synedica

Certificate of Analysis

PUBLISHED BATCH CERTIFICATE

Accession No.	SYN-COA-2026-RET040-216
Testing Laboratory	Synedica Analytical Laboratories
Report Date	Nov 3, 2026

SAMPLE IDENTIFICATION

Product	Retatrutide 40mg Injection Pen Kit	Batch	SYN-RET040-216
Analyte	Retatrutide	Manufactured	Nov 3, 2026
Format	Injection Pen	Expiry	Dec 30, 2026
Nominal Amount	40mg	Assayed Purity	99.0%
Molecular Formula	$C_{221}H_{342}N_{44}O_{68}$	Net Content	39.6 mg
Molecular Weight	4,731.4 Da	Appearance	Clear, colourless solution, free from visible particles
Storage	Store at 2–8 °C, protected from light. Do not freeze.		

All analysis performed under documented analytical methods aligned to European Pharmacopoeia (Ph. Eur.) reference procedures: HPLC-UV (C18, 220 nm) for purity and related substances; ESI-MS (≤ 5 ppm) for identity confirmation.

ANALYTICAL RESULTS

TEST NAME	METHOD	SPECIFICATION	RESULT	STATUS
Appearance	Visual inspection, Ph. Eur. 2.2.1	Clear, colourless solution, free from visible particles	Conforms	✓ PASS
Identity	ESI-MS, ≤ 5 ppm	Confirmed $[M+5H]^{5+}$ = 947.3	Confirmed	✓ PASS
Assay (content)	RP-HPLC-UV, C18, 220 nm	95.0 – 105.0% of label claim	101.9%	✓ PASS
Purity	RP-HPLC-UV, C18, 220 nm	≥ 98.0%	99.0%	✓ PASS
Related substances	RP-HPLC-UV, area normalisation	≤ 2.0% total	1.0%	✓ PASS
pH	Potentiometry, Ph. Eur. 2.2.3	7.0 – 8.0	7.20	✓ PASS
Osmolality	Ph. Eur. 2.2.35	270 – 330 mOsm/kg	285 mOsm/kg	✓ PASS

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TEST NAME	METHOD	SPECIFICATION	RESULT	STATUS
Preservative content	RP-HPLC-UV (m-cresol)	85.0 – 115.0% of label claim	95.1%	✓ PASS
Extractable volume	Ph. Eur. 2.9.17	≥ label claim	Conforms	✓ PASS
Container closure integrity	Dye ingress, ASTM F1929	No ingress	Conforms	✓ PASS
Visible particles	Ph. Eur. 2.9.20	Practically free from visible particles	Conforms	✓ PASS
Particulate matter (sub-visible)	Light obscuration, Ph. Eur. 2.9.19	Meets Ph. Eur. limits for parenteral use	Conforms	✓ PASS
Sterility	Membrane filtration, Ph. Eur. 2.6.1	No growth at 14 days	Conforms	✓ PASS
Bacterial endotoxins	LAL kinetic chromogenic, Ph. Eur. 2.6.14	< 10.0 EU/mL	< 0.13 EU/mL	✓ PASS
Elemental impurities	ICP-MS, ICH Q3D / Ph. Eur. 2.4.20	Meets ICH Q3D parenteral limits	Conforms	✓ PASS

15 total · 15 passed · 0 failed · 0 pending

CONCLUSION

Listed tests marked pass

15 of 15 tests are marked pass.

Full release panel for batch SYNRETA40. 15 tests performed against documented Synedica specifications.

PASS

AUTHORISATION

Released by

Quality Assurance, Synedica Laboratories

Electronically authorised — no handwritten signature required.

Accreditation: ISO/IEC 17025 aligned methods

SYN-COA-2026-RET040-2106

PUBLISHED BATCH CERTIFICATE

Verify this certificate at https://www.synedicalab.io

Valid Until: Dec 30, 2026

This Certificate of Analysis records testing by Synedica Analytical Laboratories and applies solely to the batch identified above. The formulation described is supplied for research and laboratory use only. Not for human consumption, or for clinical, diagnostic, or therapeutic application. Batch traceability and analytical records are retained by Synedica Laboratories.

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