

Certificate of Analysis

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| Product Name | Leuprolide Acetate | Batch No. | M23X02012 |
| CAS No. | 74381-53-6 | MFG. Date | Feb 01, 2023 |
| CAT No. | I004762 | Retest Date | Feb, 2025 |
| Items | Specification | Results | |
| Appearance | White powder | Conforms | |
| Solubility | Very soluble in water, 1% acetic acid | Conforms | |
| Specific Optical Rotation | -38.0 ° to -42.0 ° (anhydrous and acetic acid free substance) | -38.8° | |
| Water | ≤ 8.0% | 3.9% | |
| Amino acid analysis | Arg 0.9-1.1 His 0.9-1.1 Leu 1.8-2.2 Pro 0.9-1.1 Tyr 0.9-1.1 Glu 0.9-1.1 Ser present No more than the traces of the other amino acids are present, with the exception of tryptophan. | Arg 1.0 His 1.0 Leu 1.9 Pro 1.0 Tyr 0.9 Glu 1.1 Ser present No more than the traces of the other amino acids are present, with the exception of tryptophan. | |
| Related Substances | Unspecified impurity for each impurity: ≤1.0% | 0.25% (single largest impurity) | |
| Purity (HPLC) | ≥ 98% | 99.4% | |
| Assay | 97.0%-103.0% (anhydrous and acetic acid free substance) | 98.8% | |
| Acetic acid | 4.7%-9.0% | 6.8% | |

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|---|---|----------|
| MS | 1209.4±1.0 | Conforms |
| Bacterial endotoxins | Less than 16.7IU/mg | Conforms |
| Residual solvent Methanol Acetonitrile Triethylamine | ≤ 3000 ppm ≤ 410 ppm ≤ 320 ppm | Conforms |
| Conclusion | Corresponds. | |
| Storage Condition | Refrigerator. | |

QC:

Alex Foster

QA:

Felix Hobart