**Satiate**
**Research & Anatech Pvt. Ltd.**
NABL ACCREDITED GOVT. APPROVED TESTING LABORATORY
Plot No. 264, 1st & 2nd Floor, HSIIDC, Barwala-134118, Panchkula (Haryana)
E-mail: satiateresearch@gmail.com, Website : www.sralabs.com

# TEST REPORT

FDA Lic. No. : 25-LAB-HR

**Form-39A, 150-E (f) Report of test or Analysis by Approved Institution For Procurement Agency**

| | | | |
|---|---|---|---|
| Name of sample | : Cefixime Tablet IP 200 mg | AR No. | : SA/GO-181225/004 |
| Batch No. | : 0131 | Batch Size | : NM |
| D/M | : 08/2025 | D/E | : 07/2027 |
| Original Manufacturer | : NM | Name of supplier | : NM |
| Mfg. Lic. No | : NM | | |
| Sample Submitted By | : Medical Superintedent ESIC | Ref. No.(As in test request slip) | : NM |
| Address | : ESIC Pooluvapatti to Thirumurugan Poondi Ring Road Tiruppur - 641 603 Tiruppur - 641 | Ref. No.( As given by party) | : NM |
| | | Sample Quantity | : 70 Tablets |
| Date of receipt | : 17/11/2025 | Sample received on | : 18/12/2025 |
| Date of start of analysis | : 20/12/2025 | Date of completion of analysis | : 24/12/2025 |
| Protocol of test applied | : IP 2022 | Date of Issue of the report | : 25/12/2025 |

| TEST PARAMETERS | OBTAINED | | | LIMITS |
|---|---|---|---|---|
| Description | : White ciruclar shaped biconvex film coated tablet plain surface on both sides. | | | |
| Average weight | : 293.65 mg | | | |
| Uniformity of weight | : Min | Max | | Limit |
| | -1.51 % | +2.67 % | | ±5.0 % of average weight |
| Identification Test (By HPLC) | : Complies | | | To comply |
| Water | : 5.12 % | | | NMT 10.0 % |
| Dissolution Test (By UV) | : Min | Max | Avg | Limit |
| In Phosphate buffer pH 7.2 | : 90.25 % | 95.29 % | 93.27 % | Q. NLT 75.00 % |
| Leak test | : Complies | | | To comply |
| Hardness | : 3.5 kg/cm2 | | | |

| CONTENTS | OBTAINED | CLAIM | LIMITS | METHOD |
|---|---|---|---|---|
| Assay (By HPLC) :- | - | - | - | - |
| Composition | | | | |
| Each film coated tablet contains:- | | | | |
| Cefixime IP | | | | |
| (As trihydrate) | | | | |
| Eq. to anhydrous Cefixime | 199.47 mg | 200.00 mg | (180.00 - 220.00) mg | IP 2022 |

In the opinion of the undersigned, the sample referred to above is of Standard Quality as defined in the Drugs and Cosmetics Act and the Rules made under for the reasons given below in respect to Test(s) mentioned above.

***End of Report***

Satiate Research & Anatech Pvt. Ltd. Verified by QA Panchkula

Date : 25/12/2025

Person In-charge of Testing
Dr Surender Panghal (M.Pharma, Ph.D.)
(Quality Manager)

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# TEST REPORT

FDA Lic. No. : 25-LAB-HR

**Form-39A, 150-E (f) Report of test or Analysis by Approved Institution For Procurement Agency**

| | | | |
|---|---|---|---|
| Name of sample | : Telmisartan Tablet IP 40 mg | AR No. | : SA/GO-181225/005 |
| Batch No. | : 2508172 | Batch Size | : NM |
| D/M | : 08/2025 | D/E | : 07/2027 |
| Original Manufacturer | : NM | Name of supplier | : NM |
| Mfg. Lic. No | : NM | Ref. No.(As in test request slip) | : NM |
| Sample Submitted By | : Medical Superintedent ESIC | Ref. No.( As given by party) | : NM |
| Address | : ESIC Pooluvapatti to Thirumurugan Poondi Ring Road Tiruppur - 641 603 Tiruppur - 641 | Sample Quantity | : 70 Tablets |
| Date of receipt | : 17/11/2025 | Sample received on | : 18/12/2025 |
| Date of start of analysis | : 18/12/2025 | Date of completion of analysis | : 24/12/2025 |
| Protocol of test applied | : IP 2022 & IP Addendum 2024/Amendment List-07 | Date of Issue of the report | : 25/12/2025 |

| TEST PARAMETERS | OBTAINED | | | LIMITS |
|---|---|---|---|---|
| Description | : White circular shaped biconvex uncoated tablet plain surface on both sides. | | | |
| Average weight | : 222.58 mg | | | |
| Uniformity of weight | : Min<br>-1.15 % | Max<br>+2.18 % | | Limit<br>±7.5 % of average weight |
| Identification Test (By HPLC) | : Complies | | | To comply |
| Hardness | : 3.0 kg/cm2 | | | |
| Leak test | : Complies | | | To comply |
| Friability | : 0.12 % | | | NMT 1.0 % |
| Related substances (By HPLC) | : | | | |
| Any secondary impurity | : Not detected | | | NMT 0.2 % |
| Dissolution Test (By UV) | : Min | Max | Avg | Limit |
| In phosphate buffer (pH 7.5) | : 90.65 % | 95.72 % | 93.82 % | Q. NLT 75.00 % |
| Uniformity of content | : 95.18 % | 100.32 % | 98.82 % | |
| Acceptance value | : 3.8 | | | NMT 15.0 |

| CONTENTS | OBTAINED | CLAIM | LIMITS | METHOD |
|---|---|---|---|---|
| Assay | - | - | - | - |
| Composition | | | | |
| Each uncoated tablet contains:- | | | | |
| Telmisartan IP | 39.53 mg | 40.00 mg | (36.00 - 44.00) mg | IP 2022 & IP Addendum 2024/Amendment List-07 |

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# TEST REPORT

FDA Lic. No. : 25-LAB-HR

**Form-39A, 150-E (f) Report of test or Analysis by Approved Institution For Procurement Agency**

| | | | |
|---|---|---|---|
| Name of sample | : Telmisartan Tablet IP 40 mg | AR No. | : SA/GO-181225/005 |
| Batch No. | : 2508172 | Batch Size | : NM |
| D/M | : 08/2025 | D/E | : 07/2027 |
| Original Manufacturer | : NM | Name of supplier | : NM |
| Mfg. Lic. No | : NM | Ref. No.(As in test request slip) | : NM |
| Sample Submitted By | : Medical Superintedent ESIC | Ref. No.( As given by party) | : NM |
| Address | : ESIC Pooluvapatti to Thirumurugan Poondi Ring Road Tiruppur - 641 603 Tiruppur - 641 | Sample Quantity | : 70 Tablets |
| Date of receipt | : 17/11/2025 | Sample received on | : 18/12/2025 |
| Date of start of analysis | : 18/12/2025 | Date of completion of analysis | : 24/12/2025 |
| Protocol of test applied | : IP 2022 & IP Addendum 2024/Amendment List-07 | Date of Issue of the report | : 25/12/2025 |

In the opinion of the undersigned, the sample referred to above is of Standard Quality as defined in the Drugs and Cosmetics Act and the Rules made under for the reasons given below in respect to Test(s) mentioned above.

