

**GENERIC
APIs**

BACHEM

LEADING PARTNER IN TIDES

LEADING PARTNER IN TIDES

With almost 50 years of expertise in peptide and small molecule synthesis Bachem has an outstanding track record in large-scale manufacturing and excellent product quality.



GENERIC PORTFOLIO

PEPTIDE GENERIC APIs

Generic API	CEP/DMF	Application	Site
Atosiban	DMF	Reproductive Medicine	CH
Bivalirudin	DMF	Cardiovascular Disease	CH
Buserelin	DMF	Oncology, Reproductive Medicine	CH
Desmopressin Acetate	CEP, DMF	Diabetes Insipidus	USA
Exenatide Acetate	DMF	Diabetes Mellitus	USA
Glucagon	DMF	Diabetes Mellitus	CH
Gonadorelin Acetate	CEP, DMF	Oncology, Reproductive Medicine	CH
Goserelin Acetate	CEP, DMF	Oncology, Reproductive Medicine	CH
Icatibant Acetate	DMF	Hereditary Angioedema	CH
Lanreotide	DMF	Oncology	USA
Leuprolide Acetate	CEP, DMF	Oncology	CH
Octreotide Acetate	DMF	Oncology	CH
Somatostatin	CEP	Gastritis	CH
Teriparatide Acetate / pTH (1-34) (human)	DMF	Osteoporosis	USA
Tetracosactide	DMF	Oncology, Diagnostics	CH
Triptorelin Acetate	DMF	Oncology, Reproductive Medicine	CH
Triptorelin Pamoate	DMF	Oncology, Reproductive Medicine	CH
(Arg ⁸)-Vasopressin	DMF	Diabetes Insipidus	USA

SMALL MOLECULE APIs

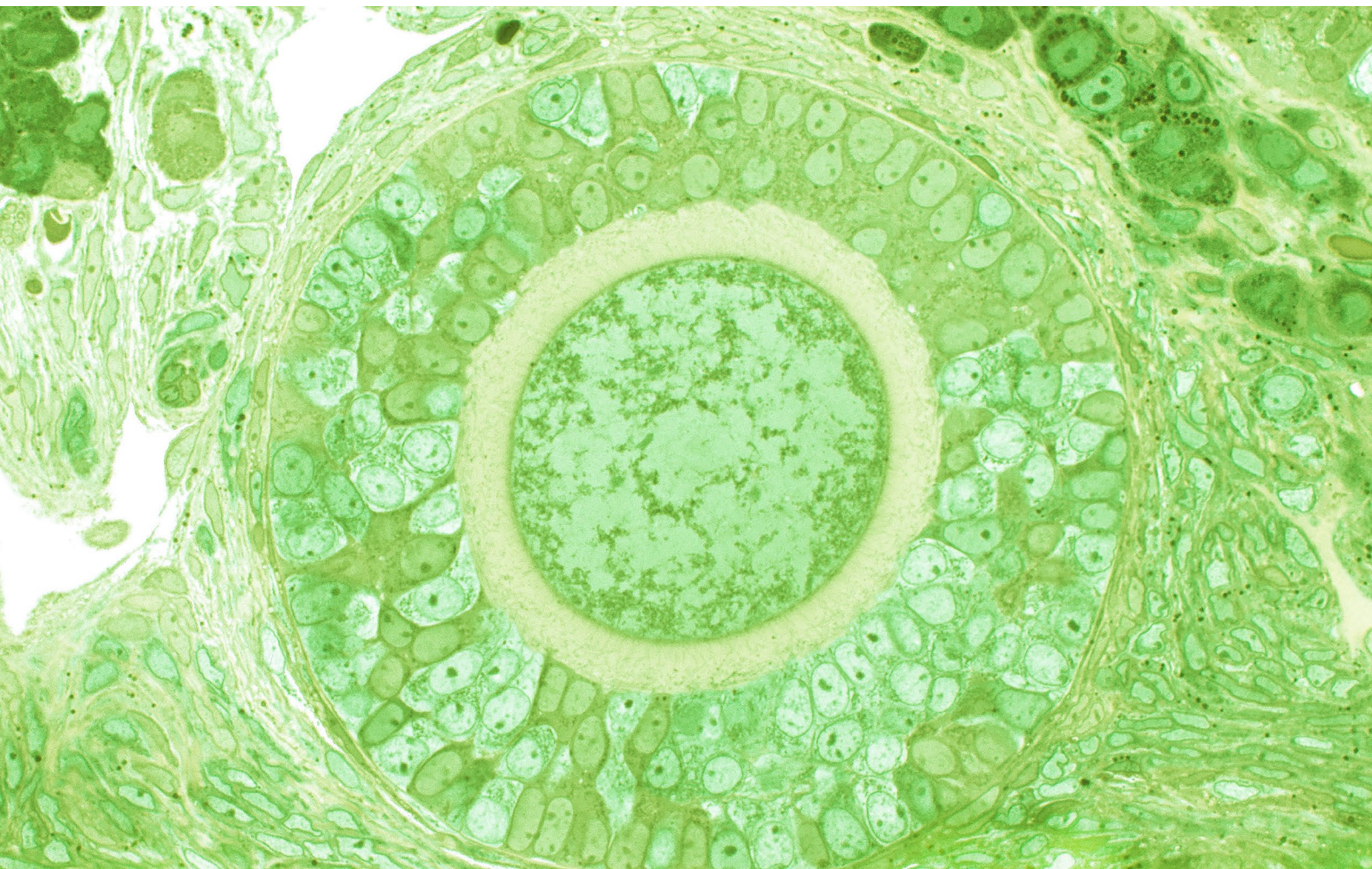
Generic API	CEP/DMF	Application	Site
Antazoline Hydrochloride	DMF	Ophthalmology	CH
Antazoline Phosphate	DMF	Ophthalmology	CH
Antazoline Sulfate	DMF	Ophthalmology	CH
Carbidopa	CEP, DMF	Epilepsy and Parkinson's Disease	CH
Etomidate	CEP, DMF	Sedatives and Anesthetics	CH
Propofol	CEP, DMF	Sedatives and Anesthetics	CH

