Grindeks group, your European partner in quality and compliance

Grindeks provides a wide range of development, analytical, and manufacturing services to support all stages of API and Final dosage form development – from early stages to GMP production.

Grindeks and its subsidiaries hold MIA and GMP certificates, as well as authorizations for IMPs and controlled substances.

Grindex

API Development and Manufacturing

- Development and optimization of new API production technologies in laboratory scale (10 mL – 10 L reactors)
- Small-scale API manufacturing and process validation under GMP conditions (batch size 1 g – 1 kg)
- Development and validation of highly potent active pharmaceutical ingredients (HPAPIs) (up to band 5) under GMP conditions (batch size 1 g – 1 kg)
- Synthesis of API impurity reference substances, including nitrosamine reference substances
- Organic syntheses of varying complexity and purification of substances (including preparative column chromatography)

Clinical Development Support

We provide full support for the clinical development of generic formulations through established collaborations with international bioequivalence centres.

FDF Development and Manufacturing

Contract development and manufacturing of solid, liquid (sterile, non-sterile), and semi-solid dosage forms. Our experience, modern technologies, and GMP-certified facilities enable us to deliver high-quality and regulatory-compliant pharmaceutical products to partners worldwide. We have dedicated facility for corticosteroids semisolids.

Solid Dosage Forms
Tablets
Capsules
Coated tablets

Semi-Solid Dosage Forms
Ointments
Creams
Gels

Liquid Dosage Forms
Solutions
Suspensions
Syrups

Sterile Liquid Forms
Small volume parenterals (ampoules)

Our Capabilities

- Blending and granulation (wet & dry, fluid bed)
- Tablet compression and coating (pan coating)
- Hard capsule filling (gelatine and HPMC)
- Conventional and flexible processing technologies tailored to client needs

Analytical Services

- Analytical method development
- Analytical method validation, verification and transfer
- Nitrosamine and genotoxic impurity control testing and consulting
- Photostability and forced degradation studies
- Drug–excipient compatibility studies
- Impurity identification studies
- Custom impurity reference standard standardization
- Intrinsic solubility studies
- Equilibrium solubility studies for BCS-based biowaivers
- IVRT method development and analysis
- Rheological behaviour
- Specific surface area determination
- Oxygen determination in the free volume of vials
- Osmolality analysis
- Particulate contamination testing (visible and sub-visible particles)
- Thermal cycle studies (freeze–thaw and cool–thaw cycles)
- Stability studies (accelerated, intermediate, long-term, in-use)

Available Equipment

- Spectrometers (FTIR, UV)
- Refractometer
- Polarimeter
- Melting point apparatus
- Differential scanning calorimetry (DSC)
- Powder X-ray diffractometer (XRD)
- Nuclear magnetic resonance (NMR)[1]
- HPLC systems (UV, PDA, RI), UPLC systems (UV, PDA, MS/MS)
- GC systems (FID, HS-FID, TCD, MS, HS-MS)
- Electrophoresis system
- Potentiometric titrator
- Karl Fischer titrator and coulometer
- Xenon lamp photostability chamber
- Laser diffraction particle size analyser (PSD)
- IVRT diffusion system
- Rheometer
- Dissolution systems (online/offline)
- BET specific surface area analyser
- Filter integrity testers (Pall Flowstar, Sartorius)
- Osmometer
- Liquid particle counter
- Turbidimeter
- Optical oxygen meter

Quality control & quality assurance & batch certification

Quality Control Testing

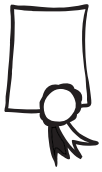
We offer quality control testing for medicinal products, including imported ones into the European Economic Area from third countries, ensuring that the testing of each medicinal product batch complies with EU standards and regulatory requirements.

Stability samples storage and testing

We offer storage and testing of APIs and FDFs for initial and on-going stability studies. We test a wide range of APIs and finished dosage forms, including powders, tablets, capsules, solutions, syrups, ointments, creams, gels, and injectables.

Microbiological Testing

We provide microbiological testing for sterile and non-sterile medicinal products, as well as comprehensive support for environmental monitoring programs development.



Batch Release

We provide batch certification by experienced Qualified Persons and batch release to the European market.

JSC Grindeks

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