ANIARA
DIAGNOSTICA INC

YOUR LAB DESERVES A PARTNER.
Not a vendor.

PHARMACOPOEIAL HEPARIN QC · USP <208> · PH. EUR. · ANTI-XA & ANTI-IIA

Heparin potency to monograph — *at manufacturing scale.*

Heparin and LMWH lot release require chromogenic **anti-Factor Xa** and **anti-Factor IIa** potency assays run to pharmacopoeial specification for API and finished product. Aniara has been a **leading global supplier** of these reagents since the USP adopted the anti-IIa method and the anti-IIa/anti-Xa ratio — complete kits, bulk reagents, and GMP-ready reference materials, from a single vile to a manufacturing campaign.

COMPLETE POTENCY KITS — GLOBAL SUPPLY

5-DIAGNOSTICS · GLOBAL

USP-UFH Heparin QC Kits

Anti-Xa Heparin Kit — chromogenic, 2-stage	A5D-50458
Anti-IIa Heparin Kit — chromogenic, 2-stage	A5D-50457

Complete reagent sets for heparin potency in purified / aqueous systems, USP <208>-compliant. **Available worldwide — bulk kit & bulk-reagent formats.**

BULK REAGENTS — SINGLE VIAL TO MANUFACTURING PACK

- **Chromogenic substrates** — Thrombin 5-CHROM-38 for anti-IIa & Factor Xa 5-CHROM-65 for anti-Xa. 1×25 mg up to 12×25 mg bulk (A5D-30805 / A5D-30807).
- **Purified Bovine Factor Xa** — certified specific activity. Single & 10-vial bulk (ABE101 series).
- **USP/EP buffer salts** — exact monograph compositions, verified pH, osmolality & ionic strength (AAR & A12 series).
- **Antithrombin (AT)** — traceable to the WHO International AT standard. 1.5, 3.75 & 10 mg vials; 10-vial bulk packs (APP004 series).
- **Human Thrombin** — 10 to 1000 NIH; 10-vial bulk (AEZ006 series).
- **System-suitability controls** — lyophilized plasma at defined heparin activity; positive & negative per batch.

STANDARDIZED
Heparin references calibrated to the current **WHO International Standard** (UFH & LMWH); AT to the WHO International AT standard.

GMP-READY
GMP-compatible certificates of analysis — specification limits, lot traceability and expiry dating for your quality system.

MONOGRAPH-BUILT
Methods and buffers to **USP <208> and Ph. Eur. 2.7.12** — the mandatory heparin-potency assays for lot release.

THE TWO-STAGE METHOD — sample heparin + antithrombin neutralizes a measured excess of **Factor Xa** (anti-Xa) or **thrombin** (anti-IIa); residual enzyme cleaves the chromogenic substrate, and color is **inversely proportional** to heparin potency. Report anti-Xa, anti-IIa, and the **anti-IIa/anti-Xa ratio**.

SELECTED REFERENCES Bovine vs. porcine/ovine heparin USP potency, measured with chromogenic anti-Xa & anti-IIa kits — *Clin Appl Thromb Hemost* 2019;25:1076029619889406. · Four-system anti-FXa assay comparison including chromogenic Heparin Anti-Xa / Anti-IIa 2-stage — *Biomedicines* 2021;9(6):700. · Heparin-source potency by chromogenic anti-Xa/anti-IIa — *Front. Med.* 2018;5:360.

For industrial / pharmacopoeial quality-control use in heparin manufacturing and API / finished-product lot release — **not for clinical diagnostic use.** These reagents are not in-vitro diagnostic medical devices and are not FDA-cleared, CE-marked, or Health Canada-licensed for clinical diagnostic use. 5-Diagnostics USP/EP QC products are supplied by Aniara **worldwide**. Assays follow USP <208> (anti-Factor Xa / anti-Factor IIa) and the corresponding European Pharmacopoeia methods. GMP-compatible certificates of analysis provided; full pack sizes and pricing on request.

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USP/EP HEPARIN QC · REQUEST A QUOTE