PIPELINE

Generic API	Application
Degarelix*	Oncology
Glepaglutide*	Short Bowel Syndrome
Liraglutide*	Diabetes Mellitus
Semaglutide*	Diabetes Mellitus
Teduglutide*	Short Bowel Syndrome
Tirzepatide*	Diabetes Mellitus

Please note: Some products may be restricted in certain countries.

* Bachem provides this product solely for uses within the scope of any statute or law providing for an immunity, exemption, or exception to patent infringement ("Exempted Uses"), including but not limited to 35 U.S.C. § 271(e)(1) in the United States, the Bolar type exemption in Europe, and any corresponding exception to patent infringement in any other country. It is the sole responsibility of the purchaser or user of this product, and the purchaser or user of this product agrees to engage only in such Exempted Uses, and to comply with all applicable intellectual property laws and/or regulations. The purchaser of this product agrees to indemnify Bachem against all claims in connection with the performance of the respective commercial agreement (e.g. supply agreement) and possible infringements of intellectual property rights.



Bachem is the leading independent supplier of active pharmaceutical ingredients (APIs) for the human and veterinary pharmaceutical market.

You can choose from our portfolio of generic APIs, which are produced in annual quantities of up to hundreds of kilograms and tons for commercial use.

«WE PROVIDE LONG TERM SUPPORT, GUIDANCE AND COMMITMENT TO OUR PARTNERS AND PROJECTS.»

- Large number of generic APIs
- Your reliable partner with outstanding experience in peptide chemistry
- Multi-kg scale cGMP peptide manufacturing facilities in Europe and in the US
- Large scale manufacturing capabilities for small molecule APIs
- Technical and regulatory support tailored to your needs



GENERIC APIs

Our partners trust in the constant quality of our generic APIs for the manufacturing of their drug products.



ST. HELENS (UK)

VISTA (CA)

TORRANCE (CA)

GLOBAL BUSINESS

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

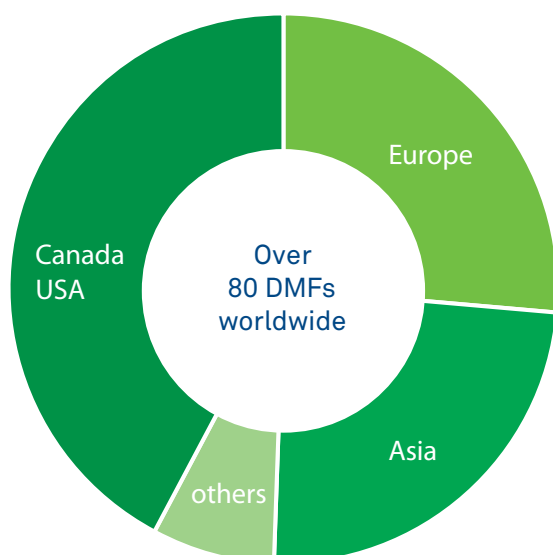
All cGMP manufacturing sites are
inspected by the US-FDA and
national authorities.

