



## 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

USP-NF Documentary Standard	Related USP Reference Standards
<b>Informational General Chapters</b>	
<a href="#">&lt;1052&gt; <i>Biotechnology-Derived Articles – Amino Acid Analysis</i></a>	
<a href="#">&lt;1503&gt; <i>Quality Attributes of Synthetic Peptide Drug Substances</i></a>	
<a href="#">&lt;1504&gt; <i>Quality Attributes of Starting Materials for the Chemical Synthesis of Therapeutic Peptides*</i>, in PF48(1)</a>	
<b>Procedural General Chapters</b>	
<a href="#">&lt;85&gt; <i>Bacterial Endotoxins Test</i></a>	<a href="#">Endotoxin Reference Standard</a>
<a href="#">&lt;123&gt; <i>Glucagon Bioidentity Tests</i></a>	<a href="#">Glucagon (Human)</a> <a href="#">Dextrose</a>
<a href="#">&lt;503&gt; <i>Acetic Acid in Peptides</i></a>	<a href="#">Glacial Acetic Acid</a>
	<a href="#">Sodium Acetate Trihydrate</a>
<a href="#">&lt;503.1&gt; <i>Trifluoroacetic Acid (TFA) in Peptides</i></a>	<a href="#">Sodium Trifluoroacetate</a>
<a href="#">&lt;1106&gt; <i>Immunogenicity Assays—Design and Validation of Immunoassays to Detect Anti-Drug Antibodies</i></a>	
<a href="#">&lt;1106.1&gt; <i>Immunogenicity Assays—Design and Validation of Assays to Detect Anti-Drug Neutralizing Antibody</i></a>	
<a href="#">&lt;1788&gt; <i>Methods for the determination of subvisible particulate matter</i></a> <a href="#">&lt;1788.1&gt; <i>Light obscuration method for the determination of subvisible particulate matter</i></a> <a href="#">&lt;1788.3&gt; <i>Flow imaging method for the determination of subvisible particulate matter</i></a>	<a href="#">Particle Count Set</a>
* = in development; specific PF listed when available (note: these are not official and may never become official)	

Effective: 22 DEC 2023