

USP Peptide Standards



Ensuring the identity, quality, purity, and consistency of medication is fundamental to protecting public health. Our peptide monographs and reference standards can give drug manufacturers confidence in developing high-quality medicines.

Monographs and general chapters currently under development

USP is continuing to increase the number of peptide-related monographs in the *United States Pharmacopeia-National Formulary (USP-NF)*. Below is a list of just some of the monographs and general chapters currently under development or in revision.

A complete listing can be found in USP's *Pharmacopeial Forum (PF)*, a free bimonthly online journal where proposed monographs and general chapters are published for public review and comment before becoming official. To learn more, visit <https://www.uspnf.com/pharmacopeial-forum>.

- Bivalirudin
- Bivalirudin Injection
- Eptifibatide
- Eptifibatide dimer
- 3-D-Asp Eptifibatide
- Ganirelix Acetate
- Ganirelix Acetate Injection
- Glatiramer Acetate
- Glatiramer Acetate Injection
- Glucagon (synthetic)
- Gonadorelin Acetate
- Icatibant Injection
- Lanreotide Acetate
- Lanreotide Injection
- General Chapter <1504> *Quality Attributes of Starting Materials for the Chemical Synthesis of Therapeutic Peptides, in PF48(1)*

USP Education supporting peptide products

- BIO-PEP-01 Evolution of specifications and analytical methods during synthetic peptide drug development
- And many more, see [USP Education](#) for other offerings

USP seeks sponsors for peptide monograph development

Your participation in our standards-setting process is vital to the development of relevant *USP-NF* monographs. USP seeks sponsors to help develop the following monographs:

- Buserelin Acetate
- Carfilzomib
- Icatibant Acetate
- Liraglutide

How to get involved with USP

- Sponsor a new monograph
- Donate bulk material for the development of new or replacement lots of USP Reference Standards
- Comment on proposals for changes to the *USP-NF* through the *PF*
- Attend a USP Peptides and Oligonucleotides Workshop
- Participate in an Expert Panel or attend a BIO1 Expert Committee meeting

To order

Or see a complete list of USP's standards for peptides, visit <https://store.usp.org>.

For more information

Visit us online at <http://www.usp.org/biologics> to learn more.

USP Peptide Standards



USP–NF documentary standards for peptides

Below is a current list of official standards for peptides published in the USP–NF:

- Calcitonin Salmon
- Calcitonin Salmon Injection
- Calcitonin Salmon Nasal Solution
- Corticotropin Injection
- Corticotropin for Injection
- Repository Corticotropin Injection
- Cosyntropin
- Desmopressin Acetate
- Desmopressin Acetate Injection
- Desmopressin Nasal Spray Solution
- Exenatide
- Exenatide Injection
- Glucagon
- Glucagon for Injection
- Gonadorelin Acetate
- Gonadorelin Hydrochloride
- Gonadorelin for Injection
- Goserelin Acetate
- Goserelin Implants
- Leuprolide Acetate
- Octreotide Acetate
- Oxytocin
- Oxytocin Injection
- Teriparatide
- Teriparatide Injection
- Triptorelin Pamoate
- Vasopressin
- Vasopressin Injection
- General Chapter <503> *Acetic Acid in Peptides*
- General Chapter <503.1> *Trifluoroacetic Acid (TFA) in Peptides*
- General Chapter <1503> *Quality Attributes of Synthetic Peptide Drug Substances*

Reference Standards for peptides under development

Below is a partial list of Reference Standards for peptides currently under development at USP. To be notified about upcoming Reference Standards under development, sign up for our Reference Standards Release Notification Service:

<http://uspgo.to/notification-RS>

(Note: URL is case sensitive.)

- Eptifibatide
- Eptifibatide dimer
- 3-D-Asp Eptifibatide

Reference Standards for peptides

USP's Reference Standards are closely tied to its documentary standards. Based directly on official monographs published in the USP–NF, these highly characterized physical specimens are used in testing by pharmaceutical and related industries to help ensure the identity, strength, quality and purity of peptide-based medicines. The following peptide-related USP Reference Standards are currently available:

- Glacial Acetic Acid
- Bivalirudin
- [Asp9]-Bivalirudin
- [des-Glu13]-Bivalirudin
- Calcitonin Salmon
- Calcitonin Salmon Related Compound A
- Calcitonin Salmon Related Compound B
- Corticotropin
- Cosyntropin Acetate
- Desmopressin Acetate
- Endotoxin
- β -3-Asp Eptifibatide
- D-Har Eptifibatide
- 6-D-Cys Eptifibatide
- [Met(O)14]-Exenatide

- [N-Acetyl1-His1]-Exenatide
- [Glu13]-Exenatide
- Exenatide
- [D-His1] Exenatide (no compendial use)
- Glucagon (Human)
- Gonadorelin Acetate
- Gonadorelin Acetate Related Compound A
- Gonadorelin Hydrochloride
- [D-His2]-Gonadorelin
- [D-Tyr5]-Gonadorelin
- Goserelin Acetate
- Goserelin Related Compound A
- Goserelin System Suitability Mixture
- Leuprolide Acetate
- Lypressin
- Octreotide Acetate
- Octreotide Non-Cyclic System Suitability Marker
- Oxytocin
- Oxytocin Identification
- Sodium Acetate Trihydrate
- Sodium Trifluoroacetate
- Teriparatide
- Triptorelin Acetate
- Triptorelin Related Compound A
- Triptorelin Related Compound B
- Triptorelin Related Compound C
- Vasopressin

About USP

USP is an independent nonprofit organization that collaborates with the world's top health and science experts to develop high-quality standards that set the bar for manufacturing safe and effective medicines, supplements and food around the globe. Two billion people worldwide have access to quality medicines, dietary supplements and food as a result of USP's standards, advocacy and education.