

Certificate of Analysis

Product Name : Insulin, Human Recombinant, From Yeast

Cat No : I4600

Lot No : 03192411

| TEST | Specification | Result |
|---|------------------------------|------------|
| Appearance | White to almost white powder | PASS |
| Assay (dry basis), as per current EP | > 95 % | 99.9 % |
| Bioburden, Total microbial limit | < 300 CFU/gm | < 5 CFU/gm |
| Bioidentity | > 15 U/mg | PASS |
| Potency (dry basis), as per current USP | > 28 U/mg | 29 U/mg |
| Host cell derived proteins, as per current USP/EP | ≤ 10 ppm | ≤ 10 ppm |
| Loss on drying, as per current USP | ≤ 10 % | 2.8 % |
| Sulfate Ash (NMT), as per current EP | ≤ 2.5 % | 0.1% |
| Zinc (dry basis), as per current USP/EP | ≤ 1% | 0.2 % |
| Endotoxin Level, as per current USP/EP (EU/mg in USP is equivalent to IU/mg in EP) | ≤ 10 EU/mg | < 5 EU/mg |

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