***End of Report***

Satiate Research & Anatech Pvt. Ltd. Verified by QA Panchkula

Date : 25/12/2025

Person In-charge of Testing
Dr Surender Panghal (M.Pharma, Ph.D.)
(Quality Manager)

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# TEST REPORT

FDA Lic. No. : 25-LAB-HR

**Form-39A, 150-E (f) Report of test or Analysis by Approved Institution For Procurement Agency**

| | | | |
|---|---|---|---|
| Name of sample | : Prednisolone Tablets IP 10mg | AR No. | : SA/GO-181225/006 |
| Batch No. | : ACT10-239 | Batch Size | : NM |
| D/M | : 09/2025 | D/E | : 08/2027 |
| Original Manufacturer | : NM | Name of supplier | : NM |
| Mfg. Lic. No | : NM | Ref. No.(As in test request slip) | : NM |
| Sample Submitted By | : Medical Superintedent ESIC | Ref. No.( As given by party) | : NM |
| Address | : ESIC Pooluvapatti to Thirumurugan Poondi Ring Road Tiruppur - 641 603 Tiruppur - 641 | Sample Quantity | : 70 Tablets |
| Date of receipt | : 17/11/2025 | Sample received on | : 18/12/2025 |
| Date of start of analysis | : 18/12/2025 | Date of completion of analysis | : 24/12/2025 |
| Protocol of test applied | : IP 2022 & IP Addendum 2024 | Date of Issue of the report | : 25/12/2025 |

| TEST PARAMETERS | OBTAINED | | | LIMITS |
|---|---|---|---|---|
| Description | : White circular shaped biconvex uncoated tablets plain on both sides. | | | |
| Average weight | : 101.67 mg | | | |
| Uniformity of weight | : Min | Max | | Limit |
| | -1.25 % | +2.51 % | | ±7.5 % of average weight |
| Identification Test | : | | | |
| A - By IR | : Complies | | | To comply |
| B - By HPLC | : Complies | | | To comply |
| Uniformity of content | : Min | Max | Avg | |
| | 96.56 % | 101.42 % | 99.48 % | |
| Acceptanc value | : 3.8 | | | NMT 15.0 |
| Dissolution test (By UV) | : Min | Max | Avg | Limit |
| In water | : 90.48 % | 95.56 % | 93.42 % | Q.NLT 70.00 % |
| Related substances (By HPLC) | : | | | |
| Any secondary impurity | : 0.12 % | | | NMT 1.00 % |
| Sum of all the impurities | : 0.12 % | | | NMT 3.00 % |
| Leak test | : Complies | | | To comply |
| Hardness | : 2.5 kg/cm2 | | | |
| Friability | : 0.11 % | | | NMT 1.0 % |

| CONTENTS | OBTAINED | CLAIM | LIMITS | METHOD |
|---|---|---|---|---|
| Assay (By HPLC) :- | | | | |
| Composition | | | | |
| Each uncoated tablet contains :- | | | | |
| Prednisolone IP | 9.95 mg | 10.00 mg | (9.00 - 11.00) mg | IP 2022 |

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# TEST REPORT

FDA Lic. No. : 25-LAB-HR

**Form-39A, 150-E (f) Report of test or Analysis by Approved Institution For Procurement Agency**

| | | | |
|---|---|---|---|
| Name of sample | : Prednisolone Tablets IP 10mg | AR No. | : SA/GO-181225/006 |
| Batch No. | : ACT10-239 | Batch Size | : NM |
| D/M | : 09/2025 | D/E | : 08/2027 |
| Original Manufacturer | : NM | Name of supplier | : NM |
| Mfg. Lic. No | : NM | Ref. No.(As in test request slip) | : NM |
| Sample Submitted By | : Medical Superintedent ESIC | Ref. No.( As given by party) | : NM |
| Address | : ESIC Pooluvapatti to Thirumurugan Poondi Ring Road Tiruppur - 641 603 Tiruppur - 641 | Sample Quantity | : 70 Tablets |
| Date of receipt | : 17/11/2025 | Sample received on | : 18/12/2025 |
| Date of start of analysis | : 18/12/2025 | Date of completion of analysis | : 24/12/2025 |
| Protocol of test applied | : IP 2022 & IP Addendum 2024 | Date of Issue of the report | : 25/12/2025 |

In the opinion of the undersigned, the sample referred to above is of Standard Quality as defined in the Drugs and Cosmetics Act and the Rules made under for the reasons given below in respect to Test(s) mentioned above.

***End of Report***

Satiate Research & Anatech Pvt. Ltd. * Panchkula * Verified by QA

Date : 25/12/2025

Person In-charge of Testing
Dr Surender Panghal (M.Pharma, Ph.D.)
(Quality Manager)

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# TEST REPORT

FDA Lic. No. : 25-LAB-HR

**Form-39A, 150-E (f) Report of test or Analysis by Approved Institution For Procurement Agency**

| | | | |
|---|---|---|---|
| Name of sample | : Carboxymethyl Cellulose Sodium Eye Drops IP 0.5% w/v | AR No. | : SA/GO-181225/007 |
| Batch No. | : 1225056 | Batch Size | : NM |
| D/M | : 09/2025 | D/E | : 08/2027 |
| Original Manufacturer | : NM | Name of supplier | : NM |
| Mfg. Lic. No | : NM | Ref. No.(As in test request slip) | : NM |
| Sample Submitted By | : Medical Superintedent ESIC | Ref. No.( As given by party) | : NM |
| Address | : ESIC Pooluvapatti to Thirumurugan Poondi Ring Road Tiruppur - 641 603 Tiruppur - 641 | Sample Quantity | : 15 Nos. |
| Date of receipt | : 17/11/2025 | Sample received on | : 18/12/2025 |
| Date of start of analysis | : 18/12/2025 | Date of completion of analysis | : 01/01/2026 |
| Protocol of test applied | : IP Addendum 2024 & Amendment list 07 | Date of Issue of the report | : 01/01/2026 |

| TEST PARAMETERS | OBTAINED | LIMITS |
|---|---|---|
| Description | : Clear colourless liquid filled in green coloured plastic vial. | |
| Identification Test | : | |
| A- By Chemically | : Complies | To comply |
| B- By UV | : Complies | To comply |
| Appearance of solution | : | |
| i) Clarity of solution | : Complies | To comply |
| II) Colour of solution | : Complies | To comply |
| pH | : 7.452 | (6.00 - 8.00) |
| Nominal volume | : 10.0 ml | |
| Uniformity of filled volume | : Min 10.2 ml Max 10.6 ml | Limit NLT 9.0 ml |
| Osmolality | : 295.5 mOsmol/L | (270.00 - 350.00) mOsmol/Kg |
| Sterility | : Complies | To comply |
| Leak Test | : Complies | To comply |

| CONTENTS | OBTAINED | CLAIM | LIMITS | METHOD |
|---|---|---|---|---|
| Assay :- (By UV) | | | | |
| Composition | | | | |
| Carboxymethyl cellulose sodium IP | 0.499 % w/v | 0.50 % w/v | (0.475 - 0.575) % w/v | IP Addendum 2024/Amendment List-07 |

