

PRODUCT INFORMATION

|                 |                                    |                   |                                           |
|-----------------|------------------------------------|-------------------|-------------------------------------------|
| Product Name    | Human Chorionic Gonadotropin (HCG) | Lot / Batch No.   | PCL-2025-HCG-004                          |
| Compound        | Human Chorionic Gonadotropin       | Manufacture Date  | Q4 2025                                   |
| Strength / Fill | 5,000 IU / vial                    | Retest / Expiry   | 24 months from manufacture                |
| Form            | Lyophilized Powder                 | Storage Condition | 2–8 °C (refrigerated), protect from light |

ANALYTICAL SUMMARY

| Test Item            | Specification                 | Result        | Status |
|----------------------|-------------------------------|---------------|--------|
| Appearance           | White lyophilized powder      | Conforms      | PASS   |
| Identification       | Immunoassay / ELISA Confirmed | Confirmed     | PASS   |
| Potency              | ≥ 4,500 IU/vial               | 5,050 IU/vial | PASS   |
| Protein Content      | Report value                  | Conforms      | PASS   |
| Water Content (KF)   | ≤ 5.0%                        | 3.8%          | PASS   |
| pH (reconstituted)   | 6.0 – 8.0                     | 7.1           | PASS   |
| Related Substances   | Total Impurities ≤ 3.0%       | 1.4%          | PASS   |
| Bacterial Endotoxins | < 2.0 EU/vial                 | < 2.0 EU/vial | PASS   |
| Sterility            | Sterile                       | Sterile       | PASS   |

METHODS / REFERENCE

Potency assessed by ELISA-based bioassay against reference standard. Identification by immunoassay. Water content by Karl Fischer titration. Sterility testing per USP <71>. Bacterial endotoxins by LAL assay per USP <85>. Related substances by RP-HPLC.

QUALITY STATEMENT

Based on the source documentation reviewed, this lot of HCG appears to conform to the listed specifications for all parameters shown above. Potency result of 5,050 IU/vial meets and exceeds the minimum specification.

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