



rHuG-CSF 75µg
 75 µg :Quantity
 rHuG-CSF-75 : Code
 200802B06 : Batch
 2010/02/15 : 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	$\geq 10\mu\text{m}$: $\leq 6000/\text{vial}$ $\geq 25\mu\text{m}$: $\leq 600/\text{vial}$	848 34
Mass Variation	Complies to EP 5 th	Complies
pH	3.50 – 4.50	4.23
Potency	80% - 150% of stated value (4.80 – 9.000 x 10 ⁶ IU/vial)	127% (7.62 x 10 ⁶ IU/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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