



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



Broad range of services for two strategic business units:

- Contract manufacturing and development of pharmaceutical products
- Development and production of active pharmaceutical ingredients



Manufacturing 600+ SKU's from more than 70 API's

Around 30 own Active Pharmaceutical Ingredients in portfolio



History of EU, US FDA, Russian, Korean and Japanese GMP inspections
Compliance with no critical observations



ISO 14001 and 45001

Our Capabilities



Pharma Plant

- Solid dosage forms
- Semisolid dosage forms
- Liquid dosage forms
- Sterile production



R&D and Regulatory Compliance

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



API Plant

- Multipurpose API units
- cGMP Kilolab



Narcotic API's

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

Other Services

- Warehousing
- Distribution
- Transportation

Quality Competence



Years of the Quality System based on EU GMP principles



Frequent customers' audits
+10 regulatory inspections from Russia since 2016



(starting from 1996,
the last one in 2007)



State Institute of Drugs and Good Practices



Ministry of Food and Drug Safety



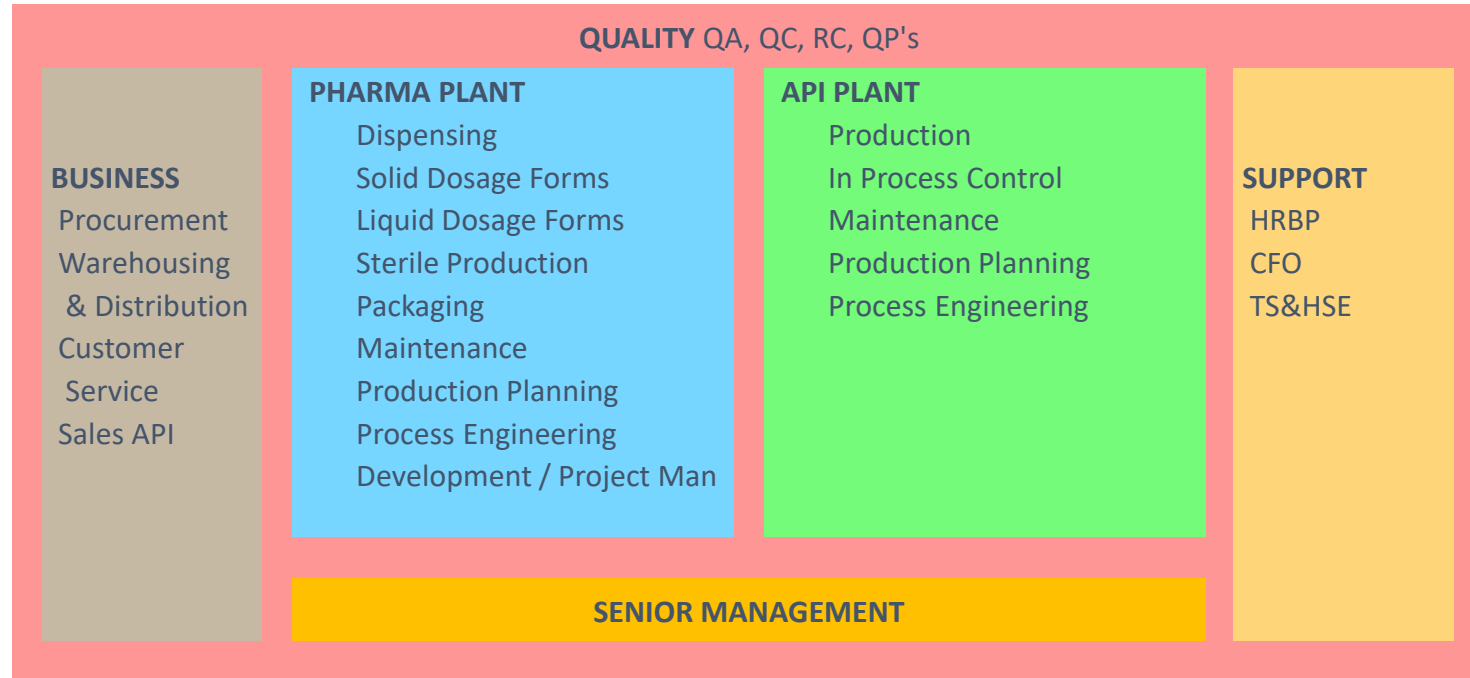
Values and Noble Mission

- Saneca has a tradition of chemical and pharmaceutical production for more than 80 years
- The trust of our customers is based on the expectation of **fair** costs, **timely** deliveries, and compliance with **quality**