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# TEST REPORT

FDA Lic. No. : 25-LAB-HR

**Form-39A, 150-E (f) Report of test or Analysis by Approved Institution For Procurement Agency**

| | | | |
|---|---|---|---|
| Name of sample | : Carboxymethyl Cellulose Sodium Eye Drops IP 0.5% w/v | AR No. | : SA/GO-181225/007 |
| Batch No. | : 1225056 | Batch Size | : NM |
| D/M | : 09/2025 | D/E | : 08/2027 |
| Original Manufacturer | : NM | Name of supplier | : NM |
| Mfg. Lic. No | : NM | Ref. No.(As in test request slip) | : NM |
| Sample Submitted By | : Medical Superintedent ESIC | Ref. No.( As given by party) | : NM |
| Address | : ESIC Pooluvapatti to Thirumurugan Poondi Ring Road Tiruppur - 641 603 Tiruppur - 641 | Sample Quantity | : 15 Nos. |
| Date of receipt | : 17/11/2025 | Sample received on | : 18/12/2025 |
| Date of start of analysis | : 18/12/2025 | Date of completion of analysis | : 01/01/2026 |
| Protocol of test applied | : IP Addendum 2024 & Amendment list 07 | Date of Issue of the report | : 01/01/2026 |

In the opinion of the undersigned, the sample referred to above is of Standard Quality as defined in the Drugs and Cosmetics Act and the Rules made under for the reasons given below in respect to Test(s) mentioned above.

***End of Report***

Satiate Research & Anatech Pvt. Ltd. Verified by QA Panchkula

Date : 01/01/2026

Person In-charge of Testing
Dr Surender Panghal (M.Pharma, Ph.D.)
(Quality Manager)

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# TEST REPORT

FDA Lic. No. : 25-LAB-HR

**Form-39A, 150-E (f) Report of test or Analysis by Approved Institution For Procurement Agency**

| | | | |
|---|---|---|---|
| Name of sample | : Spironolactone Tablets IP 25 mg | AR No. | : SA/GO-181225/008 |
| | | Batch Size | : NM |
| Batch No. | : T250920 | D/E | : 08/2027 |
| D/M | : 09/2025 | Name of supplier | : NM |
| Original Manufacturer | : NM | | |
| Mfg. Lic. No | : NM | Ref. No.(As in test request slip) | : NM |
| Sample Submitted By | : Medical Superintedent ESIC | Ref. No.( As given by party) | : NM |
| Address | : ESIC Pooluvapatti to Thirumurugan Poondi Ring Road Tiruppur - 641 603 Tiruppur - 641 | Sample Quantity | : 70 Tablets |
| Date of receipt | : 17/11/2025 | Sample received on | : 18/12/2025 |
| Date of start of analysis | : 18/12/2025 | Date of completion of analysis | : 24/12/2025 |
| Protocol of test applied | : IP 2022 | Date of Issue of the report | : 25/12/2025 |

| TEST PARAMETERS | OBTAINED | | | LIMITS |
|---|---|---|---|---|
| Description | : White circular shaped flat uncoated tablet having scored line on one side and plain on other side. | | | |
| Average weight | : 180.12 mg | | | |
| Uniformity of weight | : Min | Max | | Limit |
| | -1.21 % | +2.15 % | | ±7.5 % of average weight |
| Identification Test | : | | | |
| A-By IR | : Complies | | | To comply |
| B-By TLC | : Complies | | | To comply |
| C-By Chemical test | : Complies | | | To comply |
| Dissolution test (By UV) | : Min | Max | Avg | Limit |
| | : 90.18 % | 95.36 % | 93.42 % | Q. NLT 70.00 % |
| Uniformity of content | : 95.27 % | 100.32 % | 98.29 % | |
| Acceptance value | : 3.8 | | | NMT 15.0 |
| Related substances (By HPLC) | : | | | |
| Sum of all secondary impurities (Other than canrenone) | : 0.12 % | | | NMT 1.00 % |
| Canrenone | : 0.15 % | | | NMT 1.00 % |
| Total impurities | : 0.27 % | | | NMT 1.00 % |
| Leak test | : Complies | | | To comply |
| Hardnes | : 3.5 kg/cm2 | | | |
| Friability | : 0.15 % | | | NMT 1.0 % |

| CONTENTS | OBTAINED | CLAIM | LIMITS | METHOD |
|---|---|---|---|---|
| Assay (By UV) :- | | | | |
| Each uncoated tablet contains:- | | | | |
| Spironolactone IP | 24.57 mg | 25.00 mg | (23.75 - 26.25) mg | IP 2022 |

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# TEST REPORT

FDA Lic. No. : 25-LAB-HR

**Form-39A, 150-E (f) Report of test or Analysis by Approved Institution For Procurement Agency**

| | | | |
|---|---|---|---|
| Name of sample | : Spironolactone Tablets IP 25 mg | AR No. | : SA/GO-181225/008 |
| | | Batch Size | : NM |
| Batch No. | : T250920 | D/E | : 08/2027 |
| D/M | : 09/2025 | Name of supplier | : NM |
| Original Manufacturer | : NM | | |
| Mfg. Lic. No | : NM | Ref. No.(As in test request slip) | : NM |
| Sample Submitted By | : Medical Superintedent ESIC | Ref. No.( As given by party) | : NM |
| Address | : ESIC Pooluvapatti to Thirumurugan Poondi Ring Road Tiruppur - 641 603 Tiruppur - 641 | Sample Quantity | : 70 Tablets |
| Date of receipt | : 17/11/2025 | Sample received on | : 18/12/2025 |
| Date of start of analysis | : 18/12/2025 | Date of completion of analysis | : 24/12/2025 |
| Protocol of test applied | : IP 2022 | Date of Issue of the report | : 25/12/2025 |

In the opinion of the undersigned, the sample referred to above is of Standard Quality as defined in the Drugs and Cosmetics Act and the Rules made under for the reasons given below in respect to Test(s) mentioned above.

