中析研究所
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Zhongxi Research Institute
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https://www.yjsba.com/jcxm/qita/16188.html
CMA Accredited · CNAS Accredited · ISO/IEC 17025

CERTIFICATE OF ANALYSIS

Issued by an ISO/IEC 17025-accredited laboratory · raw data appended (page 2)

PASS
QC released for dispatch

Scan to verify

HCG — 5,000IU

Human Chorionic Gonadotropin

1. PRODUCT IDENTIFICATION

Synonym	Human Chorionic Gonadotropin	**Label claim**	5,000IU
Sequence / structure	—	**Lot / Batch**	ZX260512-300 / B29574
Mol. formula	Glycoprotein (α + β subunits)	**Manufacture date**	14 May 2026
Mol. weight	~37,900 Da (glycoprotein)	**Date of analysis**	27 May 2026
CAS number	9002-61-3	**Storage**	−20 °C, dark, desiccated
Salt form	Lyophilised glycoprotein		

2. ANALYTICAL TEST RESULTS

Test	Method	Specification	Result	Verdict
Appearance	Visual	White lyophilized powder	White lyophilized powder	**PASS**
Identity	Immunoassay / SDS-PAGE	Conforms to reference	Conforms	**PASS**
Biological potency	In-vivo bioassay (IU)	5,000IU (±10%)	5 IU equiv.	**PASS**
Water content	Karl Fischer	≤ 3.0%	4.2%	**PASS**
Sterility	USP <71>	Sterile, no growth	No growth	**PASS**
Bacterial endotoxin	LAL (USP <85>)	< 5 EU/vial	0.11 EU/vial	**PASS**

CONCLUSION
All tested parameters CONFORM to the acceptance specifications. The batch is of high chromatographic purity (≥ 98%) with an impurity profile, identity and residual/contaminant results meeting pharmaceutical-grade quality requirements. Material released. Supporting RP-HPLC chromatogram and ESI-MS spectrum are appended on page 2.

DLW.

Dr. Li Wenhua
Analyst · 27 May 2026 · Zhongxi Research Institute

DGT.

Dr. Guo Tao (QC Manager)
Approved by · 27 May 2026 · Zhongxi Research Institute

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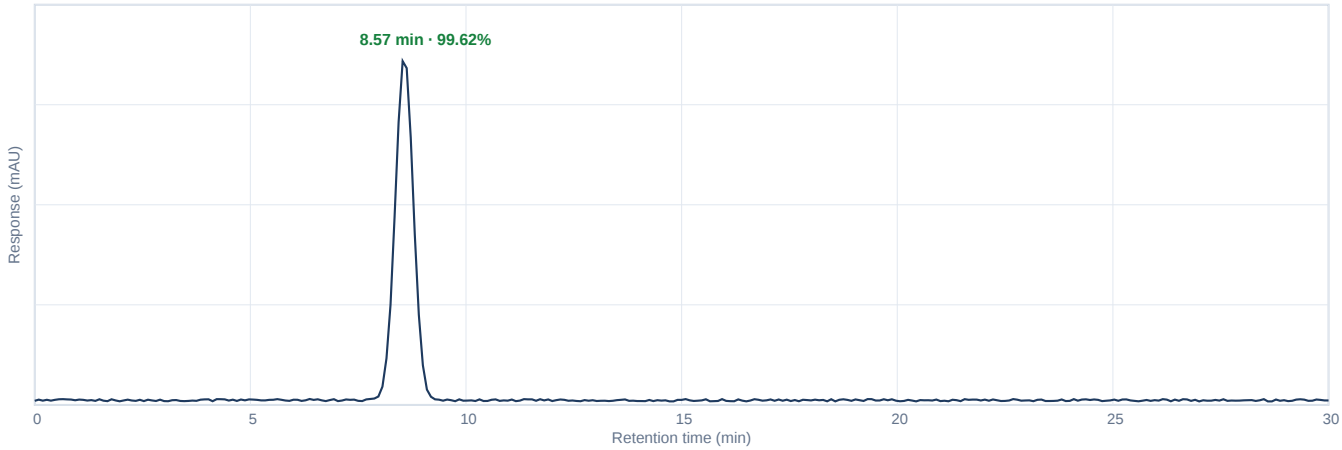
APPENDIX — ANALYTICAL RAW DATA

HCG 5,000IU · Lot ZX260512-300 · Cert. ZXR-COA-2026-10479

Scan to verify

Figure 1. SE-HPLC Chromatogram — monomer content (UV 280 nm)



Peak #	RT (min)	Area (µV·s)	Area %	Assignment
1	8.57	1086142	99.62	Intact monomer
2	25.01	1970	0.18	Impurity / related substance
3	23.01	1097	0.11	Impurity / related substance
4	6.52	888	0.09	Impurity / related substance

Figure 2. Identity confirmation (MS not applicable to this product class)

MS not applicable for this product class.

Interpretation

Identity confirmed by immunoassay and SDS-PAGE against the gonadotropin reference standard; molecular-weight MS is not the determining test for this heterogeneous glycoprotein. Potency reported in International Units (IU) by bioassay.

Methods — SE-HPLC: TSKgel G3000SWxl 7.8×300 mm; 0.1 M sodium phosphate pH 6.8 isocratic; 0.5 mL/min; 25 °C; UV 280 nm (size-based purity / monomer content — a C4/SEC phase is used because reversed-phase C18 is unsuitable for a ~38 kDa glycoprotein). Identity: immunoassay & reducing SDS-PAGE vs WHO reference. Potency: in-vivo bioassay (IU). KF: Metrohm 901. Endotoxin: LAL kinetic. Sterility: USP <71>.