       |
| <b>Actual Batch Size</b> : 50,400.000 POUCH                   | <b>STP No.</b> : MOA/FP/MALE28/02           |
| <b>Sample Size</b> : 20.00 gms                                | <b>Mfg. Lic. No.</b> : GUJ/DRUG/25/1428     |
| <b>Released Qty.</b> : 50,260.000 POUCH                       | <b>Location</b> : SANTEJ                    |
|                                                               | <b>Company</b> : SUNRISE                    |

| Sr. No. | Test | Result                                                                                                                                                                                                                                                                                                 | Specification                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
|---------|------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|         |      | ABSENT<br>ABSENT<br>ABSENT<br>ABSENT<br>ABSENT<br><br>2. BUTTERSCOTCH FLAVOUR<br><br>70 CFU/G<br>< 10 CFU/G<br><br>ABSENT<br>ABSENT<br>ABSENT<br>ABSENT<br>ABSENT<br><br>3. MANGO FLAVOUR<br><br>10 CFU/G<br>< 10 CFU/G<br><br>ABSENT<br>ABSENT<br>ABSENT<br>ABSENT<br>ABSENT<br><br>4. ORANGE FLAVOUR | PATHOGENS SHOULD BE ABSENT<br>1) E-COLI<br>2) SALMONELLA<br>3) P. AURIGINOSA<br>4) S.AUREUS<br><br>2.0 : BUTTER SCOTCH FLAVOUR<br><br>TOTAL BACTERIAL COUNT : 10 <sup>2</sup> CFU/GM<br>MOULD / YEAST COUNT : 10 <sup>1</sup> CFU/GM<br><br>PATHOGENS SHOULD BE ABSENT<br>1) E-COLI<br>2) SALMONELLA<br>3) P. AURIGINOSA<br>4) S.AUREUS<br><br>3.0 : MANGO FLAVOUR<br><br>TOTAL BACTERIAL COUNT : 10 <sup>2</sup> CFU/GM<br>MOULD / YEAST COUNT : 10 <sup>1</sup> CFU/GM<br><br>PATHOGENS SHOULD BE ABSENT<br>1) E-COLI<br>2) SALMONELLA<br>3) P. AURIGINOSA<br>4) S.AUREUS<br><br>4.0 : ORANGE FLAVOUR |

|                                                                                                                              |                                                                                                                             |
|------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------|
| <b>Checked By</b>                                                                                                            | <b>Approved BY</b>                                                                                                          |
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**FINISHED PRODUCT CERTIFICATE OF ANALYSIS**

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|                                                               | <b>T.R. Slip Dt.</b> : 07-10-2022           |
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| <b>Released Qty.</b> : 50,260.000 POUCH                       | <b>Location</b> : SANTEJ                    |
|                                                               | <b>Company</b> : SUNRISE                    |

| Sr. No. | Test                 | Result                                         | Specification                                                                                  |
|---------|----------------------|------------------------------------------------|------------------------------------------------------------------------------------------------|
|         |                      | 35 CFU/G<br>< 10 CFU/G                         | TOTAL BACTERIAL COUNT : 10 <sup>2</sup> CFU/GM<br>MOULD / YEAST COUNT : 10 <sup>1</sup> CFU/GM |
|         |                      | ABSENT<br>ABSENT<br>ABSENT<br>ABSENT<br>ABSENT | PATHOGENS SHOULD BE ABSENT<br>1) E-COLI<br>2) SALMONELLA<br>3) P. AURIGINOSA<br>4) S.AUREUS    |
|         | 5. PINEAPPLE FLAVOUR |                                                | 5.0 : PINEAPPLE FLAVOUR                                                                        |
|         |                      | 40 CFU/G<br>< 10 CFU/G                         | TOTAL BACTERIAL COUNT : 10 <sup>2</sup> CFU/GM<br>MOULD / YEAST COUNT : 10 <sup>1</sup> CFU/GM |
|         |                      | ABSENT<br>ABSENT<br>ABSENT<br>ABSENT<br>ABSENT | PATHOGENS SHOULD BE ABSENT<br>1) E-COLI<br>2) SALMONELLA<br>3) P. AURIGINOSA<br>4) S.AUREUS    |
|         | 6. RASPBERRY FLAVOUR |                                                | 6.0 : RASPBERRY FLAVOUR :                                                                      |
|         |                      | 50 CFU/G<br>< 10 CFU/G                         | TOTAL BACTERIAL COUNT : 10 <sup>2</sup> CFU/GM<br>MOULD / YEAST COUNT : 10 <sup>1</sup> CFU/GM |
|         |                      | ABSENT<br>ABSENT<br>ABSENT<br>ABSENT<br>ABSENT | PATHOGENS SHOULD BE ABSENT<br>1) E-COLI<br>2) SALMONELLA<br>3) P. AURIGINOSA<br>4) S.AUREUS    |

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**FINISHED PRODUCT CERTIFICATE OF ANALYSIS**

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|----------------------------|-----------------------------------------|----------------------------|------------------|
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|                            |                                         | <b>T.R. Slip Dt.</b> :     | 07-10-2022       |
| <b>Product Code</b> :      | MALE28                                  | <b>Specification No.</b> : | SPC/FP/MALE28/02 |
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| <b>Actual Batch Size</b> : | 50,400.000 POUCH                        | <b>STP No.</b> :           | MOA/FP/MALE28/02 |
| <b>Sample Size</b> :       | 20.00 gms                               | <b>Mfg. Lic. No.</b> :     | GUI/DRUG/25/1428 |
| <b>Released Qty.</b> :     | 50,260.000 POUCH                        | <b>Location</b> :          | SANTEJ           |
|                            |                                         | <b>Company</b> :           | SUNRISE          |

| Sr. No. | Test | Result                                                                                                    | Specification                                                                                                                                                                                                   |
|---------|------|-----------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|         |      | 7. STRAWBERRY FLAVOUR<br><br>40 CFU/G<br>< 10 CFU/G<br><br>ABSENT<br>ABSENT<br>ABSENT<br>ABSENT<br>ABSENT | 7.0 : STRAWBERRY FLAVOUR<br><br>TOTAL BACTERIAL COUNT : $10^2$ CFU/GM<br>MOULD / YEAST COUNT : $10^1$ CFU/GM<br><br>PATHOGENS SHOULD BE ABSENT<br>1) E-COLI<br>2) SALMONELLA<br>3) P. AURIGINOSA<br>4) S.AUREUS |
|         |      |                                                                                                           |                                                                                                                                                                                                                 |

Conclusion : The above sample complies as per USP

Checked By

HIMANSHU  
Q.C.OFFICER

Approved BY

BHUMIKA  
QC MANAGER