■ GMP MANUFACTURING SITES

■ BUBENDORF (CH)
■ VIONNAZ (CH)

TOKYO (JP) ■

BACHEM DMFs FOR GENERIC APIs



BACHEM'S PORTFOLIO

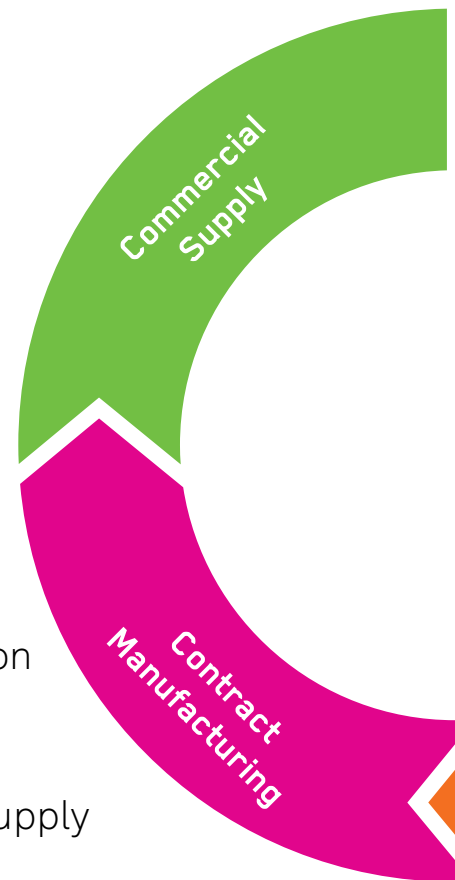
of products and services...

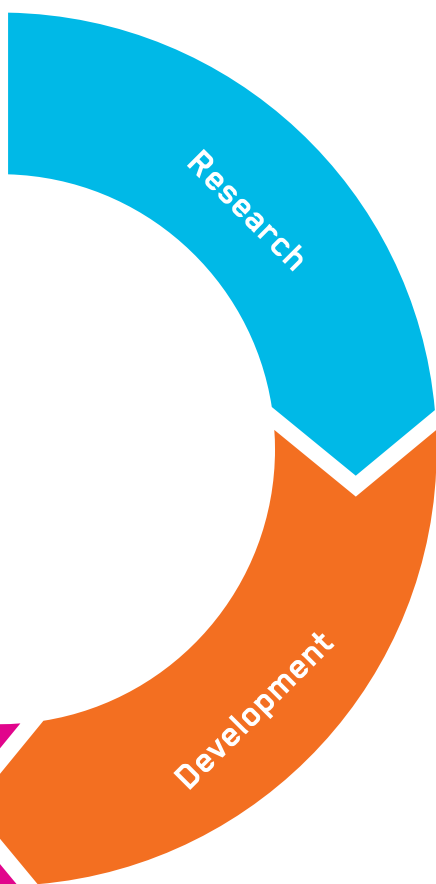
GENERIC APIs

- peptide and small molecule generics
- supply of commercial quantities
- reputation for sustained quality & supply
- high-demand APIs available from stock
- close and long term partnerships

NCEs

- process development, optimization and validation
- comprehensive analytical services
- supply of cGMP material for all clinical phases
- cGMP-manufacturing of APIs for commercial supply





CATALOG PRODUCTS

- a large variety of products available online
- peptides, amino acids, inhibitors, substrates
- fast & easy ordering @ shop.bachem.com
- bulk quantities according to your needs
- excellent customer and technical support

CUSTOM SYNTHESIS

- from discovery stages to early clinical candidates
- strong focus on quality and timely execution
- development of synthetic routes for scale up
- best industry practice
- highly motivated and experienced team

...from R&D to commercial supply

QUALITY YOU CAN TRUST

Bachem's quality management system covers the entire production process, from starting materials to production, packaging and delivery of the final product.

Our partners trust in the constant quality of our generic APIs for the manufacturing of their drug products.

«Frankly speaking and without flattery, we have never experienced such a great level of perfection. Instead of describing all that we have seen or read about Bachem, it is much easier to state that we returned from our visit to Bachem with the highest level of admiration.»

Big Pharma Company

Regular audits by customers and authorities systematically verify our quality in terms of equipment, processes and products. Successful inspections by national authorities and more than 50 customer audits per year confirm our high quality standard and our compliance with the requirements for Good Manufacturing Practice (cGMP).



PARTNERSHIP

Bachem has established long-term contracts with important industrial partners, being a reliable, independent and financially solid company. Examples of long-term supply agreements on generic APIs are Goserelin to AstraZeneca (GB) and Triptorelin to Debiopharm (CH).

«THE CLOSE RELATIONSHIP WITH OUR PARTNERS, THE TIGHT EXECUTION OF PROJECTS AND OUR CUSTOMER-FRIENDLY SERVICE AND SUPPORT SET US APART.»

FULL RANGE

of technical and regulatory support

- We enable clients to meet the requirements of the authorities by providing comprehensive technical and regulatory information for filing.
- Our service includes the compilation of technical and regulatory documents and we offer support for regulatory requests.
- Through our expertise we enable clients to be the first to file their generic drugs in a highly competitive market.



**«PROUD OF STRONG TRACK
RECORDS IN THE SUCCESSFUL
FILING OF APIs WORLDWIDE.»**

PEPTIDE APIs

ATOSIBAN

DMF

3-Mercaptopropinyl-D-Tyr(Et)-Ile-Thr-Asn-Cys-Pro-Orn-Gly-NH₂
(Disulfide bond)

Synonyms

(Deamino-Cys¹,D-Tyr(Et)²,Thr⁴,Orn⁶)-Oxytocin; RWJ 22164

Fields of Application

Premature labor

Active Substance

Atosiban is an oxytocin and vasopressin antagonist used as a tocolytic in the management of preterm labor.

