



Recombinant Human Interleukin-2 (rHuIL-2)

3MIU/vial :Quantity

rHuIL-2-3MIU : Code

08F02 : Batch

01/09/2015: 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	≥10µm: ≤6000/vial ≥25µm: ≤600/vial	162 41
Mass Variation	Complies to EP 6 th	Complies
pH	4.00 – 5.00	4.68
Potency	80% - 150% of stated value (2.40 – 4.50 x 10 ⁶ IU/vial)	113% (3.40 x 10 ⁶ IU/vial)
Sterility	Sterile	Sterile
Abnormal Toxicity test	Complies to EP 6 th	Complies
Pyrogen Test (Rabbit)	Complies to EP 6 th	Complies
Bacterial Endotoxins	Not more than 1 EU/ml	Less than 1 EU/ml
Conclusion	Complies	Complies