



Pharmaceuticals Limited

Registered & Corporate Office :

Plot No. 72, H. No. 8-2-334/3 & 4, Road No. 5,

Opp. SBI Executive Enclave, Banjara Hills,

Hyderabad - 500 034, Telangana, INDIA.

Tel : +91-40-2525 9999, Fax : +91-40-2525 9889




CIN : L24239TG1987PLC008066

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CERTIFICATE OF ANALYSIS

| Name of the Product | : Sildenafil Citrate Ph. Eur. | A.R. No. | : FP/21/0827 |
|---------------------|---|---|---|
| Batch No. | : SLC/0221054 | Date of Analysis | : 22.02.2022 |
| Mfg. Quantity | : 67.5 Kg | Expiry date | : January - 2027 |
| Dispatch Quantity | : 5.1 Kg | | |
| Mfg. Date | : February - 2022 | | |
| S. No. | TEST PARAMETER | RESULT | SPECIFICATIONS (Ref. No.:CS-FP-5042-02,Rev.05) |
| 1. | Characters | | |
| | a) Appearance | White, slightly hygroscopic crystalline powder. | White or almost white, slightly hygroscopic, crystalline powder. |
| | b) Solubility | Slightly soluble in water and in methanol, Practically insoluble in hexane. | Slightly soluble in water and in methanol, Practically insoluble in hexane. |
| 2. | Identification by IR | The infrared absorption spectrum of the potassium bromide dispersion of the sample preparation is exhibit maxima only at the same wave numbers as that of a similar preparation of Sildenafil citrate Working standard. | The infrared absorption spectrum of the potassium bromide dispersion of the sample preparation should be exhibit maxima only at the same wave numbers as that of a similar preparation of Sildenafil citrate working standard / Reference standard. |
| 3. | Impurity-E by TLC (%) | Less than 0.1 | Not more than 0.1 |
| 4. | Related substances by HPLC (% w/w) | | |
| | Sildenafil Impurity – A | BRT (0.05) | Not more than 0.15 |
| | Sildenafil Impurity – D | BRT (0.05) | Not more than 0.15 |
| | Unspecified impurity | BRT (0.05) | Not more than 0.10 |
| | Total impurities | BRT (0.05) | Not more than 0.5 |
| 5. | Water content by KF (% w/w) | 1.3 | Not more than 2.0 |
| 6. | Sulphated ash (% w/w) | 0.03 | Not more than 0.1 |
| 7. | Assay by HPLC (anhydrous substance) (% w/w) | 99.4 | Not less than 98.0 and Not more than 102.0 |

| | Prepared by | Reviewed by | Approved by |
|-------------|---|---|---|
| Sign & Date |  24/11/22 |  24/11/22 |  24/11/22 |
| Name | G. Vara Kumar | J. Naresh Babu | M. Yedukondalu |
| Designation | Chemist – QA | Dy. Manager – QC | Asst. Manager-QA |

Works : Unit-II, Plot No. 24 & 24B and 36 & 37, S.V. Co-Operative Industrial Estate, Bachupally,
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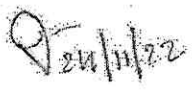


| Name of the Product | Sildenafil Citrate Ph. Eur. | | |
|---------------------|--|---|--|
| Batch No. | SLC/0221054 | | |
| Mfg. Quantity | 67.5 Kg | A.R. No. | FP/21/0827 |
| Dispatch Quantity | 5.1 Kg | Date of Analysis | 22.02.2022 |
| Mfg. Date | February - 2022 | Expiry date | January - 2027 |
| S. No. | TEST PARAMETER | RESULT | SPECIFICATIONS (Ref. No.: CS-FP-5042-02, Rev.05) |
| 8. | Residual solvents by GC (ppm) | | |
| | Methanol | Below LOQ (29) | Not more than 1000 |
| | Methylene chloride | Below LOD (17) | Not more than 100 |
| | Ethyl acetate | Below LOD (8) | Not more than 200 |
| | Toluene | Below LOD (5) | Not more than 100 |
| 9. | Identification of polymorph | | |
| | XRD | XRD diffractogram is exhibit specific 2θ value at 8.1, 10.3, 14.4, 16.2, 19.8, 22.7 and 28.9. | XRD diffractogram should exhibit specific 2θ value at ± 0.2° of 8.1, 10.3, 14.4, 16.2, 19.9, 22.7 and 28.9 |
| | DSC | The DSC thermogram is exhibit a single peak at 201.3° as an indication of melting. | The DSC thermo gram should exhibit a single peak at about 201 as an indication of melting. |
| # Skip testing | | | |
| # 10. | Determination of 'SLC-II' Content by HPLC (ppm) | Not applicable | Not more than 15 |
| # 11. | Determination of 'SLC-III' Content by HPLC (ppm) | Not applicable | Not more than 15 |
| # 12. | Determination of 'Sildenafil Methyl sulfonate' Content by HPLC (ppm) | Not applicable | Not more than 15 |

Conclusion: - The product conforms to the Sildenafil Citrate Ph. Eur. Specifications.

Note: SLC-II: 1-Methyl-3-propyl-4-nitropyrzolo-5-carboxylic acid, SLC-III: 1-Methyl-3-propyl-4-nitropyrzolo-5-carboxamide.

LOD: - Limit of detection, LOQ: - Limit of Quantitation & BRT: - Below reporting threshold.

Skip tests: Frequency - First batch produced and there after 1/10 batches produced in a year. The specified tests were performed according to the defined frequency, following the validated procedures which were incorporated in the Sildenafil Citrate standard test procedure [TP-FP-5042-02].

| | Prepared by | Reviewed by | Approved by |
|-------------|---|--|---|
| Sign & Date |  |  |  |
| Name | G. Vara Kumar | J. Naresh Babu | M. Yedukondalu |
| Designation | Chemist - QA | Dy. Manager - QC | Asst. Manager-QA |

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