BIVALIRUDIN

DMF

H-D-Phe-Pro-Arg-Pro-Gly-Gly-Gly-Gly-Asn-Gly-Asp-Phe-Glu-Glu-Ile-Pro-Glu-Glu-Tyr-Leu-OH
trifluoroacetate salt

Synonyms

BG 8967; Hirulog; Hirulog I

Fields of Application

Moderate to high risk acute coronary syndromes
Percutaneous coronary intervention

Active Substance

Bivalirudin is a hirudin analog acting as a specific and reversible direct thrombin inhibitor.

BUSERELIN

DMF

Pyr-His-Trp-Ser-Tyr-D-Ser(tBu)-Leu-Arg-Pro-NHEt acetate salt

Synonyms

(Des-Gly¹⁰,D-Ser(tBu)⁶,Pro-NHEt⁹)-LHRH

Fields of Application

Use in reproductive medicine
Advanced hormone-dependent prostate cancer
Endometriosis
Central precocious puberty
Uterine myoma

Active Substance

Buserelin is a potent LHRH agonist. After a transient increase, the continuous administration results in downregulation of LH and FSH levels followed by a suppression of ovarian and testicular steroid biosynthesis.

DESMOPRESSIN ACETATE CEP, DMF

3-Mercaptopropionyl-Tyr-
Phe-Gln-Asn-Cys-Pro-
D-Arg-Gly-NH₂ acetate salt
(Disulfide bond)

Synonyms

DDAVP; (Deamino-Cys¹,D-Arg⁸)-
Vasopressin

Fields of Application

Nocturnal enuresis
Central diabetes insipidus, polyuria,
polydipsia
Mild and moderate forms of hemo-
philia A and von Willebrand disease

Active Substance

Desmopressin is a synthetic analog
of vasopressin with low vasopressor
activity. Apart from its increasing
effect on water resorption by the
kidneys, it raises plasma levels of
von Willebrand factor and factor VIII.
In veterinary medicine, desmopres-
sin is applied in the treatment of
canine and feline diabetes insipidus.

EXENATIDE ACETATE DMF

H-His-Gly-Glu-Gly-Thr-Phe-
Thr-Ser-Asp-Leu-Ser-Lys-
Gln-Met-Glu-Glu-Glu-Ala-
Val-Arg-Leu-Phe-Ile-Glu-
Trp-Leu-Lys-Asn-Gly-Gly-
Pro-Ser-Ser-Gly-Ala-Pro-
Pro-Pro-Ser-NH₂
acetate salt

Synonyms

Exendin-4

Fields of Application

Diabetes II

Active Substance

Exendin-4 (exenatide), a 39-amino
acid peptide originally isolated from
the salivary glands of the Gila mon-
ster (*Heloderma suspectum*), differs
from exendin-3 only in two positions
close to the N-terminus. Application
of exenatide causes an increase in
acinar cAMP without stimulating
amylase release. As an incretin mi-
metic, exenatide acts as agonist of
the glucagon-like peptide-1 (GLP-1)
receptor. As GLP-1, though with pro-
longed activity, exenatide augments
the postprandial production of
insulin and suppresses secretion of
glucagon. For this reason, exenatide
has found use as a medication of
diabetes II.

GLUCAGON DMF

H-His-Ser-Gln-Gly-Thr-Phe-
Thr-Ser-Asp-Tyr-Ser-Lys-
Tyr-Leu-Asp-Ser-Arg-Arg-
Ala-Gln-Asp-Phe-Val-Gln-
Trp-Leu-Met-Asn-Thr-OH

Fields of Application

Hypoglycemia (due to diabetes
mellitus)

Active Substance

Glucagon opposes the action of
insulin. It enhances the synthesis
and mobilization of glucose in the
liver.

GONADORELIN ACETATE CEP, DMF

Pyr-His-Trp-Ser-Tyr-Gly-
Leu-Arg-Pro-Gly-NH₂
acetate salt

Synonyms

GnRH; Gonadotropin-releasing hormone; LHRH; Luteinizing hormone-releasing factor

Fields of Application

Ovarian follicular cysts (veterinary medicine)
Use in reproductive medicine
Diagnosis of the hypothalamic-pituitary-gonadal axis function
Cryptorchidism
Synchronization of ovulation (veterinary medicine)

Active Substance

Gonadorelin is also known as LHRH or GnRH. After a transient increase, continuous administration results in downregulation of LH and FSH levels followed by a suppression of ovarian and testicular steroid biosynthesis.

