



Recombinant Human GM-CSF

50 µg : Quantity
 rHuGM-CSF-50 : Code
 200802A03 : Batch
 22/02/2010 : Exp.Date

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	$\geq 10\mu\text{m}: \leq 6000/\text{vial}$ $\geq 25\mu\text{m}: \leq 600/\text{vial}$	393 21
Weight of content	90% - 110% of the stated value	Complies
PH	6.50 – 7.50	7.22
Moisture	$\leq 3.0\%$	0.6%
Potency	80% - 150% ($4.40\text{-}8.25 \times 10^5 \text{IU}/\text{vial}$)	114% ($6.25 \times 10^5 \text{IU}/\text{vial}$)
Sterility	Sterile	Sterile
Abnormal Toxicity Test	Complies to EP 5 th /CP 2005	Complies
Pyrogen Test (Rabbit)	Complies to EP 5 th	Complies
Bacterial Endotoxins	Not more than 0.25 EU/vial	Less than 0.25 EU/vial
Conclusion	Complies	Complies