



rHuG-CSF 300µg
 300 µg :Quantity
 rHuG-CSF-300 : Code
 200806B15 : Batch
 2010/06/11 : Exp.Date
 2 – 8°C : Storage

CERTIFICATE OF ANALYSIS

Tests	Specifications	Results
Identification (Immunoblot)	Positive	Positive
Appearance	Clear, colorless solution	Complies
Particulate Matter		
Visible particles	Free of Visible foreign particles	Complies
Sub-visible particles	$\geq 10\mu\text{m}$: $\leq 6000/\text{vial}$ $\geq 25\mu\text{m}$: $\leq 600/\text{vial}$	258 20
Mass Variation	Complies to EP 5 th	Complies
pH	3.50 – 4.50	4.22
Potency	80% - 150% of stated value ($1.92 - 3.60 \times 10^7 \text{IU}/\text{vial}$)	122% ($2.94 \times 10^7 \text{IU}/\text{vial}$)
Sterility	Sterile	Sterile
Abnormal Toxicity test	Complies to EP 5 th	Complies
Pyrogen Test (Rabbit)	Complies to EP 5 th	Complies
Bacterial Endotoxins	Not more than 0.25EU/ml	Less than 0.25EU/ml
Conclusion	Complies	Complies

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