GOSERELIN ACETATE CEP, DMF

Pyr-His-Trp-Ser-Tyr-D-Ser
(tBu)-Leu-Arg-Pro-
Azagly-NH₂ acetate salt

Synonyms

(D-Ser(tBu)⁶,Azagly¹⁰)-LHRH

Fields of Application

Advanced hormone-dependent prostate cancer
Advanced hormone-dependent breast cancer
Endometriosis
Uterine myoma
Use in reproductive medicine

Active Substance

Goserelin Acetate is a potent LHRH agonist. After a transient increase, continuous administration results in downregulation of LH and FSH levels followed by a suppression of ovarian and testicular steroid biosynthesis.

ICATIBANT ACETATE DMF

H-D-Arg-Arg-Pro-Hyp-Gly-
Thi-Ser-D-Tic-Oic-Arg-OH
acetate salt

Synonyms

(D-Arg⁰,Hyp³,Thi⁵,D-Tic⁷,Oic⁸)-Bradykinin; HOE140

Fields of Application

Hereditary angioedema
ACE inhibitor-induced angioedema (off-label use)

Active Substance

Icatibant Acetate is a selective competitive antagonist for the bradykinin B2 receptor. It is indicated for the treatment of acute attacks of hereditary angioedema (HAE). HAE is a rare disorder resulting in periodic attacks of acute edema. It is characterized by a deficiency of functional C1 esterase inhibitor that leads to the overproduction of bradykinin, which triggers vasodilation, vascular permeability, and edema. Icatibant Acetate inhibits bradykinin from binding to the B2 receptor and thereby treats the clinical symptoms of an acute, episodic attack of HAE.

LANREOTIDE DMF

H-D-2-Nal-Cys-Tyr-D-Trp-
Lys-Val-Cys-Thr-NH₂
(Disulfide bond)

Synonyms

Angiopeptin; BIM-23014; DC-13-116

Fields of Application

Acromegaly
Carcinoid syndrome
Thyrotrophic adenomas

Active Substance

Lanreotide is a synthetic analog of somatostatin with properties similar to octreotide.

LEUPROLIDE ACETATE CEP, DMF

Pyr-His-Trp-Ser-Tyr-D-Leu-
Leu-Arg-Pro-NH₂
acetate salt

Synonyms

Leuporelin; (Des-Gly¹⁰,D-Leu⁶,
Pro-NH₂⁹)-LHRH

Fields of Application

Advanced hormone-dependent
prostate cancer
Advanced hormone-dependent
breast cancer
Endometriosis
Uterine myoma
Central precocious puberty

Active Substance

Leuprolide Acetate is a potent LHRH agonist. After a transient increase, continuous administration results in downregulation of LH and FSH levels followed by a suppression of ovarian and testicular steroid biosynthesis.

OCTREOTIDE ACETATE DMF

H-D-Phe-Cys-Phe-D-Trp-
Lys-Thr-Cys-L-threoninol
acetate salt (Disulfide bond)

Synonyms

SMS 201-995

Fields of Application

Acromegaly
Carcinoid syndrome
VIPomas

Active Substance

Octreotide Acetate is a longer acting synthetic octapeptide analog of naturally occurring somatostatin. It inhibits the secretion of gastro-entero-pancreatic peptide hormones and the release of growth hormone.

SOMATOSTATIN CEP

H-Ala-Gly-Cys-Lys-Asn-
Phe-Phe-Trp-Lys-Thr-Phe-
Thr-Ser-Cys-OH acetate salt
(Disulfide bond)

Synonyms
Somatostatin-14; SRIF-14

Fields of Application
Ulcer bleeding
Hemorrhagic gastritis
Postoperative pancreatic and duo-
denal fistulae
Variceal hemorrhage

Active Substance
Somatostatin is an inhibitor of growth hormone release from the anterior pituitary and suppresses the release of a variety of other hormones involved in the regulation of important physiological functions of the gastrointestinal tract.

TERIPARATIDE ACETATE / pTH (1-34) (HUMAN) DMF

H-Ser-Val-Ser-Glu-Ile-Gln-
Leu-Met-His-Asn-Leu-Gly-
Lys-His-Leu-Asn-Ser-Met-
Glu-Arg-Val-Glu-Trp-Leu-
Arg-Lys-Lys-Leu-Gln-Asp-
Val-His-Asn-Phe-OH
acetate salt

Synonyms
Parathyroid hormone (1-34) (human)

Fields of Application
Osteoporosis - for synthetic peptide
not yet an approved application

Active Substance
pTH (1-34) (human) Acetate
administered in low dosage and
intermittently stimulates bone
formation.

