



Protamine sulphate

Meets USP, EP, BP, JP and IP testing specifications

Product Code: TC563M

Product Description :

CAS: 9009-65-8

Quality Control:

Appearance (JP) White powder

Appearance (EP, BP, IP) White or almost white hygroscopic powder

Solubility (IP) Sparingly soluble in water, practically insoluble in chloroform, ethanol (95%) and in ether

Solubility (EP, BP) Sparingly soluble in water, practically insoluble in ethanol (96%)

Solubility (JP) Sparingly soluble in water

Identification A (USP)

The retention times of the four major peaks of the sample solution corresponds to, those of the standard solution as obtained in the assay

Identification A : (IP) Produces a precipitate under the condition of Assay

Identification A : Specific optical rotation (BP) -85.00° to -65.00° (c = 1% in 0.1M HCl at 20°C, dried substance)

Identification A : Protamine peptide A content, HPLC (EP) 13 - 18%

Identification A : Protamine peptide B content, HPLC (EP) 21 - 28%

Identification A : Protamine peptide C content, HPLC (EP) 31 - 38%

Identification A : Protamine peptide D content, HPLC (EP) 19 - 24%

Identification 1 : (JP) A vivid red colour develops Identification B : (USP) Reactions for sulphate

Identification B : (IP) An intense red colour is produced

Identification B : (BP) Protamine sulphate forms a precipitate

Identification B : (EP) It gives the appropriate response when examined as described in the potency assay

Identification 2 : (JP) A red purple colour develops

Identification C : Bioidentity : (USP) Each mg of protamine sulphate neutralizes >= 100 USP Heparin Units on the dried basis

Identification C : (BP) An intense red colour is produced

Identification C : (EP) It complies with the tests for sulphate

Identification C : (IP) A white precipitate is produced

Identification 3 : (JP) Reactions for sulphates

Identification D (IP)

Reactions for sulfate

Identification D (BP) A precipitate is formed

Identification E (BP) Reactions for sulfate

Appearance of solution (EP, BP) The solution is not more opalescent than reference suspension II (2.2.1) and not more intensely coloured than reference solution BY6 or Y6 (2.2.2, Method II)

Appearance of solution (IP)

The resulting solution is not more opalescent than opalescent standard OS2(2.4.1) and not more intensely coloured than reference solution BY6S6 (2.4.1)

Clarity and colour of solution (JP) 1% solution in water is clear and colourless

pH (1% in water at 25°C) : (JP) 6.50 - 7.50

Specific rotation (BP, IP) -85.00° to -65.00° (c = 1% in 0.1M HCl at 20°C, dried substance)

Sulphate (USP, JP) 16 - 22% (dried substance)

Sulphate (IP, EP, BP) 16 - 24% (dried substance)

Iron (USP, EP, BP) <= 0.001%

Iron (IP) <= 0.002%

Light absorption (IP) <= 0.1 (at 260 to 280nm)

Absorbance (USP, EP, BP, JP) <= 0.1 (at 260 to 280nm)

Methyl mercury (USP) <= 0.001%

Mercury (BP, IP) <= 0.001%

Heavy metals (IP) <= 0.002%

Loss on drying (USP, EP, BP, JP, IP) <= 5.0% (at 105°C, 3 hr)

Residual solvent: (USP) Meets the requirements

Nitrogen, dried substance : (BP, IP) 21.00 - 26.00%

Nitrogen, dried substance : (JP) 22.50 - 25.50%

Related substances : System suitability : Resolution : HPLC (EP) >= 2.0

Related sunstances : HPLC (EP) <= 8.0%

Heparin-binding capacity : System suitability : RSD, sample solution A, B, C : UV (JP) <= 5.0%

Heparin-binding capacity : System suitability : RSD, Set of A, B, C : UV (JP) <= 5.0%

Heparin binding capacity : UV : (JP) min. 100 Units/mg of heparin, dried basis

Disclaimer :

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Assay : Standard deviation : Colorimetry (BP) <= 5.0%

Assay : Standard deviation of each test solution : UV (IP) <= 5.0%

Assay : RSD : HPLC (USP) <= 2.0% Assay : resolution : HPLC (USP) >= 2.0 Potency (USP, EP)

min. 100 IU of heparin, dried basis

Chromatographic purity : (USP) min. 92.00%

Assay (HPLC, dried substance) : (USP, EP) 90.00 - 110.00%

Assay : colorimetry : (BP) min. 100 IU of heparin, dried basis

Assay: UV: (IP) min. 100 Units of heparin sodium RS, dried basis

Bacterial endotoxin : (USP, IP) <= 7.0 USP endotoxin Units/mg

Bacterial endotoxin : (BP) <= 7.0 IU/mg

Storage and Shelf Life:

Store below 30°C away from bright light. Shelf life is 48 months. Use before expiry date given on the product label.

Revision : 02/2022