***End of Report***

Satiate Research & Anatech Pvt. Ltd. Verified by QA Panchkula

Date : 25/12/2025

Person In-charge of Testing
Dr Surender Panghal (M.Pharma, Ph.D.)
(Quality Manager)

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# TEST REPORT

FDA Lic. No. : 25-LAB-HR

**Form-39A, 150-E (f) Report of test or Analysis by Approved Institution For Procurement Agency**

| | | | |
|---|---|---|---|
| Name of sample | : Mupirocin Ointment IP 2 % w/w | AR No. | : SA/GO-181225/009 |
| | | Batch Size | : NM |
| Batch No. | : 2501348 | D/E | : 12/2027 |
| D/M | : 01/2025 | Name of supplier | : NM |
| Original Manufacturer | : NM | | |
| Mfg. Lic. No | : NM | Ref. No.(As in test request slip) | : NM |
| Sample Submitted By | : Medical Superintedent ESIC | Ref. No.( As given by party) | : NM |
| Address | : ESIC Pooluvapatti to Thirumurugan Poondi Ring Road Tiruppur - 641 603 Tiruppur - 641 | Sample Quantity | : 12 Nos. |
| Date of receipt | : 17/11/2025 | Sample received on | : 18/12/2025 |
| Date of start of analysis | : 18/12/2025 | Date of completion of analysis | : 24/12/2025 |
| Protocol of test applied | : IP 2022 | Date of Issue of the report | : 24/12/2025 |

| TEST PARAMETERS | | OBTAINED | | LIMITS |
|---|---|---|---|---|
| Description | : | Colourless semi solid mass filled in printed laminated tube. | | |
| Nominal weight | : | 5.00 g | | |
| Uniformity of fill. weight | : | Min. 5.02 g | Max 5.12 g | Limit NLT 4.5 g |
| Identification Test | : | | | |
| A-By TLC | : | Complies | | To comply |
| B-By HPLC | : | Complies | | To comply |
| Related substances (By HPLC) | : | | | |
| Mupirocin Impurity C3 | : | 0.58 % | | NMT 4.00 % |
| Mupirocin Impurity D1 | : | 0.69 % | | NMT 5.00 % |
| Mupirocin Impurity E2 | : | 1.65 % | | NMT 10.00 % |
| Any other secondary impurity | : | 0.15 % | | NMT 1.50 % |
| Sum of all secondary impurities | : | 3.07 % | | NMT 20.00 % |

| CONTENTS | OBTAINED | CLAIM | LIMITS |
|---|---|---|---|
| Assay (By HPLC) :- | | | |
| Composition :- | | | |
| Mupirocin IP | 1.99 % w/w | 2.00 % w/w | (1.80 - 2.30) % w/w |

In the opinion of the undersigned, the sample referred to above is of Standard Quality as defined in the Drugs and Cosmetics Act and the Rules made under for the reasons given below in respect to Test(s) mentioned above.

***End of Report***

Satiate Research & Anatech Pvt. Ltd. Verified by QA Panchkula

Date : 24/12/2025

Person In-charge of Testing
Dr Surender Panghal (M.Pharma, Ph.D.)
(Quality Manager)

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# TEST REPORT

FDA Lic. No. : 25-LAB-HR

**Form-39A, 150-E (f) Report of test or Analysis by Approved Institution For Procurement Agency**

| | | | |
|---|---|---|---|
| Name of sample | : Trypsin and Chymotrypsin (1:6) Tablets 100K AU | AR No. | : SA/GO-181225/010 |
| Batch No. | : GAET25010 | Batch Size | : NM |
| D/M | : 09/2025 | D/E | : 08/2027 |
| Original Manufacturer | : NM | Name of supplier | : NM |
| Mfg. Lic. No | : NM | Ref. No.(As in test request slip) | : NM |
| Sample Submitted By | : Medical Superintedent ESIC | Ref. No.( As given by party) | : NM |
| Address | : ESIC Pooluvapatti to Thirumurugan Poondi Ring Road Tiruppur - 641 603 Tiruppur - 641 | Sample Quantity | : 80 Tablets |
| Date of receipt | : 17/11/2025 | Sample received on | : 18/12/2025 |
| Date of start of analysis | : 20/12/2025 | Date of completion of analysis | : 24/12/2025 |
| Protocol of test applied | : As per manufacturer's specification. | Date of Issue of the report | : 25/12/2025 |

| TEST PARAMETERS | OBTAINED | LIMITS |
|---|---|---|
| Description | : Brick red coloured circular shaped biconvex enteric coated tablet plain surface on both sides. | |
| Average weight | : 147.12 mg | |
| Uniformity of weight | : Min -1.42 % Max +2.57 % | Limit ±7.5 % of average weight |
| Identification Test (By UV) | : Complies | To comply |
| Colour Identification | : Complies | To comply |
| Disintegration Time | : | |
| In 0.1 M HCl acid | : Not break | Should not break in 120 Min. |
| In phosphate buffer pH 6.8 | : 23 Min 28 Sec. | NMT 60.0 Min. |
| Leak test | : Complies | To comply |
| Hardness | : 3.5 kg/cm2 | |

| CONTENTS | OBTAINED | CLAIM | LIMITS |
|---|---|---|---|
| Assay : | | | |
| Each enteric coated tablet contains | | | |
| 100,000 Amour units trypsin chymotrypsin of enzymatic activity | 102570.00 IU | 100,000.00 IU | NLT 90,000.0 IU |
| Supplied by a purified concentrate which has | | | |
| Specified trypsin & chymotrypsin acitivity in the ratio of | | | |
| Approximately six to one | | | |

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# TEST REPORT

FDA Lic. No. : 25-LAB-HR

**Form-39A, 150-E (f) Report of test or Analysis by Approved Institution For Procurement Agency**

| | | | |
|---|---|---|---|
| Name of sample | : Trypsin and Chymotrypsin (1:6) Tablets 100K AU | AR No. | : SA/GO-181225/010 |
| Batch No. | : GAET25010 | Batch Size | : NM |
| D/M | : 09/2025 | D/E | : 08/2027 |
| Original Manufacturer | : NM | Name of supplier | : NM |
| Mfg. Lic. No | : NM | Ref. No.(As in test request slip) | : NM |
| Sample Submitted By | : Medical Superintedent ESIC | Ref. No.( As given by party) | : NM |
| Address | : ESIC Pooluvapatti to Thirumurugan Poondi Ring Road Tiruppur - 641 603 Tiruppur - 641 | Sample Quantity | : 80 Tablets |
| Date of receipt | : 17/11/2025 | Sample received on | : 18/12/2025 |
| Date of start of analysis | : 20/12/2025 | Date of completion of analysis | : 24/12/2025 |
| Protocol of test applied | : As per manufacturer's specification. | Date of Issue of the report | : 25/12/2025 |

In the opinion of the undersigned, the sample referred to above is of Standard Quality as defined in the Drugs and Cosmetics Act and the Rules made under for the reasons given below in respect to Test(s) mentioned above.

