



USP Heparin standards

Heparin is a naturally occurring carbohydrate that is isolated from the mucosal tissues of pig intestines. Fondaparinux, enoxaparin, and dalteparin are synthetically manufactured anticoagulants, with the latter two classified as low molecular-weight heparins. These drugs are used to prevent harmful blood clots that can lead to strokes or pulmonary embolisms.

USP offers documentary and reference standards for a variety of heparin products that can help speed their development and ensure their safety and efficacy during manufacturing.



Documentary



Reference standards



Safety



Efficacy

About USP

USP is an independent scientific organization that collaborates with the world's top experts in health and science to develop quality resources and standards for medicines, dietary supplements, and food ingredients. Through our resources, standards, advocacy, and education, USP helps increase the availability of quality medicines, supplements, and foods for billions of people worldwide.

USP Monographs	Monograph-associated USP Reference Standards (RS)	Excipients* and associated USP Reference Standards (RS)
HEPARINS		
USP Heparin family		
Heparin Sodium	<ul style="list-style-type: none"> ▶ Heparin Sodium Identification ▶ Heparin Sodium Molecular Weight Calibrant ▶ Heparin Sodium for Assays ▶ Adenosine ▶ Dermatan Sulfate ▶ Galactosamine Hydrochloride ▶ Glucosamine Hydrochloride ▶ Oversulfated Chondroitin Sulfate 	
Heparin Sodium Injection		<ul style="list-style-type: none"> ▶ Benzyl Alcohol ▶ Sodium Chloride
Heparin Lock Flush Solution		
USP Anticoagulant Heparin Solution family		
Anticoagulant Heparin Solution	▶ Heparin Sodium for Assays	
HEPARIN-RELATED		
USP Antithrombin III Human family		
Antithrombin III Human	<ul style="list-style-type: none"> ▶ Antithrombin III Human ▶ Heparin Sodium for Assays 	
USP Protamine family		
Protamine Sulfate	<ul style="list-style-type: none"> ▶ Protamine Sulfate ▶ Endotoxin 	
Protamine Sulfate Injection	<ul style="list-style-type: none"> ▶ Heparin Sodium for Assays ▶ Protamine Sulfate 	▶ Sodium Chloride
Scaffold Porcine Small Intestinal Submucosa	<ul style="list-style-type: none"> ▶ Bovine Acellular Dermal Matrix Reference Photomicrographs (CD) ▶ Cultured Rat Pheochromocytoma Reference Photomicrographs 	

* This list is not exhaustive and there could be other excipients used. Please visit the [USP store](#) to explore our full range of reference standards for excipients.



USP reference tables

- ▶ [Solubilities](#)
- ▶ [Description and relative solubility](#)

USP Monographs	Monograph-associated USP Reference Standards (RS)	Excipients* and associated USP Reference Standards (RS)
LOW-MOLECULAR WEIGHT HEPARINS		
Dalteparin family		
Dalteparin Sodium	<ul style="list-style-type: none"> ▶ Dalteparin Sodium ▶ Low Molecular Weight Heparin for Boron Analysis ▶ Boric Acid 	▶ Sodium Chloride
Enoxaparin family		
Enoxaparin Sodium, Enoxaparin Sodium Injection	<ul style="list-style-type: none"> ▶ Enoxaparin Sodium ▶ Enoxaparin Sodium for Bioassays ▶ Benzyl Alcohol 	▶ Benzyl Alcohol
Fondaparinux family		
Fondaparinux Sodium	<ul style="list-style-type: none"> ▶ Fondaparinux Sodium Identification ▶ Fondaparinux Sodium for Assay ▶ Fondaparinux Sodium System Suitability Mixture A Solution 	
Fondaparinux Sodium Injection	<ul style="list-style-type: none"> ▶ Fondaparinux Sodium for Assay ▶ Fondaparinux Sodium System Suitability Mixture B Solution 	

* This list is not exhaustive and there could be other excipients used. Please visit the [USP store](#) to explore our full range of reference standards for excipients.



USP general chapters to support the development and manufacturing of heparins and heparin-related products.

- ▶ [<208> Anti-Factor Xa and Anti-Factor IIa Assays for Unfractionated and Low Molecular Weight Heparins](#)
 - [USP Heparin Sodium for Assays RS](#)
 - [USP Low Molecular Weight Heparin for Bioassays RS](#)
- ▶ [<209> Low Molecular Weight Heparin Molecular Weight Determinations](#)
 - [USP Dalteparin Sodium RS](#)
 - [USP Low Molecular Weight Heparin Molecular Weight Calibrant RS](#)
- ▶ [<1051> Cleaning Glass Apparatus](#)
- ▶ [<1053> Capillary Electrophoresis](#)
- ▶ [<1761> Applications of Nuclear Magnetic Resonance Spectroscopy](#)



USP resources to monitor packaging-related impurities

- ▶ [Extractables and leachables](#)

Education



Scientific articles

- ▶ [The US regulatory and pharmacopeia response to the global heparin contamination crisis](#), Nature Biotechnology (2016)
- ▶ [USP compendial methods for analysis of heparin: chromatographic determination of molecular weight distributions for heparin sodium](#), Analytical and Bioanalytical Chemistry (2014)



Online courses

- ▶ [What's New in Biologics? Analysis of Heparin Sodium Porcine and Bovine](#)
- ▶ [Overview on USP Heparin Standards and Compendial Use](#), USP Webinar (2020)



Related resources

- ▶ To ensure safety of heparin products in the United States, the [U.S. FDA asked manufacturers of heparin-containing products to test the heparin active pharmaceutical ingredient \(API\) used in these products](#) with the two screening methods posted to FDA's website, capillary electrophoresis (CE) and proton nuclear magnetic resonance (H-NMR)
- ▶ U.S. Food & Drug Administration (FDA): [Information on Heparin](#)



USP Expert Subcommittee on [Therapeutic Peptides, Oligonucleotides and Complex Carbohydrates](#)

More information: www.usp.org/biologics/heparins

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USP Store: store.usp.org