Recombinant Human GM-CSF
300 µg : Quantity
rHuGM-CSF-300 : Code
201103A07 : Batch
31/03/2019: Exp.Date
2 – 8 °C: Storage

CERTIFICATE OF ANALYSIS

Test	Specifications	Results
Identification	Positive	Positive
Appearance	Looks like a white to off-white crisp cake. After reconstitution, the solution is clear, colorless	Complies
Particulate Matter Visible particles	Free of visible foreign particles	Complies
Matter Sub-visible particles	≥ 10µm: ≤ 6000/vial ≥ 25µm: ≤ 600/vial	8 1
Mass Variation	Complies to EP 7th	Complies
pH	6.50 – 7.50	7.06
Moisture	≤ 3.0%	0.6%
Osmolality (mOsmol/kg)	250-370	334
Residual Antibiotic Activity	No residual antibiotic activity should be detected	Complies
Potency	80% - 150% (2.64-4.95x10^6IU/vial)	108% (3.56x10^6IU/vial)
Sterility	Sterile	Sterile
Abnormal Toxicity Test	Complies to EP 7th /CP 2010	Complies
Pyrogen Test (Rabbit)	Complies to EP 7th	Complies
Bacterial Endotoxins	Not more than 0.25 EU/vial	Less than 0.25 EU/vial
Conclusion	Complies	Complies

BSE/TSE Declaration: GENTAUR BVBA manufactures GMP recombinant human GM-CSF (rHuGM-CSF-300) products under GMP controls and certifies that the entire product line is BSE (Bovine Spongiform Encephalopathy) and TSE (Transmissible Spongiform Encephalopathy) free. GENTAUR BVBA manufactures its products in Belgium.

Reconstitution : use 3000µl water for injection

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