

CHEMICAL ANALYSIS SPECIFICATION SHEET

Reference matrix of routine chemistry methods, instrumentation, working ranges, and standard turnaround for compound identity, purity, and quantitative analysis.

1. METHODOLOGICAL MATRIX CAPABILITIES

TESTING SUITE	METHODOLOGY & INSTRUMENTATION	LOQ / RANGE	STANDARD TAT
Chemical Purity Profile	Reverse-Phase HPLC with Diode Array Detection (RP-HPLC/DAD). Absorbance monitored at 214nm and 254nm.	0.01% - 100.0% Purity	3 Business Days
Molecular Identity Validation	Liquid Chromatography paired with High-Resolution Mass Spectrometry (LC-HRMS) using Electrospray Ionization (ESI-TOF).	100 - 5,000 Da MW	3 Business Days
Residual Solvents (OVI)	Headspace Gas Chromatography with Flame Ionization Detection (HS-GC/FID) per USP <467>.	1 - 5,000 ppm	5 Business Days
Elemental Impurities	Inductively Coupled Plasma Mass Spectrometry (ICP-MS) per USP <232> / <233> / ICH Q3D.	0.05 - 1,000 ppm	7 Business Days
Water Content	Karl Fischer Coulometric Titration.	10 ppm - 5% w/w	2 Business Days
Counter-Ion Quantitation	Ion Chromatography (IC) with conductivity detection.	0.1 - 50% w/w	5 Business Days

2. REPORTING DELIVERABLES

- Signed Certificate of Analysis (COA) with method references, results, and specification pass/fail.
- Raw chromatograms, spectra, and processed data on request.
- Optional digitally signed PDF with verifiable hash on the public registry.