



Recombinant Human GM-CSF

50 µg : Quantity
 rHuGM-CSF-50 : Code
 200903A05 : Batch
 2014/03/03 : 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
Sub-visible particles	$\geq 10\mu\text{m}: \leq 6000/\text{vial}$ $\geq 25\mu\text{m}: \leq 600/\text{vial}$	181 10
Mass Variation	Complies to EP 6 th	Complies
PH	6.50 – 7.50	7.19
Moisture	$\leq 3.0\%$	1.1%
Potency	80% - 150% (4.40-8.25x10 ⁵ IU/vial)	115% (6.32x10 ⁵ IU/vial)
Sterility	Sterile	Sterile
Abnormal Toxicity Test	Complies to EP 6 th /CP 2005	Complies
Pyrogen Test (Rabbit)	Complies to EP 6 th	Complies
Bacterial Endotoxins	Not more than 0.25 EU/vial	Less than 0.25 EU/vial
Conclusion	Complies	Complies

Reconstitution : use 500µl water for injection

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