
Certificate of Analysis

Description of the Material:

- (a) Chemical Name: Trastuzumab Biosimilar Human anti-Her2 mAb
- (b) Molecular Weight: 150 kDa
- (c) Appearance: Colorless to white lyophilized powder in a microcentrifuge tube
- (d) Amount: Each tube contains 25 µg of lyophilized product
- (e) Reconstitution: Dissolve in 25 µL or more of sterile water to achieve a concentration of 1 mg/mL or lower.

Antibody Information:

- (a) Immunogen: HER2/c-neu receptor (ErbB family)
- (b) Expression Host: CHO stable cell line (biosimilar to trastuzumab)
- (c) Class: Human IgG1 Kappa
- (d) Antibody Type: Monoclonal
- (e) Applications: Serves as a quantitative or qualitative control standard in assays (ELISA, FACS, IF, IHC, IP, WB)

SKU Code and Lot Number:

- (f) SKU Code: CM51000-25UG
- (g) Lot Number: S609.S6.0528E

Purity, and Other Specifications:

- (a) Purity: >99% by SEC HPLC
- (b) Endotoxin Level: ≤0.1 EU /mg of antibody by the LAL method

Intended use: For research and development use only.

Hazard Information: See SDS.

Shelf life, Storage/Stability as Supplied: The product is fairly stable as solid at ambient temperature. Recommended long-term storage is at -20 °C or preferably in a -80 °C freezer. The reconstituted lyophilized tubes should be used immediately following reconstitution with sterile water. If not used immediately, the reconstituted tubes can be stored for up to 24 hours in a 2–8 °C refrigerator.

Expiration Date: 1 year after receiving if stored at -20 °C or below.

Certified by: 

Certifying Officer: Subhakar Dey

Date Appendix: HPLC Data

Injection date: Fri, 30. May. 2025
C:\HPCHEM\1\DATA\HPLC4_25\05300004.D
Instrument: Instrument 1

Injection Time: 11:19:36 AM
Report Style: CM_Ext



CellMosaic, Inc. www.cellmosaic.com
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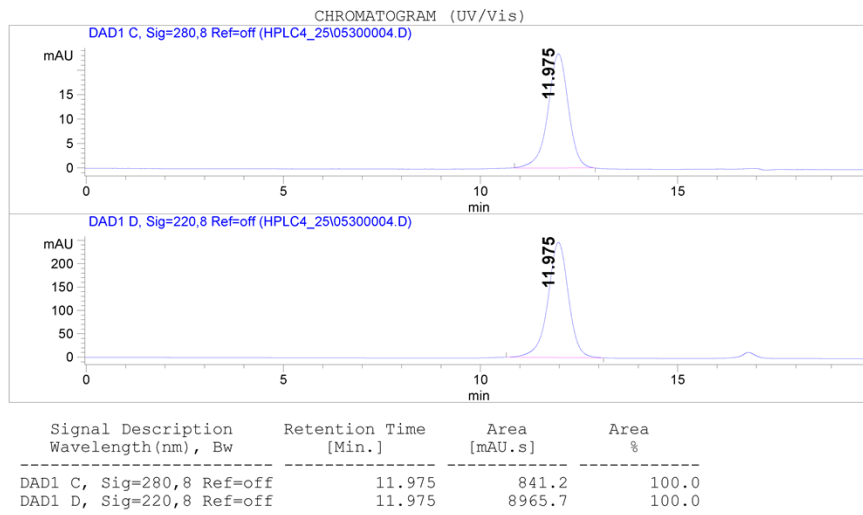
SEC HPLC Analysis Data

HPLC ANALYSIS DATA

Data Acquired By: QC
Sample Location: Vial 3
Sample Name: Trastuzumab biosimilar 25 UG

Actual injection Volume: 5.0 uL
Sequence Name:
Method: C:\HPCHEM\1\METHODS\C14-3002.M
Pressure: 38.2 bar
Flow: 0.400 uL/min
Temp (C): 25.0 C

-- SAMPLE INFORMATION --
Lot: S609.S6.0528E
1 mg/mL



*****END OF REPORT*****

Injection date: Wed, 28. May. 2025
C:\HPCHEM\1\DATA\HPLC5_25\05280003.D
Instrument: Instrument 1

Injection Time: 11:19:56 AM
Report Style: CM_EXTER



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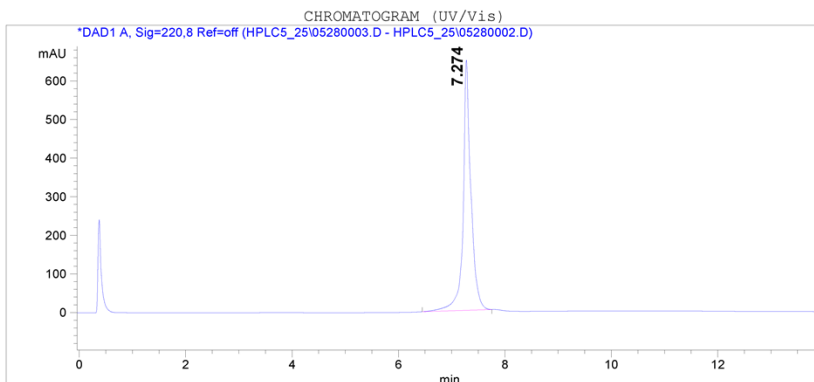
HIC HPLC Analysis Data

HPLC ANALYSIS DATA

Data Acquired By: QC
Sample Location: P1-A-02
Sample Name: S609.S3.0528E

Actual injection Volume: Actua->
Sequence Name:
Method: C:\HPCHEM\1\METHODS\C4-9601.M
Pressure: 87.6 bar
Flow: 0.800 uL/min
Temp (C): 30.0 C

-- SAMPLE INFORMATION --
Trastuzumab biosimilar
x20.154



Signal Description Wavelength(nm), Bw	Retention Time [Min.]	Area [mAU.s]	Area %
DAD1 A, Sig=220,8 Ref=off	7.274	6599.0	100.0

*****END OF REPORT*****