

Certificate of Analysis

Certificate of Analysis

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Product Name

Eloctate lyophilizate 500 IU

Article Number/Batch Number

4008-4200/ VT1035

Swedish Orphan Biovitrum AB (publ)

SE-112 76 Stockholm, Sweden

Phone +46 8 697 20 00

info@sobi.com, www.sobi.com

Release Specification: C-06-107-16

Market: Russia

Certificate of Analysis:

| Test | Method | Acceptance criteria | Result |
|--|------------|--|----------------------------------|
| Appearance, Lyophilized | PRCD-21746 | White to off white cake to Powder | conforms |
| Reconstitution time | PRCD-21746 | ≤120 seconds | 10 s |
| Residual moisture <i>Water</i> | PRCD-26652 | ≤1.5% | < 0.5% |
| Appearance of the Reconstituted Solution <i>Color, Clarity, Particulate matter (visible)</i> | PRCD-17102 | Color (Y scale): <Y4 Clarity: <18 NTU Essentially free of particles | Conforms Conforms conforms |
| pH | PRCD-4010 | 6.5-7.5 | 6.9 |
| Osmolality-Vapor pressure <i>Osmolality</i> | PRCD-11296 | 373 to 495 mOsm/kg | 440 mOsm/kg |
| Calcium ion assay <i>Calcium</i> | PRCD-32233 | 3 to 8 mM | 5 mM |
| Polysorbate 20 | PRCD-27042 | 0.009 to 0.020 % | 0.014 % |
| L-Histidine | PRCD-42613 | 5.4 to 8.0 mM | 6.6 mM |
| Sodium | PRCD-41929 | 164 to 246 mM | 202 mM |
| Chloride | PRCD-41931 | 172 to 259 mM | 232 mM |
| Sucrose | PRCD-41349 | 1.06 to 1.60% | 1.28 % |
| Fc Integrity <i>Fc fragment integrity</i> | PRCD-34100 | ≥73% of Reference standard | 94 % |
| Identity, Non reducing SDS-PAGE | PRCD-20482 | Compares to reference standard | conforms |
| Identity, Chromogenic activity assay | PRCD-25081 | Meets biological activity specification | conforms |
| Protein Concentration <i>Total Protein</i> | PRCD-32919 | 13.1 – 52.1 µg/mL | 25.5 µg/mL |
| Chromogenic Activity Assay (Specific activity) <i>Specific activity</i> | PRCD-25081 | 4200 to 10000 IU/mg | 6617 IU/mg |
| Chromogenic Activity Assay (activity/vial) <i>Specific activity</i> | PRCD-25081 | 400 to 625 IU/vial | 505 IU/vial |
| Non-Reducing SDS-PAGE <i>Purity</i> <i>Main Component, Molecular fragments</i> | PRCD-20482 | % purity ≥95.0% No Single Impurity >2.0% Non-processes Isoforms: ≤39.0% | 99.0 % Conforms 24.9 % |

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| | | | |
|--|---------------|---|---------------------------------------|
| Size Exclusion Chromatography <i>Purity</i> <i>High Molecular Impurities</i> <i>(Aggregates)</i> | PRCD-22895 | % Total Aggregates ≤ 1.8% | 1.0 % |
| Endotoxins <i>Bacterial Endotoxins</i> | Ph Eur 2.6.14 | ≤ 5.0 EU/mL | < 0.5 EU/ml |
| Sterility | Ph Eur 2.6.1 | No Growth | No Growth |
| Particulate matter <i>Sub-visible</i> | Ph Eur 2.9.19 | ≥ 10 µm particles: ≤ 6000 Particles/vial ≥ 25 µm particles: ≤ 600 Particles/vial | 82 Particles/vial 2 Particles/vial |

Reviewed by:

2020-12-11

Date/Signature

QA Supplier manager

Title

Swedish Orphan Biovitrum AB (publ)

Approved by:

2020-12-11

Date/Signature

Ewelina Juneja

Delegated Qualified Person

Swedish Orphan Biovitrum AB (publ)