



# Gentaur

## CERTIFICATE OF ANALYSIS

Product: Molgramostim for Injection (Recombinant Human Granulocyte Macrophage Colony Stimulating Factor), 300ug/vial

Supplier:	Gentaur Molecular Products BVBA.	Presentation:	Box with 1vial
Mfg. Date:	2020/05/22	Batch No.:	20200SA12
Storage:	2-8°C	Expiry Date:	2023/05/21

TESTS	SPECIFICATIONS	RESULTS
Identification	Positive reaction with anti-hGM-CSF antibody	Positive
Appearance	Looks like a white to off-white crisp cake. After reconstitution, the solution is clear	Complies
Particulate Matter	Visible Particles	Complies
	Sub-visible Particles	12/vial 1/vial
Mass Variation	Acceptance value: 10.0%	2.2%
pH	6.5-7.5	7.1
Water	3.0%	0.7%
Osmolality	250-370 mOsmol/kg	324 mOsmol/kg
Residual Antibiotic Activity	No residual antibiotic activity should be detected	Complies
Potency	80%-150%	104%
Sterility	2.64x10 <sup>6</sup> -4.95x10 <sup>6</sup> IU/vial	(3.43x10 <sup>6</sup> IU/vial)
	Sterile	Sterile
Pyrogen(Rabbit)	Summed response of rabbits does not exceed the specified temperature	Complies
	<0.25 EU/vial	<0.25 EU/vial

Approved by:




Date: 2021/03/19