

## METAPHARMACEUTICAL

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20/03/2020

## Zein Biotechnology Co.,Ltd. Certificate Of

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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 rotat                                                                                                                                                                                                                                                                                                                    | ion, 589 nm,   |                                                                                                                                                                                                                                                                            |              |                                                                                                                     |
| 20°C, c = $3%$ (m/v) in ethanol                                                                                                                                                                                                                                                                                                           |                | -48.0° to -51.0°                                                                                                                                                                                                                                                           |              | -49.3°                                                                                                              |
| (anhydrous and so                                                                                                                                                                                                                                                                                                                         | lvent-free)    |                                                                                                                                                                                                                                                                            |              |                                                                                                                     |
| 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 + TL | .c)                                                                                                                                                                                                                                                                        |              |                                                                                                                     |
| 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 (G                                                                                                                                                                                                                                                                                                                      | c)             |                                                                                                                                                                                                                                                                            |              |                                                                                                                     |
| 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                                                                                                                                                                                                                                                  |              |                                                                                                                     |
| Orlistat related compound E (HPLC) Formylleucine (HPLC) Orlistat open ring epimer(HPLC) Orlistat open ring amide(HPLC) D-Leucine orlistat(HPLC) Any individual unspecified impurity(HPLC) Residual Solvents (GC) n-Heptane Isopropyl ether Methanol Tetrahydrofuran Benzene Residue on Ignition Assay (HPLC) (anhydrous and solvent-free) |                | Not more than 0.2%  Not more than 0.2%  Not more than 0.1%  Not more than 0.2%  Not more than 0.1%  Not more than 5000ppm  Not more than 5000ppm  Not more than 3000ppm  Not more than 720ppm  Not more than 2ppm  Not more than 0.1%  98.0% to 101.5%  Not more than 0.2% |              | Not detected 0.01% Not detected 0.02% 0.06%  930ppm Not detected Not detected Not detected 0.4ppm 0.03% 99.5% 0.01% |

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