



Pharmaceutical Quality Control Testing

Ensuring product safety, consistency, and regulatory compliance is critical in pharmaceutical manufacturing. At Normec Synergy Health, we offer comprehensive GMP-compliant quality control testing for active pharmaceutical ingredients (APIs), excipients, and finished formulations—helping our clients meet EMA, FDA, and ICH standards with confidence.

As a certified CRO, we provide reliable, reproducible data that supports product safety, batch uniformity, and long-term stability—essential for successful product development and market release.



Ensuring the best quality and safety, everywhere



Active Pharmaceutical Ingredient (API) Testing

APIs must meet strict quality requirements outlined in pharmacopeias such as the USP, Ph. Eur., and BP. We test according to these compendial standards to ensure safety, purity, and consistency.

Typical Testing Protocols for APIs

- Identity Testing – HPLC, UV-Vis, IR
- Purity & Impurity Testing – Byproducts, residual solvents, related substances
- Heavy Metals / Elemental Impurities – AAS, AES, ICP-MS
- Assay / Potency – API concentration analysis
- Water Content – Karl Fischer titration
- Microbial Testing – Ph. Eur. 2.6.12 / 2.6.13 compliant

Excipients Testing

Excipients enhance formulation performance and must be tested for compatibility, consistency, and safety—especially when used as binders, emulsifiers, or stabilizers.

Typical Testing Protocols for Excipients

- Identity Testing – Chemical characterization
- Purity & Impurity – Heavy metals, residual solvents, microbial limits
- Assay – Quantification of active content
- pH and Conductivity – Compatibility verification
- Viscosity – For gels, suspensions, and polymers
- Visual Tests – Clarity, colour, and physical characteristics

Finished Formulation Testing

Finished Dosage Forms (FDFs)—including tablets, syrups, creams, and injectables—undergo extensive testing to verify quality, performance, and patient safety.

Typical Testing Protocols for Finished Formulations

- Identity, Purity, Assay & Potency
Ensuring label claim accuracy
- Dissolution & Disintegration
Drug release and breakdown profiling
- Uniformity of Dosage Units
Content consistency per dosage
- Particle Size Analysis
Contaminant detection and distribution control
- Stability Testing
Accelerated and long-term studies
- Microbial Contamination
TAMC, TYMC, and specific organism testing
- Packaging Integrity
Container-closure system verification

Partner with Normec Synergy Health

With years of experience, we excel in analysing active ingredients, excipients, and finished formulations. Our expert team is committed to delivering precise and reliable testing to support your manufacturing process. Whether you're developing a new molecule or scaling a commercial product, Normec Synergy Health delivers trusted, high-quality analytical support.

Get in touch today to learn how we can streamline your path to regulatory success.