



Recombinant Human GM-CSF

300 µg : Quantity
 rHuGM-CSF-300 : Code
 200806A09 : Batch
 17/06/2011 : 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	$\geq 10\mu\text{m}: \leq 6000/\text{vial}$ $\geq 25\mu\text{m}: \leq 600/\text{vial}$	243 13
Weight of content	90% - 110% of the stated value	Complies
PH	6.50 – 7.50	7.21
Moisture	$\leq 3.0\%$	1.1%
Potency	80% - 150% ($2.64\text{-}4.95 \times 10^6 \text{IU}/\text{vial}$)	112% ($3.68 \times 10^6 \text{IU}/\text{vial}$)
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