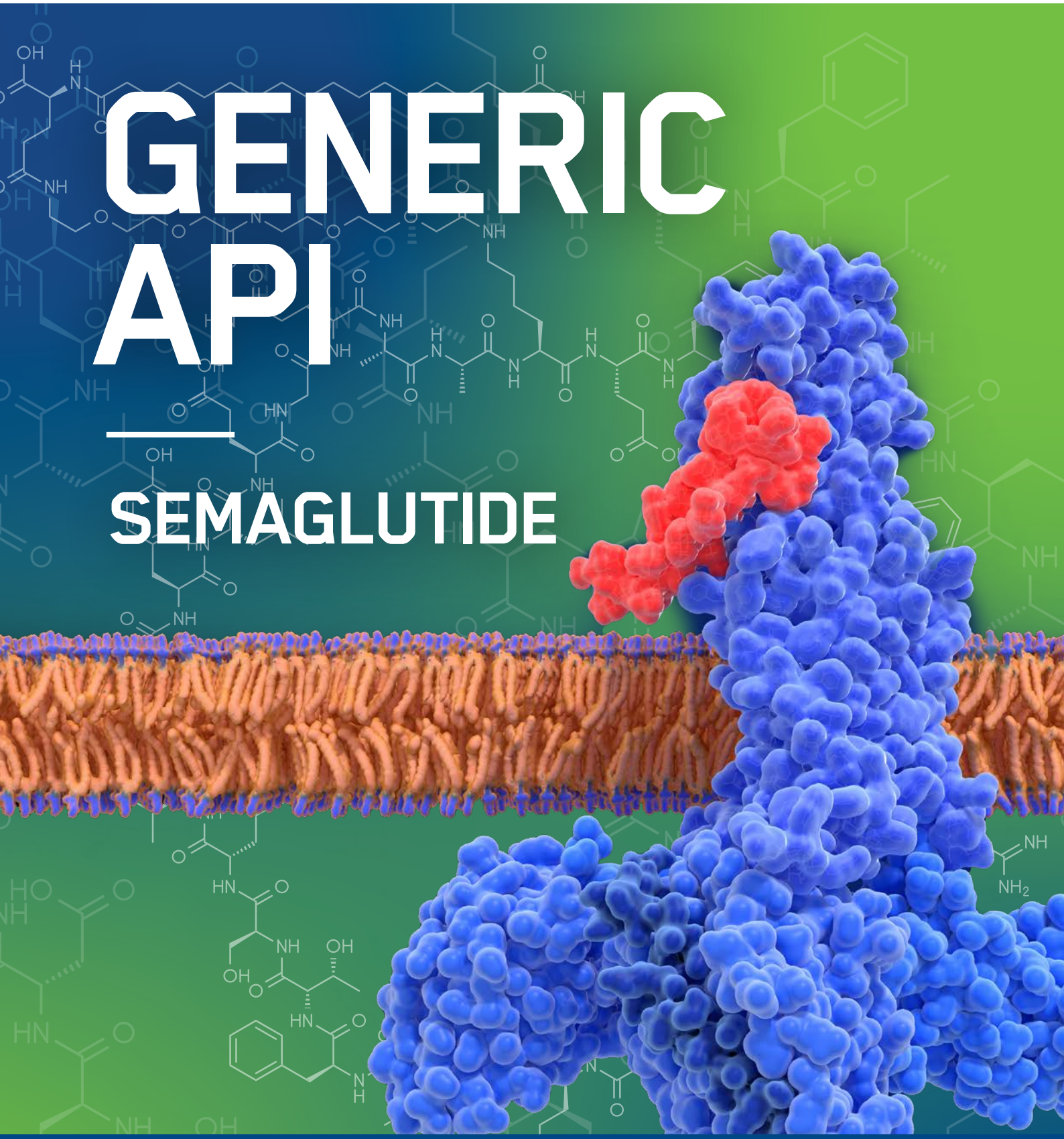
BACHEM

GENERIC API

SEMAGLUTIDE



LEADING BY EXPERIENCE

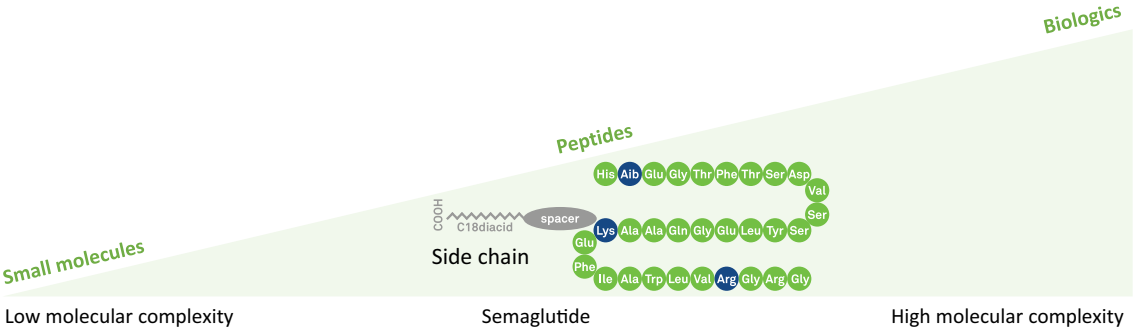
SEMAGLUTIDE

Semaglutide is a lipopeptide that can be commercialized as a synthetic generic product after approval of an abbreviated new drug application (ANDA) or comparable applications with other regulatory authorities. The length and modifications of this Glucagon like Peptide-1 (GLP-1) analogue make technical excellence and regulatory expertise a prerequisite for efficient filing and fast approval. High material quality and yield, robust processes including secure supply and innovative approaches at high-tech facilities will enable our customers to achieve their business goals.

