



BOSCH
Invented for life

Bosch Pharmalab Crailsheim

Research and services for isolator
and process technology



▲ Cleanroom class D with integrated isolator system

Bosch Pharmalab Crailsheim

Research and services for isolator and process technology

Bosch Packaging Technology in Crailsheim has a longstanding tradition in the pharmaceutical industry as a developer and producer of fill-finish equipment for sterile liquid and powder products.

In 2004 the Pharmalab was established to support investigations, studies and services in process technology, which meet the standards of the pharmaceutical industry regarding performance, environmental conditions and documentation.

Our team of scientists, engineers and lab technicians conducts physical, chemical and microbial testing and analysis based on Bosch-specific standard operating procedures (SOP) or according to customer-specific ones.

Take advantage of our global R&D offer and achieve a faster time-to-market with the support of Bosch experts.

Bosch Packaging Technology has a wide range of laboratory expertise. Besides the Bosch Pharmalab in Crailsheim, additional laboratories are available in Schopfheim and Hangzhou (China).

Bosch customers not only receive individual systems for the research and development of their pharmaceuticals. The Bosch formulation and process experts also support you with comprehensive pharmaceutical know-how and a wide range of seminars, as well as the implementation of your product ideas. The latest automation solutions facilitate the formulation development and quality control as well as data handling.

Our scope service

Our services are based on state-of-the-art equipment (e.g. two production size isolators), multiple spectroscopical and microscopical techniques, calibrated probes and a clean room lab. Bosch in Crailsheim is a DQS-certified site of Robert Bosch Packaging Technology GmbH.

Lab-based tests to support qualification and validation of aseptic fill-finish

- ▶ Quality assurance of biological indicators with microbial identification, spore count and D-value determination
- ▶ Determination of cleaning efficacy for washers with riboflavine-, sodium chloride-, particle- and endotoxin-tests
- ▶ Measurement of depyrogenation results of hot-air tunnels with thermocouples and endotoxin tests

Fundamental research on bio-decontamination processes in barrier systems

- ▶ Material studies on resistance and inactivation efficacy in processes with vaporized or fogged hydrogen peroxide
- ▶ Cavity penetration studies
- ▶ Determination of residual peroxide in ppb levels applying wet chemical and spectroscopical methods
- ▶ Support in determination of product tolerance against residual airborne hydrogen peroxide levels

Services for sterile fill-finish operation in RABS and isolators

- ▶ Development of test parameters for glove integrity testing
- ▶ Cleaning of H₂O₂ evaporators
- ▶ Development of loading schemes for material transfer airlocks
- ▶ Simulations of bio-decontamination and WIP (wash-in-place) processes



▲ Investigation of biological indicators



▲ Exterior view Pharmalab Crailsheim



▲ Product handling inside the autoclave

Robert Bosch Packaging Technology GmbH

Product Division Pharma Liquid

Blaufelder Straße 45

74564 Crailsheim

Germany

Phone +49 7951 402-0

Fax +49 7951 402-258

www.boschpackaging.com

packaging-ph@bosch.com