

Issued by:

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ITALY



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Certificate of Analysis**Certificate Date**

21-Dec-2021

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Product: SOTROVIMAB SOLUTION VIAL 500MG 1X1

Product Code: 60000000132498

Regulatory Statement:

We hereby certify that the above information is authentic and accurate. This batch of product has been manufactured, including packaging/labelling and quality control in full compliance with the GMP requirements of the local Regulatory Authority, taking into account the type of authorization under which the product is released. The batch processing, packaging and analysis records were reviewed and found to be in compliance with GMP and has been released by a Qualified Person.

Batch Number: UK3F

Expiry Date: 03-2022

Manufacturing Date: 03-2021

Importing Countries: United Kingdom

Description	Specification	Results
Color	Report result (refer to Ph Eur)	Complies
Clarity	≤ 18.0 NTU	Complies
Visible particles	Complies with required specification	Complies
Sub-Visible Particles ≥10um USP-EP	≤ 6000 pt/amp	158
Sub-Visible Particles ≥25um USP-EP	≤ 600 pt/amp	0
Sub-Visible Particles ≥2um USP-EP	Report result	4176
Sub-Visible Particles ≥5um USP-EP	Report result	902
pH	5.5 – 6.5	5.9
Osmolality	240 – 340 mOsm/kg	285
Extractable volume	> 8 mL/vial	Complies
Protein Concentration UV280	56.3 – 68.7	62.2
Identity ELISA	Complies with required specification	Complies
Identity cIEF	Complies with required specification	Complies
Charge Variant – cIEF % Main	≥ 50.0 %	66.8
Charge Variant – cIEF % Acidic	≤ 45.0 %	20.3
Charge Variant – cIEF % Basic	≤ 25.0 %	12.9
Purity - SE-HPLC % Main	≥ 90.0 %	98.1
Purity - SE-HPLC % HMWS	≤ 5.0 %	1.8
Purity - CE-SDS Reduced % LC+HC	≥ 90.0 %	98.2
Purity - CE-SDS Non-Reduced % Main	≥ 90.0 %	99.3
Bacterial Endotoxin	< 9.0 EU/mL	< 1.0
Sterility	Complies with required specification	Complies
Potency ELISA – relative potency	70 – 130%	106
Polysorbate 80	0.010% - 0.070%(w/v)	0.037

Signature Silvia Dal Pozzo

Name SILVIA DAL POZZO

Qualified Person

Date 21-DEC-2021