



Company Profile

Pharma Heritage in Slovakia

1941 Slovak Alkaloids

Focused on production of morphine

1950 National company **Slovakofarma**

2003 Acquisition by Léčiva

Launch of **Zentiva** corporate brand

2009 Zentiva combined with Sanofi

2013 Acquisition by **Wood Pharma** Holding



Who We Are

Wide range of services in 2 strategic business units:

- Contract **manufacturing** and **development** of pharmaceuticals
- Development and production of active substances

Manufacturing nearly **700** SKU's from more than **100** API's

More than **20** own Active Pharmaceutical Ingredients in portfolio

Under regulation of **EU GMP** inspectors (and Russia), as well as frequent customer audits

ISO 14001 and 45001 in place



Our Competence



Pharma Plant

- Solid dosage forms
- Soft gelatin capsules
- Nonsterile liquids
- Sterile ampoules



R&D and Regulatory Compliance

- Laboratory development
- Scale-up to pilot stage
- Validation
- Stability
- Dossier preparation
- Support in registration process



API Plant

- Multipurpose API unit
- cGMP Kilolab



Narcotic API's

- Morphine & Thebaine based API's
- Synthetic narcotic API's

Other Services

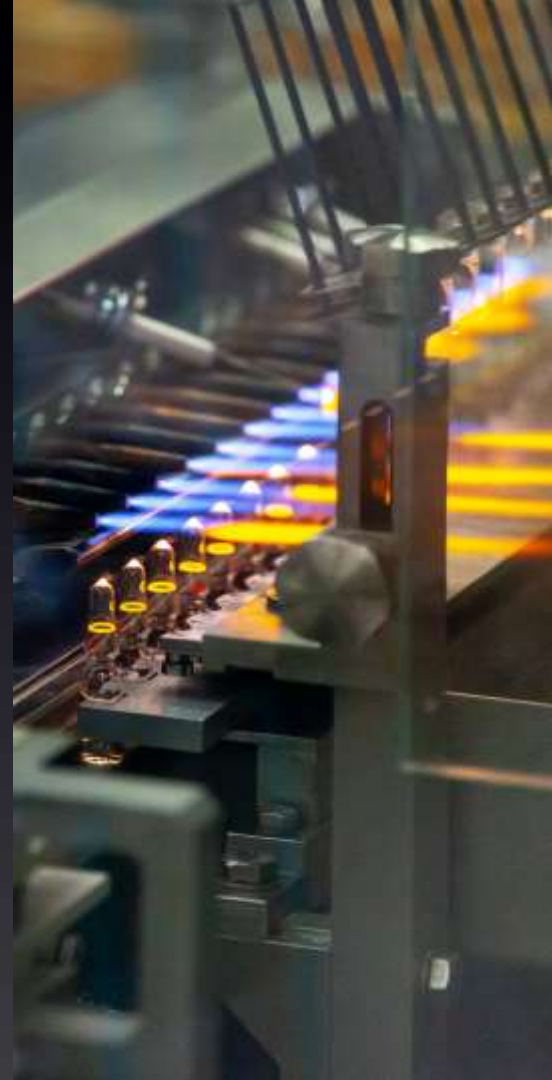
- Warehousing
- Distribution
- Transportation

Values and Noble Mission

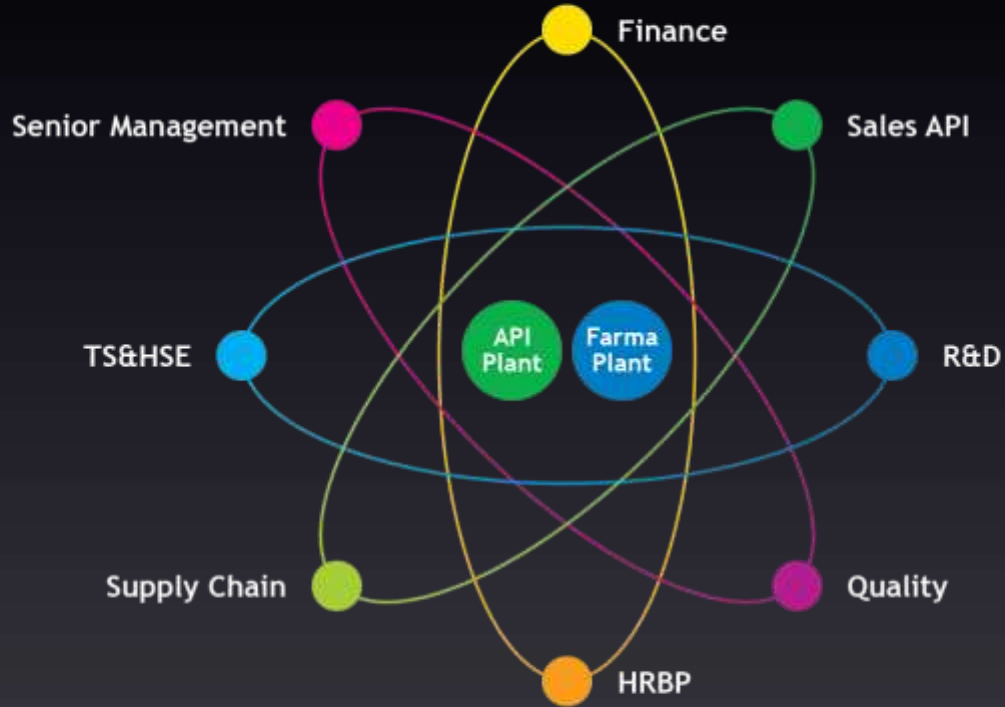
- The trust of our customers is based on the expectation of **fair** costs, **timely** deliveries, and compliance with **quality**

