Type of Document

Certificate of Compliance

Article No	1008-0512
Batch No	3957601B
Revision	A1

Swedish Orphan Biovitrum AB (publ)
SE-11276 Stockholm, Sweden
Phone +46 8 697 20 00
INFO@SOBI.COM Stockholm
SWEDEN
WWW.SOBI.COM

Product name/dosage form and strength	Eloctate 1500 IU lyophilizate for preparation of solution for intravenous administration
Market/Importing countries	RU
Market Authorization no	LP-006034
Article No	1008-0512
Batch No	3957601B
Package size and type	1 vial of powder, 1 solvent (syringe) 3 ml, 1 piston rod, 1 adapter for the bottle, 1 set for infusions, 2 alcohol napkins, 2 patches, 1 gauze napkin, packs of cardboard
Quantity of Released units	6898
Manufacturing date	11-Nov-2022
Expiry date	Oct-2026
Product Specification No	C-06-107-24

I hereby certify that all the manufacturing stages of this batch of finished product have been carried out in compliance with the GMP requirements of the EU, and with the specifications in the Normative Document ND 006034-241221 of the Marketing Authorization, with the exception of the following tests:
Lyophilizate: 1. Appearance of the reconstituted solution and Abnormal toxicity – not performed by manufacturer. 2. Visible particles tested as “essentially free of visible particles”.
Diluent (Solvent): 1. Carbon dioxide, Heavy metals, Clarity, Color – not performed by manufacturer. 2. Visible particles tested as “practically free from visible particles”. 3. Residue on evaporation tested for limit 0.004%.
The batch processing, packaging and analysis records, see attached Certificate of Analysis, were reviewed and found to be in compliance with GMP. Deviations (if any) have been reviewed, assessed for impact.

Signed by:
Rim Fayad

Role:
QP

*This Certificate has been signed and generated electronically and the electronic signature is equivalent to a handwritten signature

Digitally signed by:
Rim Fayad
DN: DC=com DC=biovitrum
OU=Organization
CN=Rim Fayad
E=Rim.Fayad@sobi.com
Reason: Approve
2023.06.22T14:57:58+02:00

Swedish Orphan Biovitrum AB (publ)
SE-11276 Stockholm, Sweden
Phone +46 8 697 20 00
INFO@SOBI.COM Stockholm
SWEDEN
WWW.SOBI.COM

The following parties have been involved in manufacturing the product:

Manufacturing step	Site/authorization number/GMP certificate no.
Release Testing	
	Vetter Pharma-Fertigung GmbH & Co. KG Eisenbahnstrasse 2-4 88085 Langenargen GERMANY Manufacturing authorisation number: DE_BW_01_MIA_2022_0099 FUJIFILM Diosynth Biotechnologies Denmark ApS Biotek Allé 1 3400 Hillerød DENMARK GMP certificate number: DK H 10000156 Vetter Pharma-Fertigung GmbH & Co. KG Mooswiesen 2 88214 Ravensburg GERMANY Manufacturing authorisation number: DE_BW_01_MIA_2022_0100 Vetter Pharma-Fertigung GmbH & Co. KG Schuetzenstrasse 87 88212 Ravensburg GERMANY Manufacturing authorisation number: DE_BW_01_MIA_2022_0101 Vetter Pharma-Fertigung GmbH & Co. KG Eisenbahnstrasse 2-4 88085 Langenargen GERMANY Manufacturing authorisation number: DE_BW_01_MIA_2022_0099 Vetter Pharma-Fertigung GmbH & Co. KG Mooswiesen 2 88214 Ravensburg GERMANY Manufacturing authorisation number: DE_BW_01_MIA_2022_0100 Vetter Pharma-Fertigung GmbH & Co. KG Schuetzenstrasse 87 88212 Ravensburg GERMANY Manufacturing authorisation number: DE_BW_01_MIA_2022_0101

Type of Document

Certificate of Compliance

Article No	1008-0512
Batch No	3957601B
Revision	A1

Swedish Orphan Biovitrum AB (publ)
SE-11276 Stockholm, Sweden
Phone +46 8 697 20 00
INFO@SOBI.COM Stockholm
SWEDEN
WWW.SOBI.COM

Packaging Info	
	Rechon Life Science AB Soldattorpsvägen 5 21613 Limhamn SWEDEN Manufacturing authorisation number: 5.9.1-2021-101141

Type of Document

Certificate of Compliance

Article No 1008-0512
Batch No 3957601B
Revision A1

Swedish Orphan Biovitrum AB (publ)
SE-11276 Stockholm, Sweden
Phone +46 8 697 20 00
INFO@SOBI.COM Stockholm
SWEDEN
WWW.SOBI.COM

The following parties have been involved in manufacturing the product:

Manufacturing step	Site/authorization number/GMP certificate no.
Sterile Diluent	
Article No 5008-0000 Batch No BZVD15BA (Labelled: 3866801A)	Vetter Pharma-Fertigung GmbH & Co. KG Eisenbahnstrasse 2-4 88085 Langenargen GERMANY Manufacturing authorisation number: DE_BW_01_MIA_2022_0099
Drug Product	
Article No 4008-8500 Batch No BUVK04 (Labelled: 3957601B)	Vetter Pharma-Fertigung GmbH & Co. KG Mooswiesen 2 88214 Ravensburg GERMANY Manufacturing authorisation number: DE_BW_01_MIA_2022_0100
Drug Substance	
Article No 6008-0003 Batch No AP6-19-RF8-011	Biogen Inc 5000 Davis Drive Research Triangle Park NC 27709 UNITED STATES GMP Certificate: DK H 00093817

Final batch release	
	Swedish Orphan Biovitrum AB (publ) Strandbergsgatan 49 112 51 Stockholm SWEDEN Manufacturing Authorisation Number: 5.9.1-2022-062946