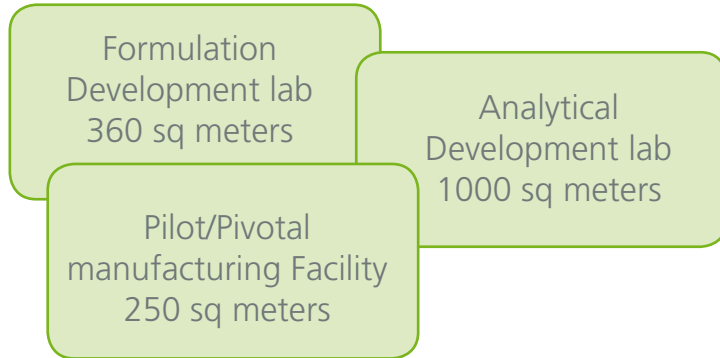


PharmaZell – Finished Dosage Form Development



Innovative development solutions

Preformulation studies

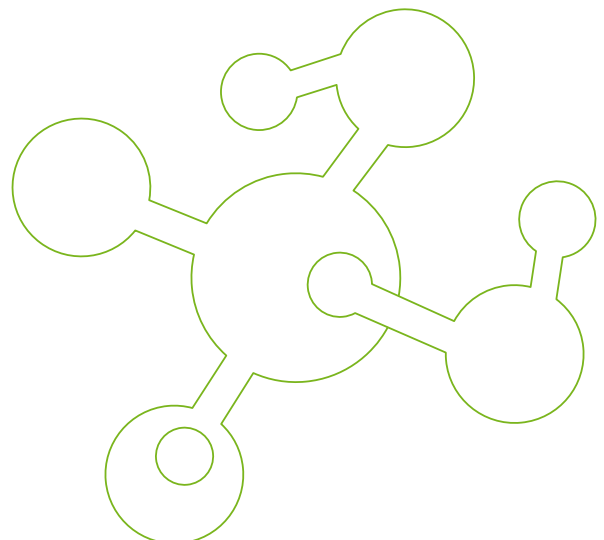
- Solubility, pH, solution stability
- Moisture content, sorption analysis
- Thermal analysis (thermal behavior, melting point).
- Structural characterization—FTIR, UV/Vis, fluorescence, NMR, MS
- Particle morphology, size and size distribution
- X-ray powder diffraction (XRPD)
- Polymorph screening
- Solid state stability
- Drug-excipient compatibility and packaging component compatibility

Formulation development

- Tablets (Immediate, modified release monolayer and bilayer)
- Capsules
- Particulate, film, enteric coating
- Oral solutions and suspensions
- Powders—blends and sachets
- Bottle, blister, sachet and tube packaging
- Clinical supply and placebo manufacture
- Review of batch documentation by developmental Quality Assurance team

Stability studies:

- Informal and formal studies (ICH)
- Including elevated, ambient, and subambient temperatures, photo stability
- Degradation studies—temperature, pH, light, oxidation



Innovative development solutions

Analytical Services

- Method development and validation for drug substance, impurities and stability-indicating analysis
- Reference standard characterization, impurity identification and release testing
- Drug substance characterization—identity, assay, impurities, moisture, pH, residual solvents
- Excipient characterization—compendia testing
- Drug product characterization—identity, assay, content, uniformity, moisture, dissolution
- Test article and dose formulation analysis—purity, homogeneity and stability
- Degradation studies on drug substance and drug product

Regulatory Services

- ANDA and EU submissions
- IND and NDA Submissions
- Dossier and DMF life cycle management
- e-CTD and SPL
- Product development strategies Pre-formulation



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