



Bosch Pharmalab in Crailsheim



Packaging Technology 



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Bosch Pharmalab in Crailsheim

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 in performance, environment 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.

Our scope includes:

These 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 (ISO grade 8). Bosch in Crailsheim is a DQS-certified site of Robert Bosch 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 heat 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 gas generator evaporators
- ▶ Development of loading schemes for material transfer airlocks
- ▶ Simulations of bio-decontamination and WIP processes with real size equipment

Robert Bosch GmbH

Packaging Technology

Product Division Pharma Liquid

Blaufelder Straße 45

74564 Crailsheim

Germany

Phone +49 7951 402-0

Fax +49 7951 402-258

www.boschpackaging.com

packaging@bosch.com

