



LIFE SCIENCES

Pharma



# Azelis Pharma Service Portfolio

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# Refilling and repackaging services for the pharmaceutical industry in Sankt Augustin

Additional services that make a difference are a key element of the Azelis service portfolio. Therefore Azelis has expanded its repackaging services for the pharmaceutical industry in Sankt Augustin, Germany. Besides the existing IPEC-GMP clean rooms for liquid excipient refilling services, in 2018 Azelis has opened a new pharmaceutical manufacturing facility with two industry leading GMP-certified clean rooms for solid API and excipient repackaging. This large investment will enable Azelis to provide an enhanced all-around service to its customers and suppliers.

2 GMP clean rooms class D for solid API & excipient repackaging

Both facilities offer a broad range of services including:

- Source selection and qualification for a variety of substances for APIs and excipients
- Incoming and outgoing goods control
- Repackaging, refilling and sampling operations under IPEC-GMP/GMP conditions
- GMP/extensive documentation
- SOP based procedures
- In-house analytical testing
- Traceability
- Controlled entry facility
- Specially trained operatives for filling, storage and laboratory
- Audit opportunity of our GMP/IPEC-GMP facility
- CAPA system in place

2 IPEC-GMP clean rooms for liquid excipient refilling



## GMP clean room class D for solid API and excipient repackaging

- Large investment in 2017 for the construction of 2 new state of the art GMP-certified clean rooms class D/ISO class 8
- Repackaging, relabeling and sampling of solid APIs and excipients with different characteristics
- Industry leading facility compliant with stringent GMP standards (GDP and EU GMP Part I and II) and Site-Master-File
- Highest flexibility and innovative solutions allow focus on small and mid-size repackaging orders
- Appropriate order volumes through our customised packaging in order to reduce your net working capital by optimising your stock levels
- GMP storage and transportation to complete our distribution services

### Main products currently repacked

- Acetylsalicylic Acid
- Atropinsulfat
- Chlorhexidine diacetate
- Epinephrinhydrogentartrat
- Paracetamol
- Salicylic acid
- Sodium cyclamate anhydrous
- Sucralose

### Technical data

- Total surface area of 161,4 m<sup>2</sup>
- Two clean rooms of 21,9 m<sup>2</sup> and 34,0 m<sup>2</sup>
- Operating temperature range: 21°C +/- 2°C
- Operating relative humidity: 50% +/- 10%
- Sample room of 28 m<sup>2</sup>

Highest flexibility to meet your requirements

## IPEC-GMP clean room for liquid excipient refilling

- 2 clean rooms with clean air classification (particles) according to ISO class 8
- Liquid excipient filling and refilling from tank truck into IBCs, drums and cans under IPEC-GMP/ESAD conditions in order to meet new regulatory requirements on risk-assessment for excipients (guideline 2015/C 95/02)
- Appropriate order volumes through our customised packaging from 1 L until 1000 L
- Reduce your incoming goods inspections through reservation of batches
- Dedicated filling hoses and batch traceability
- Kosher and halal certification of the filling site

### Main products currently refilled

- Aceton, EP
- Glycerol 85%/99.5% EP
- Isopropyl alcohol, EP/USP
- Propylene glycol, EP/USP
- Sorbitol

Reduce your working capital by optimising your stock levels

Save time and reduce risk by using Azelis clean room products



## Innovation through formulation

This is not just our strapline. It's our purpose, passion and promise to every colleague, customer and contact around the world. It's a reminder that ideas and expertise can change lives. That a world of discoveries still awaits. And that with open and collaborative minds, the future is ours to imagine.



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