*We are proud of our tradition and reputation (more than **80 years**).
We help improve the quality of life.*

- Always acting fairly and with **respect**
- Honesty and **openness** help us move forward
- Enjoying **cooperation** that leads to a **simple** solution
- Finding true **joy** in what we do
- ... and striving for **excellence**



Organization Structure



Pharma Production

- Blending (up to 1000 kg)
- Granulation
 - : High Shear Granulation (water based, solvent based)
 - : Fluid Bed Granulation
- Roller Compaction
- Pelletization (extrusion, spheronisation)
- Compression or Encapsulation (hard gel caps filled by powder or pellets, soft gel caps)
- Coating
 - : Film or Sugar Coating
 - : Pellet Coating (Wurster)
- Packaging (cold forming or thermoforming foils, glass bottles or plastic cans)
- Nonsterile liquids
 - : Drops, Syrups, and Sprays
- Sterile Production
 - : Injectables in ampoules 1, 2, (5), and 10 ml ampoules



Technology in Pharma

- Blending up to 1000 kg
- High shear granulation : Diosna CGS 800, Diosna, Glatt WG800, Glatt
- Fluid bed granulation : Glatt
- Roller Compaction : Alexanderwerk WP 200 Pharma
- Pelletization : Gabler
- Compression or Encapsulation : Fette, Killian, IMA ADAPTA 200, IMA, Pharmagel
- Coating : Glatt GCSmart 950, Glatt
- Packaging : Uhlmann BEC300, IMA, IWKA, Swiftpack, Marchesini
- Sterile Production : Syntegon, Steris, Optrel, Marchesini



API Production

- Portfolio of own IP generic API's - mainly **narcotic** substances
- Wide range of chemical and technological expertise in the field of **multi-step** synthesis of various size
- Active portfolio consists of:
 - 23 Active Pharmaceutical Ingredients
 - 1 API intermediates
 - 1 Pharmaceutical Excipient
- 13 CEP's active, 2 under registration, ASMF's in various formats
- Processes and safety know-how to handle **controlled substances**



Technology in API

Reaction / Reactors

Total mixing capacity **112.000 Liters**, **85** stainless steel and glass lined **reactors**

Volume from **60** to **6 000** Liters

Batch size in GMP from **0,5** to **700** kg/batch

Media

Current working pressure: **-100 / +600** kPa

Current working temperature: **-20 / +200** °C

Catalytic Processes

Catalytic hydrogenation (max. pressure **10** bar)

Separation Solid-Liquid

Pressure filters, Process filters, Centrifuges, Nutsch filter

Separation Liquid-Liquid

Extractions of water/organic solvent systems

Absorption

Disposal of emissions, Absorption of gases

Distillation, Rectification

Distillations, Rectifications, Molecular distillation (Kilolab)

Crystallization

Crystallizers from **60-2500** L (glass lined and stainless steel)

Drying

Vacuum tray dryers, Fluid bed dryer, Vacuum mixed dryers (**400-2000** L)

Particle Size Modification

Sieving, Milling (**pin mill**), Micronization (**nitrogen jet mill**), Vibrational sieving

Recycling of Solvents

Recovery of solvents from processes - **Recycling module**



Chemical Reactions Expertise

- Amination
- Amination Reductive
- Aminolysis
- Aminomethylation
- Carbamate Hydrolysis
- Condensation
- Crystallization of Diastereomeric Salts
- Cyclization
- Debenzylation Catalytic
- Demethylation, N- and O-
- Deprotection
- Enolization
- Epimerization
- Epoxidation
- Esterification
- Grignard Reaction
- Hydrogenation Catalytic
- Hydrolysis
- Isomerization
- Lactonization
- Mannich Reaction
- N-Acylation
- N-Alkylation
- O-Alkylation
- Oxidation (Hydrogen Peroxide)
- Reduction with Hydrides
- Schiff Reaction
- Urethane Synthesis



References

