



## CERTIFICATE OF ANALYSIS

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

PASS

QC released for dispatch



Scan to verify

HMG — 75IU

Human Menopausal Gonadotropin (Menotropin)

## 1. PRODUCT IDENTIFICATION

|                      |                                            |                  |                          |
|----------------------|--------------------------------------------|------------------|--------------------------|
| Synonym              | Human Menopausal Gonadotropin (Menotropin) | Label claim      | 75IU                     |
| Sequence / structure | —                                          | Lot / Batch      | ZX260512-882 / B97262    |
| Mol. formula         | Glycoprotein complex (FSH + LH)            | Manufacture date | 19 May 2026              |
| Mol. weight          | ~30,000–50,000 Da (glycoprotein)           | Date of analysis | 31 May 2026              |
| CAS number           | 61489-71-2                                 | 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)  | 75IU (±10%)              | 77 IU equiv.             | PASS    |
| Water content       | Karl Fischer           | ≤ 3.0%                   | 0.9%                     | PASS    |
| Sterility           | USP <71>               | Sterile, no growth       | No growth                | PASS    |
| Bacterial endotoxin | LAL (USP <85>)         | < 5 EU/vial              | 0.16 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.

DHR.

Dr. Huang Rui

Analyst · 31 May 2026 · Zhongxi Research Institute

DLX.

Dr. Lin Xia (QC Manager)

Approved by · 31 May 2026 · Zhongxi Research Institute

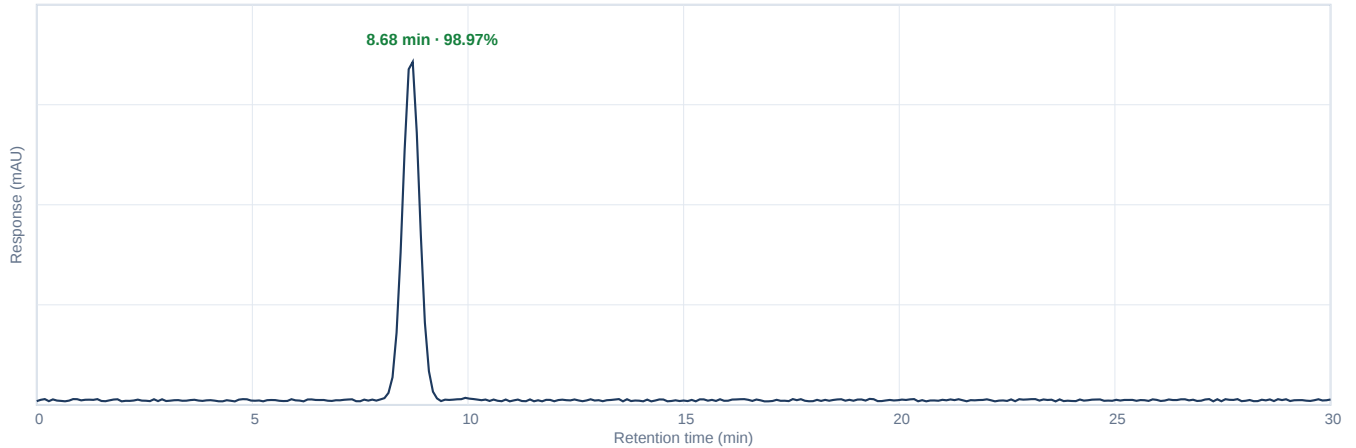


## APPENDIX — ANALYTICAL RAW DATA

HMG 75IU · Lot ZX260512-882 · Cert. ZXR-COA-2026-81304



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



| Peak # | RT (min) | Area (μV·s) | Area % | Assignment                   |
|--------|----------|-------------|--------|------------------------------|
| 1      | 8.68     | 1030184     | 98.97  | Intact monomer               |
| 2      | 9.92     | 4554        | 0.46   | Impurity / related substance |
| 3      | 12.27    | 2563        | 0.27   | Impurity / related substance |
| 4      | 19.13    | 2538        | 0.26   | Impurity / related substance |
| 5      | 13.19    | 427         | 0.04   | 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>.