LONG EXPERIENCE WITH COMPLEX ACTIVE PHARMACEUTICAL INGREDIENTS – ENSURING YOU A SMOOTH REGISTRATION PROCESS

Experience and compliance with FDA Guidance*

Bachem has a long-standing track record with successful registrations of highly purified synthetic peptide drugs of the glucagon family. Our regulatory intelligence keeps track of important changes in the relevant legislation. This enables us to be a leading global innovator in the field of glucagon and glucagon-like synthetic peptide drugs. Our services have been optimized to shorten timelines and reduce complexity for our clients.



SCALABILITY – WE'VE GOT YOU COVERED FROM GRAMS TO HUNDREDS OF KILOGRAMS

From small to large-scale production with high quality

Our high-tech Good Manufacturing Practice (GMP) facilities based in Switzerland and the US, plus the commitment of our technical and scientific experts to quality, are the cornerstones for continuous compliance. We deliver small-scale to multi-kg active pharmaceutical ingredients (APIs) with impurities below 0.5%, and identification and characterization of impurities above 0.10% using orthogonal analytical techniques.

INNOVATION AND AUTOMATION – OUR ANSWER TO YOUR NEED FOR COMPETITIVE PRICES WITH SUPERIOR QUALITY

Optimized, automated high-yield production

Our long experience in complex APIs allows us to optimize the processes for high yields at outstanding quality. Our high level of process automation allows for cost-efficient and large-scale production resulting in excellent overall material purity (>99.5%). Innovative solutions like continuous chromatography let us use equipment and resources more efficiently and help us and our partners to achieve their commitment to sustainability and environment-friendly production. Our GMP sites in Switzerland and California comply with and surpass the most stringent regulations.

*U.S. Department of Health and Human Services. Food and Drug Administration. Center for Drug Evaluation and Research (CDER): FDA Guidance for Industry: ANDAs for Certain Highly Purified Synthetic Drug Products That Refer to Listed Drugs of rDNA Origin. May 2021.

OUR TIMELINES FOR SEMAGLUTIDE – TRANSPARENCY AND FLEXIBILITY TO MAKE US YOUR PREFERRED PARTNER

Technical information	2019	2020	2021	2022	2023
Ultrahigh performance liquid chromatography method developed	→				
Non GMP material available	→				
Process for fatty acid moiety completed	→	→			
GMP process development completed	→	→			
GMP material available		→	→		
DMF-registration batches manufactured			→	→	
US GDUFA DMF available					→

ROBUST PROCESSES AND REDUNDANCY – TO GUARANTEE YOUR SUPPLY

Robust processes and supply security
Having our in-house building blocks for peptide synthesis as well as long-term cooperation with trusted suppliers ensures on-time production. Redundancy of multi-purpose equipment and facilities helps to mitigate risks in the supply chain, together with our stock of finished APIs and is the key for on-time product deliveries to our customers.

SERVICES – WE STRIVE TO DELIVER THE COMPLETE SOLUTION FOR YOUR NEEDS

Semaglutide impurities
The success of an abbreviated new drug application depends largely on the impurity profile of the synthetic peptide drug compared to the impurity profile of the reference listed drug (RLD) and the level of achieved "sameness". Bachem identifies impurities, characterizes peptide-related impurities that are above 0.10% of the drug substance or greater, and provides impurities as catalog products.

Related products (for research purposes only)
Beyond GMP-grade semaglutide, we provide semaglutide in research grade, variants thereof and in different salt forms.

Related APIs
Bachem also provides exenatide, liraglutide, glucagon and other APIs for diabetes management.

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Technical Information	Semaglutide
Amino acid sequence	H-His-Aib-Glu-Gly-Thr-Phe-Thr-Ser-Asp-Val-Ser-Ser-Tyr-Leu-Glu-Gly-Gln-Ala-Ala-Lys(AEEAc-AEEAc-γ-Glu-carboxyheptadecanoyl)-Glu-Phe-Ile-Ala-Trp-Leu-Val-Arg-Gly-Arg-Gly-OH
Molecular formula, relative molecular mass	$C_{187}H_{291}N_{45}O_{59}$
Relative molecular mass	4113.64 g/mol
CAS-Number	910463-68-2

Innovative processes and high-tech automation deliver sustainable, eco-friendly material with consistent quality

Large-scale production means economic pricing and high volumes

High-quality regulatory dossier meets the new FDA guideline*

Compliant production facilities in Switzerland and the US with regular inspections by Swissmedic and FDA

Optimized services reduce complexity for our clients, allowing them to concentrate on their business objectives

About Bachem:

Bachem is a leading, innovation-driven company specializing in the development and manufacture of peptides and oligonucleotides. The company, which has over 50 years of experience and expertise, 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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