***End of Report***

Satiate Research & Anatech Verified by QA

Date : 25/12/2025

Person In-charge of Testing
Dr Surender Panghal (M.Pharma, Ph.D.)
(Quality Manager)

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# TEST REPORT

FDA Lic. No. : 25-LAB-HR

## Form-39A, 150-E (f) Report of test or Analysis by Approved Institution For Procurement Agency

| | | | |
|---|---|---|---|
| Name of sample | : Methylcobalamin Injection 500mcg | AR No. | : SA/GO-181225/011 |
| | | Batch Size | : NM |
| Batch No. | : D31Y017 | D/E | : 06/2027 |
| D/M | : 07/2025 | Name of supplier | : NM |
| Original Manufacturer | : NM | | |
| Mfg. Lic. No | : NM | Ref. No.(As in test request slip) | : NM |
| Sample Submitted By | : Medical Superintedent ESIC | Ref. No.( As given by party) | : NM |
| Address | : ESIC Pooluvapatti to Thirumurugan Poondi Ring Road Tiruppur - 641 603 | Sample Quantity | : 30 Nos. |
| Date of receipt | : 17/11/2025 | Sample received on | : 18/12/2025 |
| Date of start of analysis | : 18/12/2025 | Date of completion of analysis | : 01/01/2026 |
| Protocol of test applied | : As per manufacturer's specification. | Date of Issue of the report | : 02/01/2026 |

| TEST PARAMETERS | OBTAINED | LIMITS |
|---|---|---|
| Description | : Red coloured liquid filled in amber coloured glass ampoule. | |
| Identification test | : Complies | To comply |
| pH | : 4.751 | |
| Nominal volume | : 1.0 ml | |
| Extractable volume | : 1.1 ml | NLT 1.0 ml |
| Particulate Matter | : | |
| Greater than or Equal to 10 µm | : 265 Particles/Container | NMT 6000 Particles/Container |
| Greater than or Equal to 25 µm | : 55 Particles/Container | NMT 600 Particles/Container |
| Sterility | : Complies | To comply |
| Leak Test | : Complies | To comply |

| CONTENTS | OBTAINED | CLAIM | LIMITS |
|---|---|---|---|
| Assay | | | |
| Composition | | | |
| Each ml contains | | | |
| Methylcobalamin IP | 512.25 mcg | 500.00 mcg | (450.00 - 550.00) mcg |

Note:- 1.The result listed refers only to the tested samples & applicable parameters; endorsement of products is neither inferred nor implied.
2.Total liability of our institute is limited to the invoiced amount
3.This report is not to be reproduced wholly or in part and cannot be used as evidence in the court of law and should not be used in any advertising media without our special permission in writing.
4.Sample drawn and submitted by the party for Analysis unless otherwise stated.
5.Party has asked for the above tests only.

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# TEST REPORT

FDA Lic. No. : 25-LAB-HR

## Form-39A, 150-E (f) Report of test or Analysis by Approved Institution For Procurement Agency

| | | | |
|---|---|---|---|
| Name of sample | : Methylcobalamin Injection 500mcg | AR No. | : SA/GO-181225/011 |
| Batch No. | : D31Y017 | Batch Size | : NM |
| D/M | : 07/2025 | D/E | : 06/2027 |
| Original Manufacturer | : NM | Name of supplier | : NM |
| Mfg. Lic. No | : NM | Ref. No.(As in test request slip) | : NM |
| Sample Submitted By | : Medical Superintedent ESIC | Ref. No.( As given by party) | : NM |
| Address | : ESIC Pooluvapatti to Thirumurugan Poondi Ring Road Tiruppur - 641 603 | Sample Quantity | : 30 Nos. |
| Date of receipt | : 17/11/2025 | Sample received on | : 18/12/2025 |
| Date of start of analysis | : 18/12/2025 | Date of completion of analysis | : 01/01/2026 |
| Protocol of test applied | : As per manufacturer's specification. | Date of Issue of the report | : 02/01/2026 |

In the opinion of the undersigned, the sample referred to above is of Standard Quality as defined in the Drugs and Cosmetics Act and the Rules made under for the reasons given below in respect to Test(s) mentioned above.

***End of Report***

Satiate Research & Anatech Pvt. Ltd. Verified by QA Panchkula

Date : 02/01/2026

Person In-charge of Testing
Dr Surender Panghal (M.Pharma, Ph.D.)
(Quality Manager)

**Note:-**
1. The result listed refers only to the tested samples & applicable parameters; endorsement of products is neither inferred nor implied.
2. Total liability of our institute is limited to the invoiced amount
3. This report is not to be reproduced wholly or in part and cannot be used as evidence in the court of law and should not be used in any advertising media without our special permission in writing.
4. Sample drawn and submitted by the party for Analysis unless otherwise stated.
5. Party has asked for the above tests only.

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# TEST REPORT

**FDA Lic. No. : 25-LAB-HR**

## Form-39A, 150-E (f) Report of test or Analysis by Approved Institution For Procurement Agency

| | | | | | |
|---|---|---|---|---|---|
| Name of Sample | : | Diclofenac Diethylamine 1.16 % w/w, Linseed Oil 3%, w/w Methyl Salicylate 10 % w/w and Menthol 5 % w/w Spray | AR. No. | : | SA/GO-181225/012 |
| Batch No. | : | W250120 | Batch size | : | NM |
| D/M | : | 08/2025 | D/E | : | 07/2028 |
| Original Manufacturer | : | NM | Name of supplier | : | NM |
| Mfg. Lic. No | : | NM | Ref. No.( As in test req. Slip) | : | NM |
| Sample Submitted By | : | Medical Superintedent ESIC | Ref. No,( As given by party) | : | NM |
| Address | : | ESIC Pooluvapatti toThirumurugan Poondi Ring Road Tiruppur-641603 | Sample quantity | : | 03 Nos. |
| Date of receipt | : | 17/11/2025 | Sample received on | : | 18/12/2025 |
| Date of start analysis | : | 18/12/2025 | Date of completion of analysis | : | 21/12/2025 |
| Protocol of test applied | : | As per manufacturer's specification. | Date of Issue of the report | : | 23/12/2025 |

