Recombinant Human Interferon alfa-2b

(rHuIFNa-2b)

3MIU/vial :Quantity

rHuIFN a-2b : Code

200807E01 : Batch

2010/07/04 : 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 paticles** | **Complies** |
|  **Sub-visible particles** | **≥10µm: ≤6000/vial****≥25µm: ≤600/vial** | **179****7** |
| **Mass Variation** | **Complies to EP 5th** | **Complies** |
| **pH** | **6.50 – 7.50** | **6.87** |
| **Potency** | **80% - 150% of stated value****(2.40 –4.50 x 106IU/vial)** | **109%****(3.28 x 106IU/vial)** |
| **Sterility** | **Sterile** | **Sterile** |
| **Abnormal Toxicity test** | **Complies to EP 5th** | **Complies** |
| **Pyrogen Test (Rabbit)** | **Complies to EP 5th** | **Complies** |
| **Bacterial Endotoxins** | **Not more than 1 EU/ml** | **Less than 1 EU/ml** |
| **Conclusion** | **Complies** | **Complies** |

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