

# Protamine

## Quality Solutions

Category: Peptide

USP can support your development and manufacturing activities on Protamine-based medicines with these existing and upcoming standards.

### Official and Proposed Documentary Standards and Associated Physical Materials



Authorized Distributor

#### MONOGRAPH 1

<b>PROTAMINE SULFATE</b> Official as of 01-Jun-2023	
USP Protamine Sulfate RS	<a href="#">USP-1578612</a>
USP Heparin Sodium for Assays RS	<a href="#">USP-1304016</a>
USP Endotoxin RS	<a href="#">USP-1235503</a>

#### MONOGRAPH 2

<b>PROTAMINE SULFATE INJECTION</b> Official as of 01-May-2018	
USP Protamine Sulfate RS	<a href="#">USP-1578612</a>

#### INCLUDED GENERAL CHAPTERS

<b>&lt;1&gt; INJECTIONS AND IMPLANTED DRUG PRODUCTS (PARENTERALS)—PRODUCT QUALITY TESTS   NEW</b> Official as of 01-May-2024
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<b>&lt;11&gt; USP REFERENCE STANDARDS</b> Official as of 01-Nov-2020
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<b>&lt;85&gt; BACTERIAL ENDOTOXINS TEST</b> Official as of 01-May-2018	
USP Endotoxin RS	<a href="#">USP-1235503</a>

<b>&lt;191&gt; IDENTIFICATION TESTS—GENERAL</b> Official as of 01-May-2021
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<b>&lt;241&gt; IRON</b> Official as of 01-Jun-2023
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<b>&lt;467&gt; RESIDUAL SOLVENTS</b> Official as of 01-Sep-2022
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<b>&lt;621&gt; CHROMATOGRAPHY</b> Official as of 01-Oct-2023
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<b>&lt;731&gt; LOSS ON DRYING</b> Official as of 01-Nov-2020
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<b>&lt;788&gt; PARTICULATE MATTER IN INJECTIONS</b> Official as of 01-May-2013	
USP Particle Count RS	<a href="#">USP-1500502</a>

<b>&lt;791&gt; PH</b> Official as of 01-Nov-2020
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<b>&lt;1052&gt; BIOTECHNOLOGY-DERIVED ARTICLES - AMINO ACID ANALYSIS</b> Official as of 01-May-2018
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<b>&lt;1503&gt; QUALITY ATTRIBUTES OF SYNTHETIC PEPTIDE DRUG SUBSTANCES</b> Official as of 01-Aug-2021
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<b>&lt;1504&gt; QUALITY ATTRIBUTES OF STARTING MATERIALS FOR THE CHEMICAL SYNTHESIS OF THERAPEUTIC PEPTIDES</b> Official as of 01-Dec-2023
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#### INCLUDED EXCIPIENTS

<b>STERILE WATER FOR INJECTION</b> Official as of 01-May-2021	
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<b>GLYCERIN</b> Official as of 01-May-2020	
USP Diethylene Glycol RS	<a href="#">USP-1193265</a>
USP Ethylene Glycol RS	<a href="#">USP-1265515</a>
USP Glycerin RS	<a href="#">USP-1295607</a>

<b>HYDROCHLORIC ACID</b> Official as of 01-Jan-2018
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<b>SODIUM HYDROXIDE</b> Official as of 01-Jan-2018
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<b>PHENOL</b> Official as of 31-Dec-2012
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<b>SODIUM CHLORIDE</b> Official as of 01-Jun-2023
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<b>SODIUM PHOSPHATE, DIBASIC, ANHYDROUS</b> Official as of 31-Dec-2012
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<b>ZINC CHLORIDE   NEW</b> Official as of 01-Jun-2024	
USP Zinc Chloride RS	<a href="#">USP-1724736</a>

<b>ZINC OXIDE</b> Official as of 01-Jun-2023	
USP Zinc Oxide RS	<a href="#">USP-1724747</a>

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