HALANXIII
Labs Private Limited, Unit-1

Works :
Plot No. 74B,
Jawaharlal Nehru Pharma City,
Parawada, Visakhapatnam-531 021.
Andhra Pradesh, INDIA.
Tel : +91-8924-236149

# CERTIFICATE OF ANALYSIS



| | | | |
|---|---|---|---|
| Name of the Product | : **Tadalafil Ph. Eur. (Product No.: 0110201901)** | Date of Analysis | : 28/08/2019 |
| Batch No | : TDL/0819019 | A.R. No. | : FP/19/0109 |
| Dispatch Quantity | : 5.0 Kgs | Mfg. Quantity | : 56.20 Kg |
| Mfg. Date | : August ,2019 | Expiry Date | : July,2024 |

| S. No. | Test parameter | Specification | Results |
|---|---|---|---|
| 6. | **Impurities A, B and C by HPLC (%)** | | |
| | Impurity A | Not more than 0.15 | 0.01 |
| | Unspecified impurity | Not more than 0.10 | Not Detected |
| 7. | **Related substances by HPLC (%)** | | |
| | TDL-III content | Not more than 0.10 | Not Detected |
| | Unspecified impurity | Not more than 0.10 | BDL |
| | Total impurities | Not more than 0.3 | BDL |
| 8. | Loss on drying Under vacuum at 105°C for 3hours (%, w/w) | Not more than 0.5 | 0.26 |
| 9. | Sulphated ash (%, w/w) | Not more than 0.1 | 0.04 |
| 10. | Assay by HPLC (On dried substance) (%, w/w) | Not less than 97.5 and Not more than 102.0 | 99.8 |
| 11. | **Residual solvents by GC (ppm)** | | |
| | **Method-I** | | |
| | Methanol | Not more than 3000 | Not Detected |
| | Acetone | Not more than 5000 | 278 |
| | Isopropyl alcohol | Not more than 5000 | Not Detected |
| | Methylene chloride | Not more than 600 | Not Detected |
| | **Method-II** | | |
| | Triethylamine | Not more than 320 | Not Detected |

*Conclusion: - The product confirms the **Ph.Eur.** Specifications.*

| | Prepared by | Reviewed by | Approved by |
|---|---|---|---|
| Sign & Date | 10/10/2019. | 10/10/2019 | 10/10/2019. |
| Name | G. Rama Krishna | K.Bhaskara Rao | K.Pavan Chand |
| Designation | Tr.Chemist – QA | Sr.Manager – QC | Asst.Manager – QA |

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| Mfg. Date | : August .2019 | Expiry Date | : July.2024 |

| S. No. | Test parameter | Specification | Result |
|---|---|---|---|
| 1. | Appearance | White or almost white powder. | White powder |
| 2. | Solubility | Practically insoluble in water, Freely soluble in dimethyl -sulfoxide, and Slightly soluble in Methylene chloride. | Practically insoluble in water, Freely soluble in dimethyl - sulfoxide, and Slightly soluble in Methylene chloride. |
| 3. | Identification by IR | 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 Tadalafil working standard/Reference standard. | 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 Tadalafil working standard |
| 4. | Identification by HPLC | The principal peak in the chromatogram obtained with the test solution should be similar in retention time and size to the principal peak in the chromatogram obtained with reference solution (a). | The principal peak in the chromatogram obtained with the test solution is similar in retention time and size to the principal peak in the chromatogram obtained with reference solution (a). |
| 5. | Specific optical rotation $[\alpha]^{20}_{D}$ (dried substance) | + 78.0 to + 84.0 | +82.0 |

| | Prepared by | Reviewed | Approved by |
|---|---|---|---|
| Sign & Date | 10/10/2019. | 10/10/19 | 10/10/2019. |
| Name | G. Rama Krishna | K.Bhaskarao | K.Pavan Chand |
| Designation | Tr.Chemist – QA | Sr.Manag QC | Asst.Manager – QA |