# Analytical methodology

HPLC, mass-spec, and LAL endotoxin assay — the full method set we run per lot.

Identity is confirmed by reversed-phase HPLC coupled with high-resolution accurate-mass spectrometry. The principal peak's monoisotopic mass must match the theoretical mass to within four decimal places of the expected molecular formula.

Purity is integrated from the same HPLC trace at 220 nm using a C18 column under a water/acetonitrile gradient with 0.1% trifluoroacetic acid. The principal-peak area must be at least 99.0% of the total integrated area for release.

Endotoxin burden is quantified by the kinetic-turbidimetric Limulus Amebocyte Lysate assay against an internal standard curve. The release ceiling is 0.25 EU/mg.

Each lot is also assessed visually — appearance, color, and physical state — and the result is recorded in the lot's release record.