



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 Bioidentity 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 Standard (RS) or Analytical Reference Material (ARM)
<u>Bivalirudin</u> *, in PF48(2) - To be official 01-Dec-2023	<u>Bivalirudin RS</u>	<u>Asp9-Bivalirudin RS</u>
<u>Bivalirudin Injection</u> *, in PF48(2) - To be official 01-Dec-2023		<u>[des-Glu13]-Bivalirudin RS</u>
<u>Calcitonin Salmon</u>	<u>Calcitonin Salmon RS</u>	<u>Calcitonin Salmon Related Compound A RS</u>
<u>Calcitonin Salmon Injection</u>		<u>Calcitonin Salmon Related Compound B RS</u>
<u>Calcitonin Salmon Nasal Solution</u>		
<u>Corticotropin Injection</u>	<u>Corticotropin RS</u>	
<u>Corticotropin for Injection</u>		
<u>Repository Corticotropin Injection</u>		
<u>Cosyntropin</u>	<u>Cosyntropin Acetate RS</u>	
<u>Desmopressin Acetate</u>	<u>Desmopressin Acetate RS</u>	
<u>Desmopressin Acetate Injection</u>		
<u>Desmopressin Nasal Spray Solution</u>		
<u>Eptifibatide</u> * ((not yet official, in PF 49(2))	<u>Eptifibatide RS</u>	<u>Eptifibatide dimer RS</u>
		<u>Beta-3-Asp Eptifibatide RS</u>
		<u>D-Har Eptifibatide RS</u>
		<u>3-D-Asp Eptifibatide RS</u>
		<u>6-D-Cys Eptifibatide RS</u>
<u>Exenatide</u>	<u>Exenatide RS</u>	<u>[D-His1]-Exenatide RS</u>
<u>Exenatide Injection</u>		<u>[Glu13]-Exenatide RS</u>
		<u>[Met(O)14]-Exenatide RS</u>



		[N-Acetyl-His1]-Exenatide RS
Glatiramer Acetate*		
Glatiramer Acetate Injection*		
Glucagon*, in PF48(2) - Revision to be official 01-Dec-2023	Glucagon (HUMAN) RS	
Glucagon for Injection		
Gonadorelin Acetate	Gonadorelin Acetate RS	[D-His2]-Gonadorelin RS
Gonadorelin Hydrochloride	Gonadorelin Hydrochloride RS	[D-Tyr5]-Gonadorelin RS
Gonadorelin for Injection		Gonadorelin Acetate Related Compound A RS
Goserelin Acetate	Goserelin Acetate RS	Goserelin Related Compound A RS
Goserelin Implants		Goserelin System Suitability Mixture RS
Icatibant Injection*		
Lanreotide Acetate*		
Lanreotide Injection*		
Leuprolide Acetate	Leuprolide Acetate RS	Acetyl-Leuprolide ARM – Coming Soon!
		D-His-Leuprolide ARM – Coming Soon!
		[L-Leu6]-Leuprolide ARM – Coming Soon!
		D-Ser-Leuprolide ARM – Coming Soon!
		[Ser(Ac)]4-Leuprolide, Acetyl-leuprolide ARM – Coming Soon!
Octreotide Acetate	Octreotide Acetate RS	Octreotide Non-Cyclic System Suitability Marker RS



		[Acetyl-Lys5]-Octreotide ARM – Coming Soon!
		Parallel Dimer-Octreotide ARM – Coming Soon!
		Anti-Parallel Dimer-Octreotide ARM – Coming Soon!
		O1,8-acetyloctreotide, EP Impurity F ARM – Coming Soon!
		N2,1-acetyloctreotide, EP Impurity I ARM – Coming Soon!
		N-Acetyl-Lys-Octreotide Trifluoroacetate ARM – Coming Soon!
		N-Acetyl-Phe-Octreotide ARM – Coming Soon!
<u>Oxytocin</u>	<u>Oxytocin RS</u>	Ac-Oxytocin ARM – Coming Soon!
<u>Oxytocin Injection</u>	<u>Oxytocin Identification RS</u>	[Asp]5-Oxytocin ARM – Coming Soon!
		[Glu]4-Oxytocin ARM – Coming Soon!
		D-[Asp]5-Oxytocin ARM – Coming Soon!
		Parallel Dimer-Oxytocin ARM – Coming Soon!
		Anti-parallel Dimer-Oxytocin ARM – Coming Soon!
<u>Protamine Sulfate</u>	<u>Protamine Sulfate RS</u>	
<u>Protamine Sulfate Injection</u>		
<u>Teriparatide</u>	<u>Teriparatide RS</u>	[MetO8]-Teriparatide ARM – Coming Soon!



<u>Teriparatide Injection</u>		[MetO18]-Teriparatide ARM – Coming Soon!
		[Met+O8,18] Teriparatide ARM – Coming Soon!
<u>Triptorelin Pamoate*</u> , in PF 48(5)	<u>Triptorelin Acetate RS</u>	Triptorelin Related Compound RSs: <u>A</u> <u>/B/C</u>
<u>Vasopressin</u>	<u>Vasopressin RS</u>	
<u>Vasopressin Injection</u>	<u>Lypressin RS</u>	
* = in development; specific PF listed when available		

Effective: 07 NOV 2023