

Hameln rds is a well recognised pharmaceutical service provider

for health-care industry. We focus on different steps during development and production of pharmaceutical products. We are covering analytical and galenical development of pharmaceuticals, Quality Control Services (stabilities and batch release) and development and GMP manufacturing of APIs.



2014

Specialised in marketing of products for acute treatments

- Germany based office

2014

After the ownership changes have been realised within hameln pharmaceuticals gmbh and hameln rds gmbh, today we are a part of hameln group with following companies:



2014

Specialised in marketing of products for acute treatments

- UK based office



2014

Development and all health care market services

- Slovakia based office

2007

Name of the company has been changed into hameln rds a.s

2006

Acquisition of 100% shares of VULM a.s. by hameln rds gmbh

1996

Transformation of the Drug Research Institute, š.p., (state enterprise) into VULM, a.s. (joint-stock company) with approximately 165 employees. Slovakofarma, a.s. became the main shareholder having 51% of the equity

1991

The Section of Biological research and the Section of Analytical Chemistry were awarded with the Certificate of Good Laboratory Praxis (GLP). The Institute became a first organisation obtaining GLP Certificate in Slovakia

1989

Finishing of the construction of new buildings in Modra and organisation of the official opening ceremony. At this time, Institute had 395 employees

1977

Decision of the Ministry of Health to move the main seat of the Institute from Hlohovec to Modra

1972

Foundation of the Drug Research Institute as an independent Institution of Spofa having its office location in Hlohovec with 54 employees

APIs commercially produced and marketed

- Piritramide
- Alfentanil Hydrochloride(CEP)
- Sufentanil Base(CEP)
- Remifentanil Hydrochloride (CEP)
- Propentofylline
- Moxastini Theoclas

APIs under development

- Dexmedetomidine
- Noradrenaline Tartrate
- Sufentanil Citrate

CAPABILITY OF API PRODUCTION PLANT

- Established GMP certificate since December 2012
- Production focused on manufacture of API class OEB 3 to OEB 5
- Production capacity 100 kg of high potent APIs per year in the 1st facility
- Production capacity 500 kg of high potent APIs and Intermediates per year in the 2nd facility

DEPARTMENT OF API PRODUCTION IS EQUIPPED TO PROVIDE:

- Production of API and intermediates fully compliant with GMP rule
- Batch size of produced batches in range 100 g – 5 000 g
- Rooms for safety production of HP API with thorough filtration of air input and exhaust
- Full protection of staff and products
- Monitoring of water waste with unit for decomposition of dangerous pollutant

OPERATIONS:

- Reaction in temperature range 20°C to +140°C
- Reaction (hydrogenation) under higher pressure (12 bar)
- Extraction
- Filtration
- Evaporation
- Crystallisation and Isolation
- Drying with raking in process filter or on trays in drying oven
- Sieving

MAIN EQUIPMENT:

- 2 glass reactors double jacketed 30 – 50 L, connected with thermostat temperature range: 20°C to +140°C
- 1 glass 50 L reactor for crystallisation connected to process filter temperature range: 20°C to +140°C
- process filter with capacity maximally 5.000 g
- sieving and milling device
- 50 L hydrogenator for work pressure up to 12 bar (in construction)



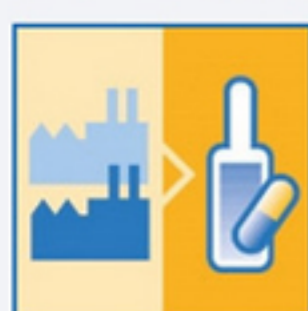
SERVICES

	▪ Quality Control
	▪ API Production / Development
	▪ Galenic Formulation / Tech Transfer
	▪ Regulatory Affairs
	▪ Trading API/FDF



Quality Control and Galenical Development

[Read more](#)



Development and GMP production of APIs

[Read more](#)



Regulatory Affairs (Registration, Compilation of Dossiers)

Pharmaceutical R&D Facility with Manufacturing Authorization and FDA Approval

[1] Administrative Building/Clinical Facility
[2] [3] [4] R&D Facility/Laboratories

[5] API GMP Facility
[6] Toxicology and Preclinical Studies



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