GVK BIO
Accelerating R&D

Formulation and Analytical Solutions

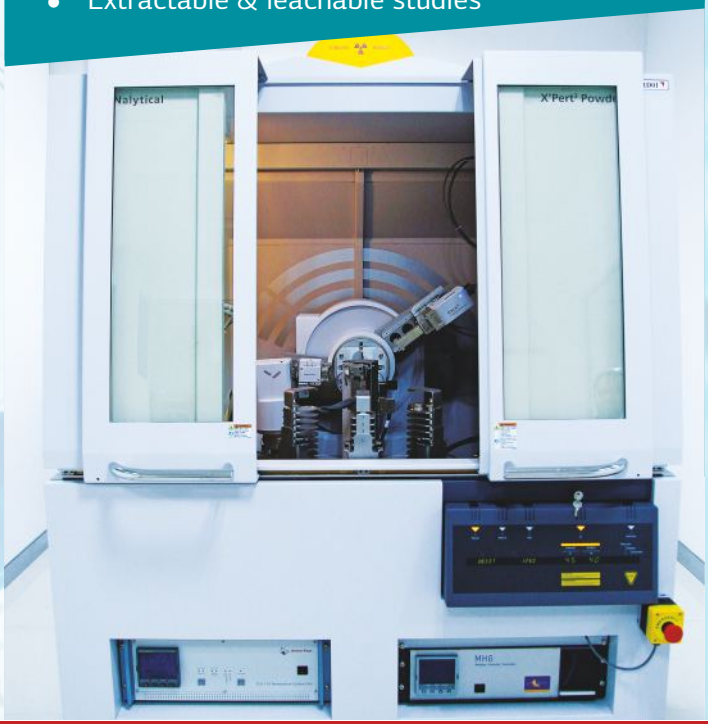
GVK BIO offers a range of Formulation R&D solutions that include pre-formulation studies, formulation development, analytical R&D, reformulation and stability studies. We can also support clinical supplies and manufacturing of exhibit batches in collaboration with our partners and offer standalone analytical solutions for third party formulation products. In addition, we offer regulatory and IP services through our collaboration with third party consultants.

Our pre-formulation solutions encompasses working with discovery research teams to predict and assess the developability of new chemical entities and enable them for development to reach clinics faster. Our formulation development solutions aims at delivering robust, production friendly formulations, incorporating best practices and adhering to stringent regulatory compliance procedures. Our analytical solutions supports method development, validation and transfer of cGMP compliant methods, stability analysis, quality control and release testing as per cGMP requirements for a broad spectrum of pharma compounds with speed and quality.

Our expertise lies in overcoming the challenges faced during development in terms of identifying risks and mitigating timely, biopharmaceutics evaluation, solubility/dissolution improvement, stability indicating method development, impurity profiling, bioavailability enhancement and achieving bioequivalence.

Our Capabilities:

- Pre-formulation studies
- Salt/cocrystal/polymorph selection
- Preclinical formulation development
- Clinical formulation development
- Generic formulation development
- Analytical method development & validation
- Quality control and release
- Impurity profiling & trace metal analysis
- Stability & photostability testing
- Extractable & leachable studies



Leading Small Molecule **CRDO**
GVK BIO

Large Molecule Discovery Partner
ARAGEN

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