| | | |
|---|---|---|
| Description | Colourless liquid filled in printed aluminium container. | |
| Identification Test (By HPLC) | | |
| A- Diclofenac Diethylamine | Complies | To comply |
| B- Menthol & Methyl Salicylate | Complies | To comply |
| C- Linseed Oil | Complies | To comply |
| Nominal weight | 142.00 g | |
| Extractable weight | 142.5 g | NLT 142.00 g |
| Can pressure @ 25°C | 39.12 pSi° | NLT 35 pSi° |
| Delivery rate @ 25°C | 0.870 g/sec. | (0.300 – 1.500) g/sec |
| Leak test | Complies | To comply |

| TEST PARAMETERS | RESULT | CLAIM | LIMIT |
|---|---|---|---|
| Assay:- | | | |
| Composition | | | |
| Diclofenac Diethylamine IP (1.16 % w/w) | | | |
| Eq. to Diclofenac Sodium IP | 0.987 % w/w | 1.00 % w/w | (0.90 – 1.100) % w/w |
| Virgin Linseed Oil BP | 2.98 % w/w | 3.00 % w/w | (2.70 – 3.30) % w/w |
| Methyl Salicylate IP | 9.89 % w/w | 10.00 % w/w | (9.00 – 11.00) % w/w |
| Menthol IP | 4.97 % w/w | 5.00 % w/w | (4.50 – 6.00) % w/w |

In the opinion of the undersigned, the sample referred to above is of Standard Quality as defined in the Drugs and Cosmetics Act and the Rules made under for the reasons given below in respect to Test(s) mentioned above.

***End of Report***

Satiate Research & Anatech Pvt. Ltd. Verified by QA Panchkula

Person-in charge of testing
Dr Surender Panghal (M. Pharma, Ph.D.)
(Quality Manager)

Date : 23/12/2025

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# TEST REPORT

FDA Lic. No. : 25-LAB-HR

**Form-39A, 150-E (f) Report of test or Analysis by Approved Institution For Procurement Agency**

| | | | |
|---|---|---|---|
| Name of sample | : Cilnidipine Tablets IP 10 mg | AR No. | : SA/GO-181225/013 |
| Batch No. | : WCB25012G | Batch Size | : NM |
| D/M | : 07/2025 | D/E | : 06/2027 |
| Original Manufacturer | : NM | Name of supplier | : NM |
| Mfg. Lic. No | : NM | Ref. No.(As in test request slip) | : NM |
| Sample Submitted By | : Medical Superintedent ESIC | Ref. No.( As given by party) | : NM |
| Address | : ESIC Pooluvapatti to Thirumurugan Poondi Ring Road Tiruppur - 641 603 Tiruppur - 641 | Sample Quantity | : 70 Tablets |
| Date of receipt | : 17/11/2025 | Sample received on | : 18/12/2025 |
| Date of start of analysis | : 18/12/2025 | Date of completion of analysis | : 24/12/2025 |
| Protocol of test applied | : IP 2022 | Date of Issue of the report | : 25/12/2025 |

| TEST PARAMETERS | | OBTAINED | | | LIMITS |
|---|---|---|---|---|---|
| Description | : | White circular shaped biconvex film coated tablet plain surface on both sides. | | | |
| Average weight | : | 136.95 mg | | | |
| Uniformity of weight | : | Min | Max | | Limit |
| | | -1.32 % | +2.51 % | | ± 7.5 % of average weight |
| Identification Test (By HPLC) | : | Complies | | | To comply |
| Dissolution Test (By UV) | : | Min | Max | Avg | Limit |
| | : | 90.56 % | 95.88 % | 93.82 % | Q. NLT 70.00 % |
| Uniformity of content | : | 96.52 % | 101.56 % | 99.48 % | |
| Acceptance value | : | 3.9 | | | NMT 15.0 |
| Related Substances (By HPLC) | : | | | | |
| Any secondary impurity | : | Not detected | | | NMT 0.5 % |
| Sum of all secondary impurities | : | Not detected | | | NMT 1.0 % |
| Leak Test | : | Complies | | | To comply |
| Hardness | : | 2.5 kg/cm2 | | | |

| CONTENTS | OBTAINED | CLAIM | LIMITS | METHOD |
|---|---|---|---|---|
| Assay (By HPLC) | | | | |
| Composition | | | | |
| Each film coated tablet contains | | | | |
| Cilnidipine IP | 9.95 mg | 10.00 mg | (9.00 - 11.00) mg | IP 2022 |

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# TEST REPORT

FDA Lic. No. : 25-LAB-HR

**Form-39A, 150-E (f) Report of test or Analysis by Approved Institution For Procurement Agency**

| | | | |
|---|---|---|---|
| Name of sample | : Cilnidipine Tablets IP 10 mg | AR No. | : SA/GO-181225/013 |
| Batch No. | : WCB25012G | Batch Size | : NM |
| D/M | : 07/2025 | D/E | : 06/2027 |
| Original Manufacturer | : NM | Name of supplier | : NM |
| Mfg. Lic. No | : NM | Ref. No.(As in test request slip) | : NM |
| Sample Submitted By | : Medical Superintedent ESIC | Ref. No.( As given by party) | : NM |
| Address | : ESIC Pooluvapatti to Thirumurugan Poondi Ring Road Tiruppur - 641 603 Tiruppur - 641 | Sample Quantity | : 70 Tablets |
| Date of receipt | : 17/11/2025 | Sample received on | : 18/12/2025 |
| Date of start of analysis | : 18/12/2025 | Date of completion of analysis | : 24/12/2025 |
| Protocol of test applied | : IP 2022 | Date of Issue of the report | : 25/12/2025 |

In the opinion of the undersigned, the sample referred to above is of Standard Quality as defined in the Drugs and Cosmetics Act and the Rules made under for the reasons given below in respect to Test(s) mentioned above.

***End of Report***

Satiate Research & Anatech Pvt. Ltd. Verified by QA Panchkula

Date : 25/12/2025

Person In-charge of Testing
Dr Surender Panghal (M.Pharma, Ph.D.)
(Quality Manager)

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# TEST REPORT

FDA Lic. No. : 25-LAB-HR

**Form-39A, 150-E (f) Report of test or Analysis by Approved Institution For Procurement Agency**

| | | | |
|---|---|---|---|
| Name of sample | : Paracetamol 162.5mg and Tramadol 18.75mg Tablet | AR No. | : SA/GO-181225/014 |
| Batch No. | : AR2TF01 | Batch Size | : NM |
| D/M | : 08/2025 | D/E | : 07/2027 |
| Original Manufacturer | : NM | Name of supplier | : NM |
| Mfg. Lic. No | : NM | Ref. No.(As in test request slip) | : NM |
| Sample Submitted By | : Medical Superintedent ESIC | Ref. No.( As given by party) | : NM |
| Address | : ESIC Pooluvapatti to Thirumurugan Poondi Ring Road Tiruppur - 641 603 Tiruppur - 641 | Sample Quantity | : 70 Tablets |
| Date of receipt | : 17/11/2025 | Sample received on | : 18/12/2025 |
| Date of start of analysis | : 18/12/2025 | Date of completion of analysis | : 24/12/2025 |
| Protocol of test applied | : IP Addendum 2024 | Date of Issue of the report | : 25/12/2025 |

