**INNOVA CAPTAB LTD**
**1281/1, HILLTOP INDUSTRIAL ESTATE, NEAR EPIP PHASE-I, JHARMAJRI, BADDI (HP) INDIA**

# Certificate of Analysis

**Product Name: Sitasmart-M 50/1000**

| | | | |
|---|---|---|---|
| **Generic Name** | Sitagliptin & Metformin Hydrochloride Tablets | **Packing Code** | G7700005 |
| **Batch Log No** | 32453652 | **Packing Batch No** | G7704010B |
| **Bulk Batch No** | G7704010 | **Batch Size** | 3.0 Lac |
| **Packing Type** | (10*2*15)Tabs | **Date of Analysis** | 28/11/2024 |
| **A.R. No.** | 2003FP324006135 | **Reference** | In house |
| **Mfg. Date** | 11/2024 | **Exp. Date** | 10/2026 |
| **Specification No** | FPS-G770-00 | **Date of Release** | 10/12/2024 |

| S. No. | TEST | SPECIFICATION | RESULT |
|---|---|---|---|
| 1 | **Description** | Brown colour biconvex, oval shaped, film coated tablet having plain on both side. | Brown colour biconvex, oval shaped, film coated tablet having plain on both side. |
| 2 | **Identification (By HPLC ) For Sitagliptin & Metformin HCl** | The retention times of the peaks of sample solution should correspond to those of the standard solution, as obtained in the Assay. | The retention times of the peaks of sample solution correspond to those of the standard solution, as obtained in the Assay. |
| 3 | **Average weight** | 1380.0mg ± 5.0% | 1393.30 mg |
| 4 | **Uniformity of weight** | ± 5.0% of average weight | %Maximum +ve deviation : 1.8 %<br>%Maximum –ve deviation:-1.8 % |
| 5 | **Disintegration time** | Not more than 30 minutes | Disintegration time:11.55 Minutes |
| 6 | **Dissolution For Sitagliptin (By HPLC)** | Not less than 70% (Q) of the labeled amount of Sitagliptin should be dissolved in 30 minutes. | Min: : 93.5 %<br>Max: : 95.3 %<br>Average::94.6 % |
| 7 | **Dissolution For Metformin Hydrochloride (By UV)** | Not less than 70% (Q) of the labeled amount of Metformin Hydrochloride should be dissolved in 30 minutes. | Min: : 99.8 %<br>Max: : 101.3 %<br>Average::100.7 % |
| 8 | **Related Substances** | | |
| 8.1 | **For Metformin Hydrochloride** | | |
| 8.1.1 | **Dicyandiamide** | Not more than 0.02% w/w | Not detected |
| 8.1.2 | **Any other secondary peak** | Not more than 0.1% | Not detected |
| 8.2 | **For Sitagliptin** | | |
| 8.2.1 | **Single maximum impurity** | Not more than 0.2% | Not detected |
| 8.2.2 | **Total impurities** | Not more than 0.5% | Not detected |
| 9 | **Assay-Each Film Coated tablet contains:** | | |
| 9.1 | **Sitagliptin Phosphate Monohydrate IP equivalent to Sitagliptin.....50mg** | 47.50mg to 52.50mg (95.0% to 105.0% of Labeled claim) | Assay % of Label Claim: : 99.0 %<br>Assay:mg/Tab:49.52 mg/tab |
| 9.2 | **Metformin Hydrochloride IP..... 1000mg** | 950.00mg to 1050.00mg (95.0% to 105.0% of Labeled claim) | Assay (i) % : 100.7 % |

**Remarks: APPROVED (Sample conforms to above Specification)**
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| **Prepared By** | **Reviewed By** | **Approved By** |
|---|---|---|
| ranjit.nayak(Analyst) | omprakash.sharma(Manager) | Mahendra.Bisht(Manager) |
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| S. No. | TEST | SPECIFICATION | RESULT |
|---|---|---|---|
| | | | Assay:mg/Tab:1006.80 mg/tab |

**Remarks: APPROVED (Sample conforms to above Specification)**
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| Prepared By | Reviewed By | Approved By |
|---|---|---|
| ranjit.nayak(Analyst) | omprakash.sharma(Manager) | Mahendra.Bisht(Manager) |
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