

Certificate of Analysis

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%	

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