TETRACOSACTIDE DMF

H-Ser-Tyr-Ser-Met-Glu-His-
Phe-Arg-Trp-Gly-Lys-Pro-
Val-Gly-Lys-Lys-Arg-Arg-
Pro-Val-Lys-Val-Tyr-Pro-OH
acetate salt

Synonyms
Cosyntropin; Tetracosactrin;
 α^{1-24} -Corticotropin; ACTH (1-24)

Fields of Application
Investigation of adrenocortical
insufficiency
Neurological diseases
Rheumatic diseases
Skin diseases
Diseases of the intestinal tract
Oncology

Active Substance
Tetracosactide is a synthetic peptide that corresponds to the first 24 amino acids of the naturally occurring hormone ACTH (adrenocorticotrophic hormone). It stimulates the adrenal cortex to produce corticosteroids, mineralocorticoids, and, to a lesser extent, androgens. In veterinary medicine, tetracosactide (cosyntropin) is used as a diagnostic for detecting adrenal disorders in dogs, horses, and cats.

TRIPTORELIN ACETATE

DMF

Pyr-His-Trp-Ser-Tyr-D-Trp-
Leu-Arg-Pro-Gly-NH₂
acetate salt

Synonyms
(D-Trp⁶)-LHRH

Fields of Application
Advanced hormone-dependent
prostate cancer
Use in reproductive medicine
Endometriosis
Central precocious puberty

Active Substance
Triptorelin Acetate is a potent LHRH
agonist. After a transient increase,
continuous administration results
in downregulation of LH and FSH
levels followed by a suppression
of ovarian and testicular steroid
biosynthesis.

TRIPTORELIN PAMOATE

DMF

Pyr-His-Trp-Ser-Tyr-D-Trp-
Leu-Arg-Pro-Gly-NH₂
pamoate salt

Synonyms
(D-Trp⁶)-LHRH; Triptorelin Embonate

Fields of Application
Advanced hormone-dependent
prostate cancer
Use in reproductive medicine

Active Substance
Triptorelin Pamoate is a potent
LHRH agonist. After a transient
increase, continuous administration
results in downregulation of LH and
FSH levels followed by a suppres-
sion of ovarian and testicular steroid
biosynthesis.

(ARG⁸)- VASOPRESSIN

DMF

H-Cys-Tyr-Phe-Gln-Asn-
Cys-Pro-Arg-Gly-NH₂
acetate salt (Disulfide bond)

Synonyms
Argipressin; AVP; Arginine
Antidiuretic Hormone; Leiormone

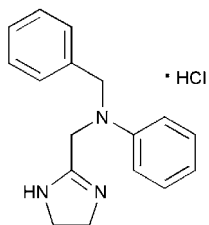
Fields of Application
Central diabetes insipidus
Variceal bleeding
Vasoconstrictor in local anesthetic
injections

Active Substance
(Arg⁸)-Vasopressin or argipressin
is an antidiuretic peptide hormone
that plays a key role in maintain-
ing plasma osmolality. The peptide
released from the posterior pituitary
gland promotes renal tubular reab-
sorption of water.
Argipressin is involved in the control
of circadian rhythm, thermoregula-
tion, and ACTH release in the brain.

SMALL MOLECULE APIs

ANTAZOLINE HYDROCHLORIDE

DMF



Synonyms

2-(N-Phenyl-N-benzyl-amino-methyl)imidazoline · HCl;
2-[(N-Benzylanilino)methyl]-2-imidazoline · HCl;
4,5-Dihydro-N-phenyl-N-(phenyl-methyl)-1H-imidazole-2-methanamine · HCl

Fields of Application

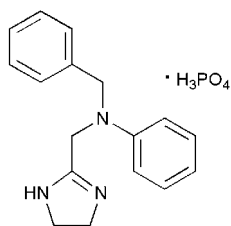
Conjunctivitis

Active Substance

Antazoline Hydrochloride is an ethylenediamine derivative with antihistaminic properties and is used in conjunction with a vasoconstrictor for ocular allergies.

ANTAZOLINE PHOSPHATE

DMF



Synonyms

2-(N-Phenyl-N-benzyl-amino-methyl)imidazoline · phosphate;
2-[(N-Benzylanilino)methyl]-2-imidazoline · phosphate;
4,5-Dihydro-N-phenyl-N-(phenyl-methyl)-1H-imidazole-2-methanamine · phosphate

Fields of Application

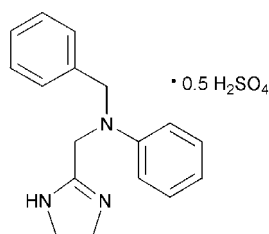
Conjunctivitis

Active Substance

Antazoline Phosphate is an ethylenediamine derivative with antihistaminic properties and is used in conjunction with a vasoconstrictor for ocular allergies.

ANTAZOLINE SULFATE

DMF



Synonyms

2-(N-Phenyl-N-benzyl-aminomethyl)imidazoline · sulfate;
2-[(N-Benzylanilino)methyl]-2-imidazoline · sulfate;
4,5-Dihydro-N-phenyl-N-(phenyl-methyl)-1H-imidazole-2-methanamine · sulfate

Fields of Application

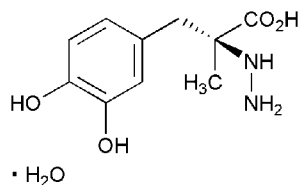
Conjunctivitis

Active Substance

Antazoline Sulfate is an ethylenediamine derivative with antihistaminic properties and is used in conjunction with a vasoconstrictor for ocular allergies.