| TEST PARAMETERS | OBTAINED | | | LIMITS |
|---|---|---|---|---|
| Description | : White circular shaped biconvex film coated tablet plain surface on both sides. | | | |
| Identification Test (By HPLC) | : Complies | | | To comply |
| Average weight | : 258.17 mg | | | |
| Uniformity of weight | : Min -1.25 % | Max +2.61 % | | Limit ±5.0 % of average weight |
| Dissolution Test (By HPLC) | : Min | Max | Avg | Limit |
| 0.1 M HCl Acid | : | | | |
| For Paracetamol | : 90.56 % | 95.42 % | 93.65 % | Q. NLT 80.00 % |
| For Tramadol HCl | : 91.42 % | 96.66 % | 94.72 % | Q. NLT 80.00 % |
| 4-Aminophenol (By HPLC) | : Not detected | | | NMT 0.15 % |
| Related sustances (By HPLC) | : | | | |
| O -Desmethyl - tramadol | : Not detected | | | NMT 0.2 % |
| Tramadol compound A | : Not detected | | | NMT 0.2 % |
| Any other secondary impurities | : Not detected | | | NMT 0.2 % |
| Sum of all secondary impurities | : Not detected | | | NMT 0.8 % |
| Uniformity of content | : Min | Max | Avg | |
| For-Tramadol | : 96.56 % | 101.48 % | 99.58 % | |
| Acceptance value | : 3.8 | | | NMT 15.0 |
| Leak test | : Complies | | | To comply |
| Hardness | : 3.5 kg/cm2 | | | |

| CONTENTS | OBTAINED | CLAIM | LIMITS | METHOD |
|---|---|---|---|---|
| Assay (By HPLC) | | - | - | - |
| Each film coated tablet contains | | | | |
| Paracetamol IP | 160.16 mg | 162.50 mg | (146.25 - 178.75) mg | IP Addendum |

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# TEST REPORT

FDA Lic. No. : 25-LAB-HR

**Form-39A, 150-E (f) Report of test or Analysis by Approved Institution For Procurement Agency**

| | | | |
|---|---|---|---|
| Name of sample | : Paracetamol 162.5mg and Tramadol 18.75mg Tablet | AR No. | : SA/GO-181225/014 |
| Batch No. | : AR2TF01 | Batch Size | : NM |
| D/M | : 08/2025 | D/E | : 07/2027 |
| Original Manufacturer | : NM | Name of supplier | : NM |
| Mfg. Lic. No | : NM | Ref. No.(As in test request slip) | : NM |
| Sample Submitted By | : Medical Superintedent ESIC | Ref. No.( As given by party) | : NM |
| Address | : ESIC Pooluvapatti to Thirumurugan Poondi Ring Road Tiruppur - 641 603 Tiruppur - 641 | Sample Quantity | : 70 Tablets |
| Date of receipt | : 17/11/2025 | Sample received on | : 18/12/2025 |
| Date of start of analysis | : 18/12/2025 | Date of completion of analysis | : 24/12/2025 |
| Protocol of test applied | : IP Addendum 2024 | Date of Issue of the report | : 25/12/2025 |

| CONTENTS | OBTAINED | CLAIM | LIMITS | METHOD |
|---|---|---|---|---|
| Tramadol HCl IP | 18.67 mg | 18.75 mg | (16.88 - 20.63) mg | IP Addendum 2024 |

In the opinion of the undersigned, the sample referred to above is of Standard Quality as defined in the Drugs and Cosmetics Act and the Rules made under for the reasons given below in respect to Test(s) mentioned above.

***End of Report***

Satiate Research & Anatech Pvt. Ltd. Verified by QA Panchkula

Date : 25/12/2025

Person In-charge of Testing
Dr Surender Panghal (M.Pharma, Ph.D.)
(Quality Manager)

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# TEST REPORT

FDA Lic. No. : 25-LAB-HR

**Form-39A, 150-E (f) Report of test or Analysis by Approved Institution For Procurement Agency**

| | | | |
|---|---|---|---|
| Name of sample | : Iron sucrose injection USP | AR No. | : SA/GO-181225/015 |
| | | Batch Size | : NM |
| Batch No. | : MPJ253642 | D/E | : 08/2027 |
| D/M | : 09/2025 | Name of supplier | : NM |
| Original Manufacturer | : NM | | |
| Mfg. Lic. No | : NM | Ref. No.(As in test request slip) | : NM |
| Sample Submitted By | : Medical Superintedent ESIC | Ref. No.( As given by party) | : NM |
| Address | : ESIC Pooluvapatti to Thirumurugan Poondi Ring Road Tiruppur - 641 603 Tiruppur - 641 | Sample Quantity | : 30 Nos. |
| Date of receipt | : 17/11/2025 | Sample received on | : 18/12/2025 |
| Date of start of analysis | : 18/12/2025 | Date of completion of analysis | : 01/01/2026 |
| Protocol of test applied | : USP | Date of Issue of the report | : 01/01/2026 |

| TEST PARAMETERS | OBTAINED | LIMITS |
|---|---|---|
| Description | : Brown coloured liquid filled in amber coloured glass ampoule. | |
| Identification Test | : | |
| Identification A -Iron | : Complies | |
| Identification B -Sucrose | : Complies | |
| Identification C | : | |
| Molecular weight Determination (MW/MN) | : | |
| MW | : 47113.46 Da | (34000 - 60000) Da |
| MN | : 36241.12 Da | NLT 24000 Da |
| MW/MN | : 1.3 | NMT 1.7 |
| Nominal Volume | : 5.0 ml | |
| Extractable Volume | : 5.2 ml | NLT 5.0 ml |
| Specific gravity | : 1.152 | (1.135 - 1.165) |
| pH | : 10.942 | (10.5 - 11.1) |
| Absence of low molecular weight | : | |
| Iron [Fe(II) & FE(III)] Complex | : Complies | To comply |
| Turbidity | : 4.9 | (4.4 -5.3) |
| Osmolarity | : 1252.45 mOsmol/L | (1150.0 - 1350.0) mOsmol/L |
| Alkalinity | : 0.6 ml of 0.1 N hydrochloric acid was consumed. | (0.5 - 0.8) ml of 0.1 N hydrochloric acid be consumed per ml of injection |
| Particulate matter | : | |
| Greater than or equal to 10 µm | : 255 Particles/Container | NMT 6000 Particles/Container |
| Greater than or equal to 25 µm | : 85 Particles/Container | NMT 600 Particles/Container |
| Limit of iron FE[(II)] | : 0.12 % | NMT 0.40 % |

