

Third Party Analytical Support

Scope	Technique
<p>Analytical method development (QBD based), Validation, Verification, Transfer</p> <p>[As per ICH Q2(R2) guideline]</p> <p>(For API and Formulations)</p>	<p>Assay, Organic impurities, Chiral impurities, Residual solvents, Polymorphic impurity, Particle size by Malvern Master sizer</p> <p>(by HPLC, UHPLC, UPLC, GC-LS-HS, Ion Chromatography)</p>
<p>Nitrosamine impurities (26 Declared impurities)</p> <p>(For API and Formulations)</p> <p>(As per current FDA / Regulatory guideline)</p>	<p>By LC-MS-MS, GC-MS-MS</p> <p>(With Risk assessment support and FDA acceptable document)</p>
<p>Elemental impurities (Class-I, Class-IIA, mandatory and product manufacturing based)</p> <p>(As per ICH Q3D guideline)</p> <p>(For API and Formulations)</p>	<p>By ICP-MS</p> <p>(With Risk assessment support and FDA acceptable document)</p>
<p>Genotoxic and Carcinogenic impurities</p> <p>(as per ICH M7 guideline)</p> <p>[for API and Formulations]</p>	<p>In Silico QSAR based model approach to identify DNA reactive or unreactive followed by suitable classification, method development, control and validation</p>
<p>Carryover impurities for API</p>	<p>By HPLC, GC, GC-HS, Ion chromatography</p>
<p>Inorganic impurities</p>	<p>By Ion chromatography</p>
<p>Extractable and Leachable study</p> <p>(For Ophthalmic, Injectable, Inhaler and OSD products)</p>	<p>By LC-MS-MS, GC-MS-MS, ICP-MS, Ion chromatography</p>
<p>Microbiological testing support</p>	<p>MLT, BET, Sterility, Antibiotics assay, PET, Microbiology area validation, etc.</p>
<p>Nutraceutical and Ayurvedic products</p> <p>(All types Vitamins, Proteins, Amino acids, Carbohydrates, phytochemicals, Minerals, Natural ingredients, etc.)</p>	<p>By HPLC, GC, LC-MS-MS, GC-MS-MS, ICP-MS, etc</p>