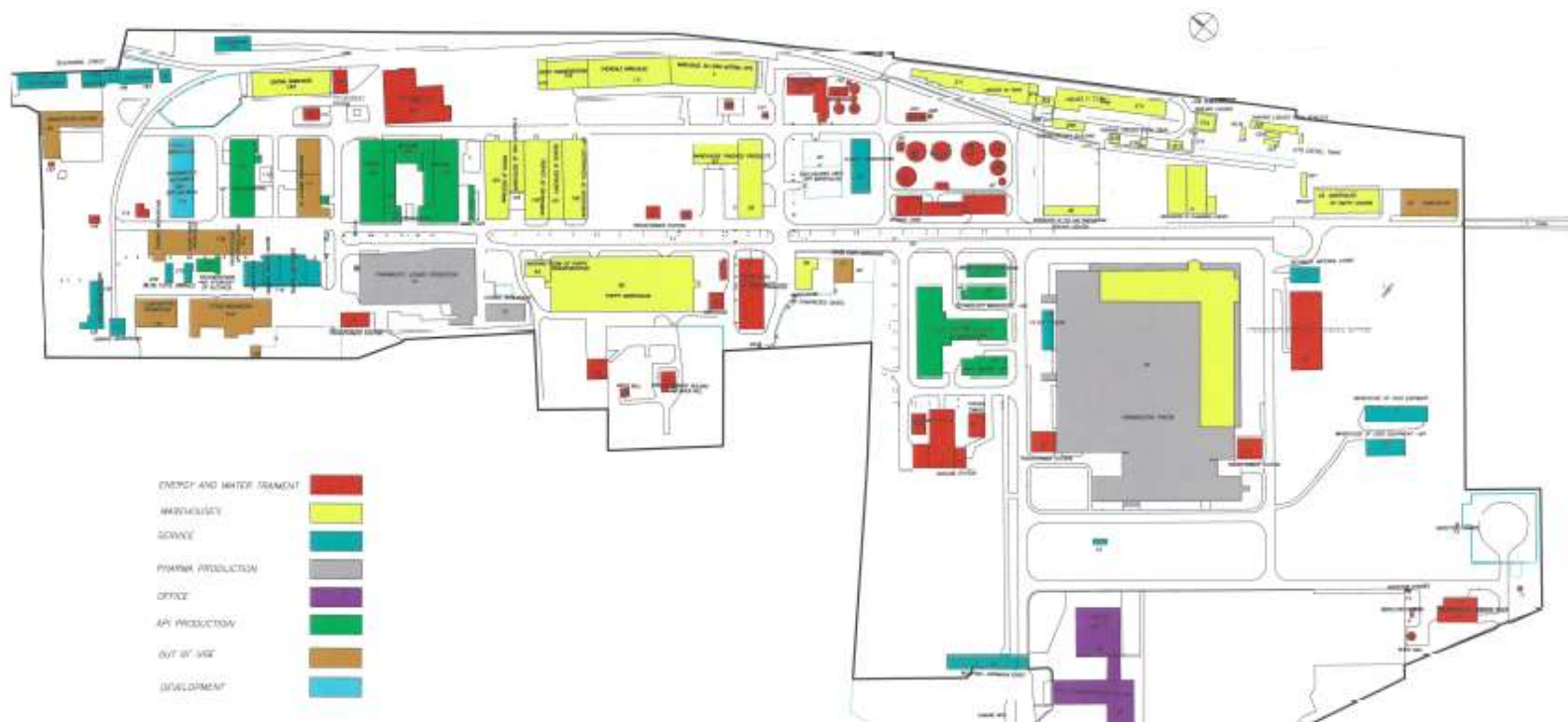
We are proud of our tradition and reputation. We help improve the quality of life.

- Approaching the requirements 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



Business Premises



(a) Pharma Production

Solids



Tablets
uncoated
coated (sugar/film)
bi-layered

Pellets
extrusion spheronisation
wurster layering



Hard gel capsules
filled by powder or pellets

Effervescent
low humidity manufacture

Liquids



Nonsterile liquids
drops
syrups
sprays

Soft gel capsules
water and oily based

Sterile Production

Injectables in ampoules
1, 2, (5), and 10 ml ampoules

Technologies in Pharma

Homogenisation

Slow speed
blender

Homogenisation
+ filling equipment



Granulation

Dry / roller compaction
Wet granulation

High shear

Fluid bed



Pelletization

Extrusion
Spheronisation

Layering
„Wurster“



Coating

Perforated
drum

Sugar
coated pan



Tabletting

Rotary tablet press



Encapsulation

Hard gel
filling

Soft gel
rotary die



(b) API Production



Portfolio of own IP based generic API's (mainly **narcotic products**)



Wide range of chemical and technological expertise from bio-mass extraction to multi-step synthesis of various size



Active portfolio consists of:

- **27 Active Pharmaceutical Ingredients** (plus R&D pipeline)
- 2 API intermediates
- 1 Pharmaceutical Excipient (with cGMP certificate)



14 CEP's active / **25 ASMF's** (US DMF & CTD) available



Processes and safety know-how to handle controlled substances

Narcotic API's



Limited competition in the market (in the average up to 8 worldwide and 5 European competitors in each product category)

25% of synthetic products covered

60+% of morphine-based products covered

50% of thebaine-based products covered

35% estimated worldwide market share in Pethidine (Meperidine)

Key Opiate / Narcotic API's marketed worldwide as medicinal products

Synthetic	Morphine based	Thebaine based
Alfentanil	Apomorphine	Buprenorphine
Dextromoramide	Codeine Phosphate	Butorphanol
Diphenoxylate	Dihydrocodeine	Levorphanol
Dipipanone	Dihydromorphine	Methylnaltrexone
Fentanyl	Ethylmorphine	Nalbuphine
Ketobemidone	Heroin	Naldemedine
Levomethadone	Hydrocodone	Nalfurafine
Methadone	Hydromorphone	Nalmefene
Pethidine	Morphine (Sulfate)	Naloxegol
Piritramide	Nicomorphine	Naloxone
Propoxyphene	Pholcodine	Naltrexone
Remifentanil		Oxycodone
Sufentanil		Oxymorphone
Tapentadol		Thebacon
Tilidine		
<i>Commercially available / manufacturing know-how available / being developed by Saneca</i>		

References