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# TEST REPORT

FDA Lic. No. : 25-LAB-HR

**Form-39A, 150-E (f) Report of test or Analysis by Approved Institution For Procurement Agency**

| | | | |
|---|---|---|---|
| Name of sample | : Iron sucrose injection USP | AR No. | : SA/GO-181225/015 |
| | | Batch Size | : NM |
| Batch No. | : MPJ253642 | D/E | : 08/2027 |
| D/M | : 09/2025 | Name of supplier | : NM |
| Original Manufacturer | : NM | | |
| Mfg. Lic. No | : NM | Ref. No.(As in test request slip) | : NM |
| Sample Submitted By | : Medical Superintedent ESIC | Ref. No.( As given by party) | : NM |
| Address | : ESIC Pooluvapatti to Thirumurugan Poondi Ring Road Tiruppur - 641 603 Tiruppur - 641 | Sample Quantity | : 30 Nos. |
| Date of receipt | : 17/11/2025 | Sample received on | : 18/12/2025 |
| Date of start of analysis | : 18/12/2025 | Date of completion of analysis | : 01/01/2026 |
| Protocol of test applied | : USP | Date of Issue of the report | : 01/01/2026 |

| TEST PARAMETERS | OBTAINED | LIMITS |
|---|---|---|
| Description | : Brown coloured liquid filled in amber coloured glass ampoule. | |
| Content of chloride | : 0.015 % | (0.012 - 0.025) % |
| Bacterial Endotoxins | : Less than 3.7 USP EU/mg | NMT 3.7 USP EU/mg |
| Sterility | : Complies | To comply |
| Sucrose (By AAS) | : 301.41 mg/ml | (260 - 340) mg/ml |
| Leak test | : Complies | To comply |

| CONTENTS | OBTAINED | CLAIM | LIMITS |
|---|---|---|---|
| Assay:- | | | |
| Composition | | | |
| Ferric hydroxide in complex with sucrose | | | |
| eq. to elemental iron | 20.31 mg | 20.00 mg | (19.00 - 21.00) mg |

In the opinion of the undersigned, the sample referred to above is of Standard Quality as defined in the Drugs and Cosmetics Act and the Rules made under for the reasons given below in respect to Test(s) mentioned above.

***End of Report***

Satiate Research & Anatech Pvt. Ltd. Verified by QA Panchkula

Date : 01/01/2026

Person In-charge of Testing
Dr Surender Panghal (M.Pharma, Ph.D.)
(Quality Manager)

Satiate
Research & Anatech Pvt. Ltd.
NABL ACCREDITED GOVT. APPROVED TESTING LABORATORY
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E-mail: satiateresearch@gmail.com, Website : www.sralabs.com

# TEST REPORT

FDA Lic. No. : 25-LAB-HR

**Form-39A, 150-E (f) Report of test or Analysis by Approved Institution For Procurement Agency**

| | | | |
|---|---|---|---|
| Name of sample | : Glimepiride Tablets IP 1 mg | AR No. | : SA/GO-181225/016 |
| Batch No. | : 0065 | Batch Size | : NM |
| D/M | : 09/2025 | D/E | : 08/2027 |
| Original Manufacturer | : NM | Name of supplier | : NM |
| Mfg. Lic. No | : NM | | |
| Sample Submitted By | : Medical Superintedent ESIC | Ref. No.(As in test request slip) | : NM |
| Address | : ESIC Pooluvapatti to Thirumurugan Poondi Ring Road Tiruppur - 641 603 Tiruppur - 641 | Ref. No.( As given by party) | : NM |
| | | Sample Quantity | : 70 Tablets |
| Date of receipt | : 17/11/2025 | Sample received on | : 18/12/2025 |
| Date of start of analysis | : 20/12/2025 | Date of completion of analysis | : 25/12/2025 |
| Protocol of test applied | : IP 2022 | Date of Issue of the report | : 26/12/2025 |

| TEST PARAMETERS | OBTAINED | LIMITS |
|---|---|---|
| Description | : Light yellow coloured circular shaped biconvex uncoated tablet plain surface on both sides. | |
| Average weight | : 167.15 mg | |
| Uniformity of weight | : Min -1.26 % Max +2.63 % | Limit ±7.5 % of average weight |
| Identification Test (By HPLC) | : Complies | To comply |
| Leak Test | : Complies | To comply |
| Hardness | : 3.5 kg/cm2 | |
| Friability | : 0.12 % | NMT 0.1 % |
| Related substances (By HPLC) | : | |
| Glimepiride impurity B | : 0.26 % | NMT 2.50 % |
| Any other secondary impurity | : Not detected | NMT 0.50 % |
| Sum of all secondary impurities (Other than impurity B) | : 0.12 % | NMT 1.00 % |
| Sum of all secondary impurities | : 0.38 % | NMT 3.50 % |
| Dissolution test (By HPLC) | : Min Max Avg | Limit |
| In Phosphate buffer (pH 7.8) | : 89.32 % 94.46 % 92.87 % | Q. NLT 75.00 % |
| Uniformity of content (By HPLC) | : 96.82 % 101.63 % 99.17 % | |
| Acceptance value | : 3.5 | NMT 15.0 |

| CONTENTS | OBTAINED | CLAIM | LIMITS | METHOD |
|---|---|---|---|---|
| Assay (By HPLC) :- Composition | | | | |
| Each uncoated tablet contains :- | | | | |
| Glimepiride IP | 0.992 mg | 1.00 mg | (0.90 - 1.10) mg | IP 2022 |

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# TEST REPORT

FDA Lic. No. : 25-LAB-HR

## Form-39A, 150-E (f) Report of test or Analysis by Approved Institution For Procurement Agency

| | | | |
|---|---|---|---|
| Name of sample | : Glimepiride Tablets IP 1 mg | AR No. | : SA/GO-181225/016 |
| Batch No. | : 0065 | Batch Size | : NM |
| D/M | : 09/2025 | D/E | : 08/2027 |
| Original Manufacturer | : NM | Name of supplier | : NM |
| Mfg. Lic. No | : NM | | |
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| Date of receipt | : 17/11/2025 | Sample Quantity | : 70 Tablets |
| Date of start of analysis | : 20/12/2025 | Sample received on | : 18/12/2025 |
| Protocol of test applied | : IP 2022 | Date of completion of analysis | : 25/12/2025 |
| | | Date of Issue of the report | : 26/12/2025 |

In the opinion of the undersigned, the sample referred to above is of Standard Quality as defined in the Drugs and Cosmetics Act and the Rules made under for the reasons given below in respect to Test(s) mentioned above.

***End of Report***

Satiate Research & Anatech Pvt. Ltd. Verified by QA Panchkula

Date : 26/12/2025

Person In-charge of Testing
Dr Surender Panghal (M.Pharma, Ph.D.)
(Quality Manager)