CARBIDOPA

CEP, DMF



Synonyms

(S)-3-(3,4-Dihydroxyphenyl)-2-hydrazino-2-methylpropanoic acid · H₂O;
(S)-α-Hydrazino-3,4-dihydroxy-α-methylbenzenepropanoic acid monohydrate;
(-)-L-α-Hydrazino-3,4-dihydroxy-α-methylhydrocinnamic acid monohydrate;
α-Methyl dopahydrazine monohydrate

Fields of Application

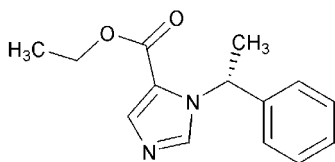
Parkinson's disease

Active Substance

Carbidopa, an aromatic L-amino acid decarboxylase inhibitor, which does not cross the blood-brain barrier, is routinely administered in combination with levodopa to patients with Parkinson's disease to reduce the peripheral decarboxylation of levodopa to dopamine.

ETOMIDATE

CEP, DMF



Synonyms

1-[(1R)-1-Phenylethyl]-1H-imidazole-5-carboxylic acid ethyl ester;
(+)-Ethyl 1-(α-methylbenzyl)-imidazole-5-carboxylate

Fields of Application

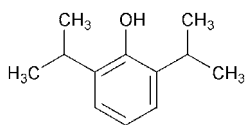
Anesthesia

Active Substance

Etomidate is a rapid, short acting intravenous anesthetic agent with no analgesic properties and a relative lack of significant hemodynamic and respiratory effects.

PROPOFOL

CEP, DMF



Synonyms

2,6-Bis(1-methylethyl)phenol;
2,6-Diisopropylphenol;
ICI 35868

Fields of Application

Sedation
Anesthesia

Active Substance

Propofol is an intravenous, short acting anesthetic with rapid onset of action.

STRATEGIC MOVES REQUIRE STRATEGIC PARTNER- SHIPS

We manufacture APIs with excellent batch-to-batch reproducibility. This guarantees consistent high quality and makes Bachem a reliable partner for you.



SITE CERTIFICATIONS

swissmedic

CERTIFICATE OF GMP COMPLIANCE

We certify herewith

that the company **BACHEM AG, Hauptstrasse 144, 4416 Bubendorf, Switzerland**, has been duly authorized to manufacture and distribute active pharmaceutical ingredients (APIs), investigational active pharmaceutical ingredients and medicinal products;

that the manufacturing licence is including following types of active pharmaceutical ingredients (APIs):

- highly active or sensitising APIs such as Peptide
- biological APIs such as
 - APIs produced by means of recombinant technologies, hybridoma and monoclonal antibodies
 - APIs (extracts) of human or animal origin
- investigational active pharmaceutical ingredients

that the company is performing the following activities:

- quality control (chemical, physical) of medicinal products as contract laboratory
- quality control (microbiological) of medicinal products as contract laboratory excluding tests of sterility

that the company is keeping the required level for good practices in the manufacture of active pharmaceutical ingredients (APIs), investigational active pharmaceutical ingredients and medicinal products according to the Swiss regulations in force. These regulations are in accordance with the requirements for good practices in the manufacture and quality control of the Pharmaceutical Inspection Convention /Co-operation Scheme (PIC/S) and the Directives of the European Commission;

that the manufacturing plant of the company is subject to official periodic inspections; the last regular inspection was conducted on **October 18-20 and 23-24, 2017**;

that the requirements regarding manufacture and quality control for active pharmaceutical ingredients (APIs), investigational active pharmaceutical ingredients and medicinal products for export are identical to those applicable to active pharmaceutical ingredients (APIs), investigational active pharmaceutical ingredients and medicinal products sold in Switzerland.

Berne, December 18, 2017
No. 17-2372

Swissmedic, Swiss Agency for Therapeutic Products
Dr. Alfred Rytz

Schweizerisches Helvetisches Institut
Institut suisse des produits thérapeutiques
Istituto svizzero per gli agenti terapeutici
Swiss Agency for Therapeutic Products

I-303 AA-01-AC4e / V04 / bja / gme / sm / 21.09.2017

Swissmedic | Hallenstrasse 7 | Postfach | CH-3000 Bern 9 | www.swissmedic.ch | Tel. +41 58 462 02 11 | Fax +41 58 462 02 12

