GENERIC APIS BACHEM LEADING PARTNER IN TIDES

LEADING PARTNER INTIDES

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

SMALL MOLECULE APIS

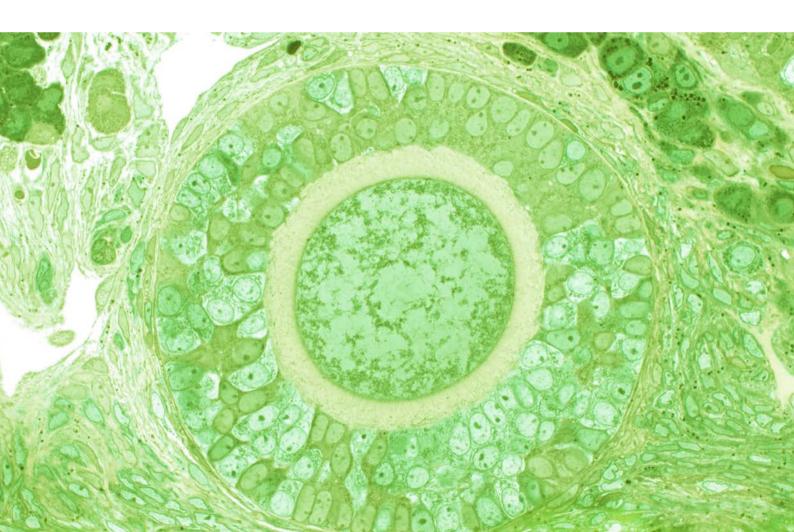
Generic API	CEP/DMF	Application	Site
Antazoline Hydrochloride	DMF	Ophthalmology	СН
Antazoline Phosphate	DMF	Ophthalmology	СН
Antazoline Sulfate	DMF	Ophthalmology	СН
Carbidopa	CEP, DMF	DMF Epilepsy and Parkinson's Disease	
Etomidate	CEP, DMF	Sedatives and Anesthetics CH	
Propofol	CEP, DMF	Sedatives and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



VISTA (CA)

TORRANCE (CA)

GLOBAL BUSINESS

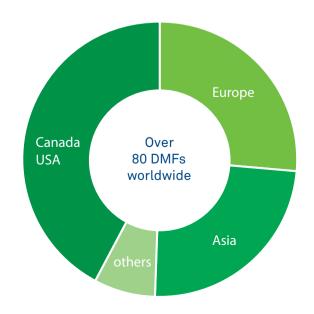
Bachem facilities are located in Switzerland, the UK, and in the USA.

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



TOKYO (JP) ■

BACHEM DMFs FOR GENERIC APIs



BACHEM'S PORTFOLIO

of products and services...

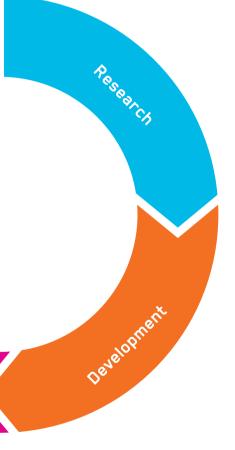
GENERIC APIS

- 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

Manufacturin



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

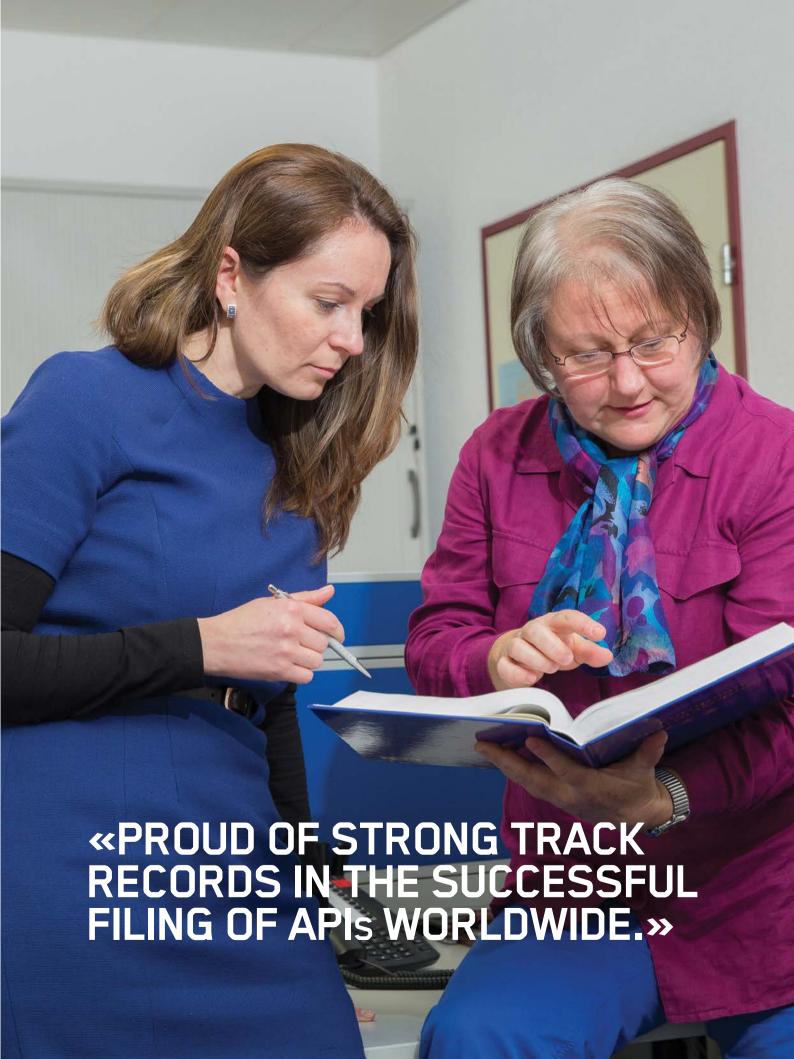
Bachem has established long-term contracts with important industrial partners, being a reliable, independent and financially solid company. Examples of long-term supply agreements on generic APIs are Goserelin to AstraZeneca (GB) and Triptorelin to Debiopharm (CH).

