



**BIMAL PHARMA PVT. LTD.**

**TYPICAL CERTIFICATE OF ANALYSIS**

**Name of the Product : NEOTAME FCC X / USP 39**

<b>Sr. No.</b>	<b>TEST</b>	<b>SPECIFICATIONS</b>	<b>RESULTS</b>
1.	Appearance	White to Off-White Crystalline Powder	White Crystalline Powder
2.	Solubility	Sparingly soluble in water & very soluble in Alcohol	Conforms
3.	Specific Rotation	- 40 .0° to - 43.4°	- 41.59°
4.	Water Content	Less than 5.0 %	4.30 %
5.	pH	5.0 to 7.0	5.75
6.	Identifications	As per USP and FCC X	Conforms
7.	Residue on Ignition	Less than 0.2%	0.02%
8.	Lead Content	Less than 1 ppm	Not Detected
9.	Related Substances	Related Compound A: ≤1.5% Total other Impurities: ≤2.0%	0.29% 0.11%
10.	Residual Solvents	Methanol ≤0.1% Ethanol ≤0.1%	Not Detected Not Detected
11.	Assay	97.0% to 102.0%	99.87%

**Conclusion : Conforms with above specification of USP 39 / FCC X.**

**ANALYST**

**LAB-IN-CHARGE**