BACHEM AG

- Development and manufacturing of active pharmaceutical ingredients (APIs)
- Registered with and inspected by the FDA, Swissmedic, and national authorities
- Licensed for the manufacture of APIs for the Japanese market
- Peptides and small organic molecules
- Manufacturing of catalog products
- Custom synthesis
- Production of peptides by solid-phase peptide synthesis (SPPS) and solution-phase chemistry

swissmedic

CERTIFICATE OF GMP COMPLIANCE

We certify herewith

that the company **Bachem SA, succursale de Vionnaz, Route du Simplon 22, 1895 Vionnaz, Switzerland**, has been duly authorized to manufacture and distribute active pharmaceutical ingredients (APIs), investigational active pharmaceutical ingredients and medicinal products;

that the manufacturing licence is including following types of active pharmaceutical ingredients (APIs):

- highly active or sensitising APIs
- investigational active pharmaceutical ingredients

that the company is performing the following activities:

- quality control (chemical, physical, biochemical) of medicinal products as contract laboratory

that the company is keeping the required level for good practices in the manufacture of active pharmaceutical ingredients (APIs), investigational active pharmaceutical ingredients and medicinal products according to the Swiss regulations in force. These regulations are in accordance with the requirements for good practices in the manufacture and quality control of the Pharmaceutical Inspection Convention /Co-operation Scheme (PIC/S) and the Directives of the European Commission;

that the manufacturing plant of the company is subject to official periodic inspections; the last regular inspection was conducted on **June 17-19, 2019**;

that the requirements regarding manufacture and quality control for active pharmaceutical ingredients (APIs), investigational active pharmaceutical ingredients and medicinal products for export are identical to those applicable to active pharmaceutical ingredients (APIs), investigational active pharmaceutical ingredients and medicinal products sold in Switzerland.

Berne, August 13, 2019
No. 19-1072

Swissmedic, Swiss Agency for Therapeutic Products
Dr. Alfred Rytz

Schweizerisches Helvetisches Institut
Institut suisse des produits thérapeutiques
Istituto svizzero per gli agenti terapeutici
Swiss Agency for Therapeutic Products

I-303 AA-01-AD4e / V04 / bja / gme / sm / 21.09.2017

Swissmedic | Hallenstrasse 7 | Postfach | CH-3000 Bern 9 | www.swissmedic.ch | Tel. +41 58 462 02 11 | Fax +41 58 462 02 12

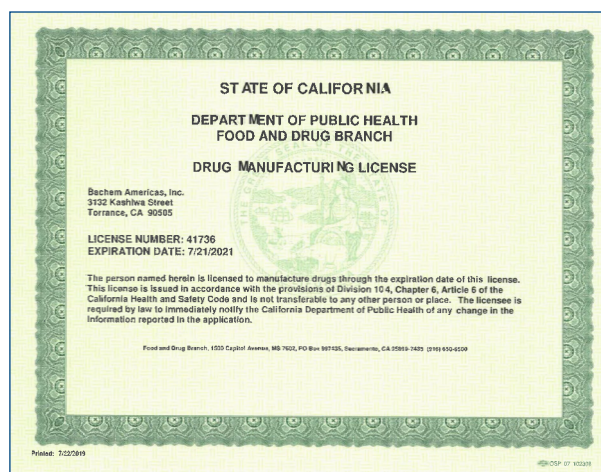
BACHEM SA, SUCCURSALE DE VIONNAZ

- Development and manufacturing of small-molecule active pharmaceutical ingredients (APIs)
- Registered with and inspected by the FDA, Swissmedic, and national authorities
- Licensed for the manufacture of APIs for the Japanese market
- Broad expertise in amino acid chemistry, chiral synthesis, metal catalysis, heterocyclic chemistry, enzymatic reactions, high-pressure reactions, electrochemistry, continuous flow technology



BACHEM AMERICAS, INC. (VISTA)

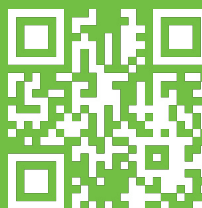
- Development and manufacturing of active pharmaceutical ingredients (APIs)
- Registered with and inspected by the FDA
- Custom synthesis
- Production of peptides by solid-phase peptide synthesis (SPPS) and solution-phase chemistry




BACHEM AMERICAS, INC. (TORRANCE)

- Development and manufacturing of active pharmaceutical ingredients (APIs)
- Registered with and inspected by the FDA
- Licensed for the manufacture of APIs for the Japanese market
- Manufacturing of catalog products and custom synthesis
- Production of peptides by solid-phase peptide synthesis (SPPS)

OUR REGULATORY DOCUMENTS



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For almost 50 years, Bachem holds a leading position in the process development and manufacturing of peptides.



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Marketing & Sales Contact

Americas

Bachem Americas, Inc.

Tel. +1 888 422 2436 (toll free in USA & Canada)

+1 310 539 4171

sales.us@bachem.com

Asia Pacific

Bachem Japan K.K.

Tel. +81 3 6661 0774

sales.jp@bachem.com

Europe, Africa, Middle East and India

Bachem AG

Tel. +41 58 595 2020

sales.ch@bachem.com

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