



Peptide-related *USP-NF* Documentary Standards and USP Reference Standards

Below is a current list of Peptide-related USP official standards published in the *United States Pharmacopeia-National Formulary (USP-NF)*, with related USP Reference Standards and Associated Impurity Reference Standards.

USP General Chapters

<i>USP-NF</i> Documentary Standard	Related USP Reference Standards
Informational General Chapters	
<1052> <i>Biotechnology-Derived Articles – Amino Acid Analysis</i>	
<1503> <i>Quality Attributes of Synthetic Peptide Drug Substances</i>	
<1504> <i>Quality Attributes of Starting Materials for the Chemical Synthesis of Therapeutic Peptides*</i>, in <i>PF48(1)</i>	
Procedural General Chapters	
<85> <i>Bacterial Endotoxins Test</i>	Endotoxin Reference Standard
<123> <i>Glucagon Biodentity Tests</i>	Glucagon (Human) Dextrose
<503> <i>Acetic Acid in Peptides</i>	Glacial Acetic Acid Sodium Acetate Trihydrate
<503.1> <i>Trifluoroacetic Acid (TFA) in Peptides</i>	Sodium Trifluoroacetate
<1106> <i>Immunogenicity Assays—Design and Validation of Immunoassays to Detect Anti-Drug Antibodies</i>	
<1106.1> <i>Immunogenicity Assays—Design and Validation of Assays to Detect Anti-Drug Neutralizing Antibody</i>	
<1788> <i>Methods for the determination of subvisible particulate matter</i> <1788.1> <i>Light obscuration method for the determination of subvisible particulate matter</i> <1788.3> <i>Flow imaging method for the determination of subvisible particulate matter</i>	Particle Count Set



USP Product-Specific Monographs

USP-NF Documentary Standards	Corresponding USP API Reference Standards	Associated Impurity Reference Standards
<u>Bivalirudin</u> [*] , in PF48(2)	<u>Bivalirudin</u>	<u>Asp9-Bivalirudin</u>
<u>Bivalirudin Injection</u> [*] , in PF48(2)		<u>[des-Glu13]-Bivalirudin</u>
<u>Calcitonin Salmon</u>	<u>Calcitonin Salmon</u>	<u>Calcitonin Salmon Related Compound A</u>
<u>Calcitonin Salmon Injection</u>		<u>Calcitonin Salmon Related Compound B</u>
<u>Calcitonin Salmon Nasal Solution</u>		
<u>Corticotropin Injection</u>	<u>Corticotropin</u>	
<u>Corticotropin for Injection</u>		
<u>Repository Corticotropin Injection</u>		
<u>Cosyntropin</u>	<u>Cosyntropin Acetate</u>	
<u>Desmopressin Acetate</u>	<u>Desmopressin Acetate</u>	
<u>Desmopressin Acetate Injection</u>		
<u>Desmopressin Nasal Spray Solution</u>		
<u>Eptifibatide</u> [*] , in PF 49(2)	<u>Eptifibatide</u>	<u>Eptifibatide dimer</u>
		<u>Beta-3-Asp Eptifibatide</u>
		<u>D-Har Eptifibatide</u>
		<u>3-D-Asp Eptifibatide</u>
		<u>6-D-Cys Eptifibatide</u>
<u>Exenatide</u>	<u>Exenatide</u>	<u>[D-His1]-Exenatide</u>
<u>Exenatide Injection</u>		<u>[Glu13]-Exenatide</u>
		<u>[Met(O)14]-Exenatide</u>
		<u>[N-Acetyl-His1]-Exenatide</u>



<i>Glatiramer Acetate*</i>		
<i>Glatiramer Acetate Injection*</i>		
<i><u>Glucagon*</u>, in PF48(2)</i>	<u>Glucagon (HUMAN)</u>	
<i><u>Glucagon for Injection</u></i>		
<i><u>Gonadorelin Acetate</u></i>	<u>Gonadorelin Acetate</u>	<u>[D-His2]-Gonadorelin</u>
<i><u>Gonadorelin Hydrochloride</u></i>	<u>Gonadorelin Hydrochloride</u>	<u>[D-Tyr5]-Gonadorelin</u>
<i><u>Gonadorelin for Injection</u></i>		<u>Gonadorelin Acetate Related Compound A</u>
<i><u>Goserelin Acetate</u></i>	<u>Goserelin Acetate</u>	<u>Goserelin Related Compound A</u>
<i><u>Goserelin Implants</u></i>		<u>Goserelin System Suitability Mixture</u>
<i>Icatibant Injection*</i>		
<i>Lanreotide Acetate*</i>		
<i>Lanreotide Injection*</i>		
<i><u>Leuprolide Acetate</u></i>	<u>Leuprolide Acetate</u>	
<i><u>Octreotide Acetate</u></i>	<u>Octreotide Acetate</u>	<u>Octreotide Non-Cyclic System Suitability Marker</u>
<i><u>Oxytocin</u></i>	<u>Oxytocin</u>	
<i><u>Oxytocin Injection</u></i>	<u>Oxytocin Identification</u>	
	<u>Protamine Sulfate</u>	
<i><u>Teriparatide</u></i>	<u>Teriparatide</u>	
<i><u>Teriparatide Injection</u></i>		
<i><u>Triptorelin Pamoate*</u>, in PF 48(5)</i>	<u>Triptorelin Acetate</u>	Triptorelin Related Compound <u>A</u> / <u>B</u> / <u>C</u>
<i><u>Vasopressin</u></i>	<u>Vasopressin</u>	
<i><u>Vasopressin Injection</u></i>	<u>Lypressin</u>	
* = in development; specific PF listed when available		

Effective: 08 JUN 2023