

Zein Biotechnology Co.,Ltd.

Certificate Of Analysis

20/03/2024

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|---|------|---|--------------|------------------|
| Product Name | | Orlistat | Batch Number | T12B-A010-240101 |
| Grade | | USP API | Refer to | USP-NF 2022 |
| Batch size | | 213.00kg | Quantity | 50.00kg |
| Manufacture Date | | 2024.01.19 | Packaging | 25kg/piece |
| Retest Date | | 2026.01.18 | Test Date | 2024.01.20 |
| Test Items | | Specifications | | Results |
| Appearance | | White to off-white fine powder or fine powder with lumps | | Conforms |
| Specific optical rotation, 589 nm, 20°C, c = 3% (m/v) in ethanol (anhydrous and solvent-free) | | -48.0° to -51.0° | | -49.3° |
| Identification | HPLC | The retention time of the major peak of the sample solution corresponds to that of the standard solution, as obtained in the assay. | | Conforms |
| | IR | Corresponds to Reference Spectrum | | Conforms |
| Organic impurities (HPLC + GC + TLC) | | | | |
| Total of all (organic impurities) | | Not more than 1.0% | | 0.26% |
| Orlistat related compound A (TLC) | | Not more than 0.2% | | Not detected |
| Orlistat related compound B (GC) | | Not more than 0.05% | | Not detected |
| Orlistat related compound C (HPLC) | | Not more than 0.05% | | Not detected |
| Orlistat related compound D (HPLC) | | Not more than 0.2% | | Not detected |
| Orlistat related compound E (HPLC) | | Not more than 0.2% | | Not detected |
| Formylleucine (HPLC) | | Not more than 0.2% | | Not detected |
| Orlistat open ring epimer(HPLC) | | Not more than 0.2% | | 0.01% |
| Orlistat open ring amide(HPLC) | | Not more than 0.1% | | Not detected |
| D-Leucine orlistat(HPLC) | | Not more than 0.2% | | 0.02% |
| Any individual unspecified impurity(HPLC) | | Not more than 0.1% | | 0.06% |
| Residual Solvents (GC) | | | | |
| n-Heptane | | Not more than 5000ppm | | 930ppm |
| Isopropyl ether | | Not more than 5000ppm | | Not detected |
| Methanol | | Not more than 3000ppm | | Not detected |
| Tetrahydrofuran | | Not more than 720ppm | | Not detected |
| Benzene | | Not more than 2ppm | | 0.4ppm |
| Residue on Ignition | | Not more than 0.1% | | 0.03% |
| Assay (HPLC) (anhydrous and solvent-free) | | 98.0% to 101.5% | | 99.5% |
| Water | | Not more than 0.2% | | 0.01% |
| Conclusion | | Conforms with USP-NF 2022 | | |

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