IN VITRO DIAGNOSTIC PEPTIDES

BACHEM

LEADING PARTNER FOR IN VITRO DIAGNOSTIC PEPTIDES

Bachem's success relies on

- commitment to our partners
- innovation and technology
- our excellence and quality
- our responsibility towards our people and environment.

With these pillars, we assist our partners at every stage of product development: from early stage R&D all the way through to commercialization. Together with our clients, we define the requirements (e.g. specifications, quality, dedicated equipment) and establish a robust manufacturing process for future commercial supply.

ENQUIRY	PROCESS DEVELOPMENT	SPECIFICATIONS	COMMERCIAL SUPPLY
• Sequence supplied by customer • Identification of customer needs	• 2 to 3 Independent Research Grade batches • Definition of additional services	• Customer specification dossier • Bachem technical specification sheet • Master production record • Quality agreement	• Batch production record available for review on-site • Critical change control • Supply based upon purchase order or supply agreement
Evaluation completed	**Process established**	**Specifications defined**	**Research Grade Plus peptides provided**

Our Center of Excellence for Custom Synthesis in St. Helens (UK) is certified according to ISO 13485 for the manufacture of peptides as critical raw materials for medical devices. It offers a state-of-the-art quality management system and peptide manufacturing equipment. Additional services such as the use of dedicated equipment during manufacturing and customized vialing of the finished product are available.

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QUALITY YOU CAN TRUST

Regulatory requirements and standards in documentation and change control for in the in vitro diagnostic industry are constantly evolving. Bachem's Research Grade Plus (RGP) service has been established for our customers with additional quality requirements that can be adapted «à la carte» to meet your specific needs (see table below).

Benefits of the Bachem Research Grade Plus

Research Grade Plus guarantees full traceability of critical raw materials throughout the whole supply chain, manufacturing according to an established and robust process, as well as batch-to-batch consistency for your peptides.

	Research Grade	Research Grade Plus
Audits	✓*	✓
Critical Change Control	✗	✓
Master Production Record	✗	✓
Full Traceability of Critical Chemicals	✗	✓
TSE/BSE Certificate	✓	✓
Dedicated Equipment	✗	✓
Additional QC Specification Sheet	✗	✓
Customized Vials	✓	✓
Customized Peptide Mixture	✗	✓
Customized Shipment	✓	✓

*Possible under certain circumstances

BACHEM SETS INDUSTRY STANDARDS FOR HIGH QUALITY CUSTOM PEPTIDES.

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IN VITRO DIAGNOSTICS AT BACHEM

Our high capacity and state-of-the-art production equipment are dedicated to yield your peptide in the quality and purity you require.
Further, we offer you experienced technical support that will help you to identify the additional services that best suit your requirements.

Chemistry & Quality

- SPPS including a large selection of modifications
- State-of-the-art manufacturing & analytical capabilities

Capacity

- From mg up to 100g production scale
- Parallel production of multiple peptides

Dispensing

- Manual and fully automated dispensing capabilities
- Experienced in peptide mixture preparation

Support

- Stability study
- MDF (Medical Device File)

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SUPPLY AND TECHNICAL AGREEMENTS

At Bachem, our priority is to build trustful, sustainable, and long-lasting relationships with our partners.

Bachem is a leading, innovation-driven company specializing in the development and manufacture of peptides and oligonucleotides. With 50 years of experience and expertise Bachem provides products for research, clinical development and commercial application to pharmaceutical and biotechnology companies worldwide and offers a comprehensive range of services. Bachem operates internationally with headquarters in Switzerland and locations in Europe, the US and Asia. The company is listed on the SIX Swiss Exchange. For further information, see www.bachem.com.

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GLOBAL BUSINESS

Bachem facilities are located in Switzerland, the EU, and in the USA.

All cGMP manufacturing sites are inspected by the US-FDA and national authorities.

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