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.



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,Orn⁸) -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-Gly 10 ,D-Ser(tBu) 6 ,Pro-NHEt 9)-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 hemophilia 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, desmopressin 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 monster (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 mimetic, exenatide acts as agonist of the glucagon-like peptide-1 (GLP-1) receptor. As GLP-1, though with prolonged 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

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

Ovarian follicular cysts (veterinary

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-NH, 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-Arg^o,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-NHEt acetate salt

Synonyms

Leuprorelin; (Des-Gly¹⁰,D-Leu⁶, Pro-NHEt⁹)-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 gastroentero-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 duodenal 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)

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 (adrenocorticotropic 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

Svnonvms

(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 suppression 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

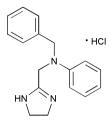
Active Substance

(Arg⁸)-Vasopressin or argipressin is an antidiuretic peptide hormone that plays a key role in maintaining plasma osmolality. The peptide released from the posterior pituitary gland promotes renal tubular reabsorption of water.

Argipressin is involved in the control of circadian rhythm, thermoregulation, 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

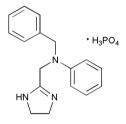
Fields of Application

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



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

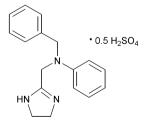
Fields of Application

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)-a-Hydrazino-3,4-dihydroxya-methylbenzenepropanoic acid monohydrate;

(-)-L-a-Hydrazino-3,4-dihy-droxy-a-methylhydrocinnamic acid monohydrate;

α-Methyldopahydrazine 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 RATEGIC RINER-

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



SITE CERTIFICATIONS



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



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

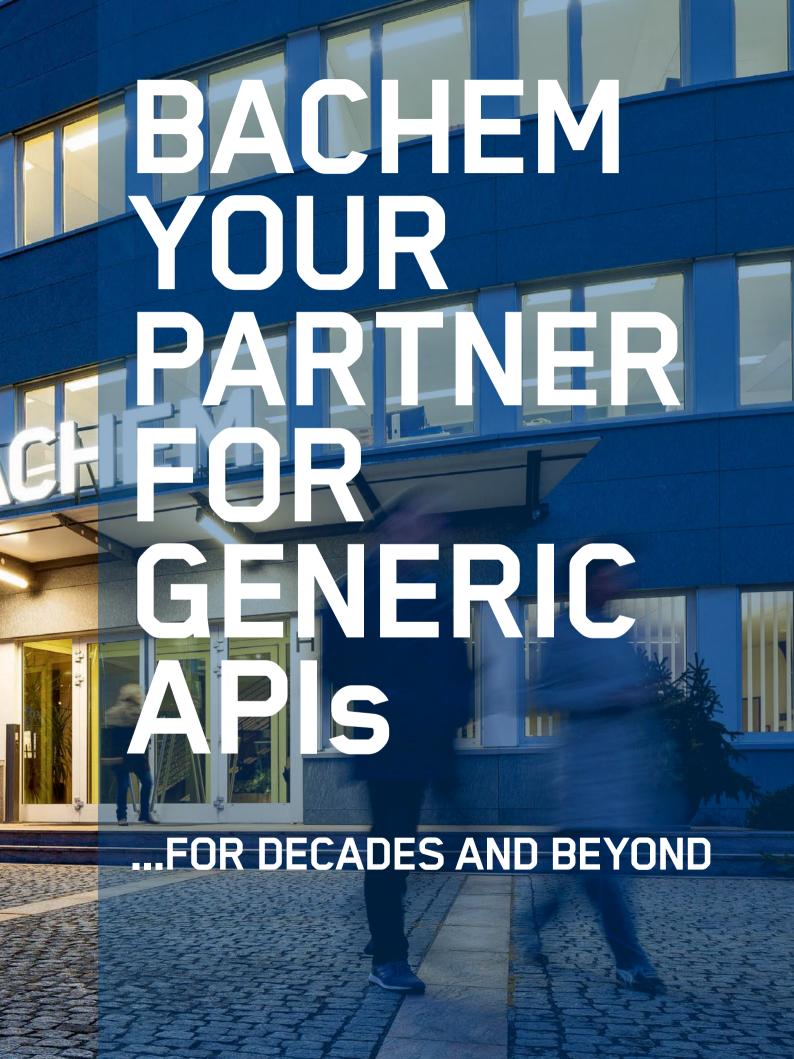


BACHEM AMERICAS, INC. (TORRANCE)

- 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)









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