spectrum chemicals & laboratory products

CERTIFICATE OF ANALYSIS

Item Number	P1291	**Lot Number**	3GH0040
Item	Protamine Sulfate, USP, EP		
CAS Number	9009-65-8		
Molecular Formula		**Molecular Weight**	

TEST	SPECIFICATION MIN	SPECIFICATION MAX	RESULT
APPEARANCE			WHITE CRYSTALLINE POWDER
ASSAY (DRIED BASIS) (USP)	90.0%	110.0%	92.4%
CHROMATOGRAPHIC PURITY (USP)	92 %		98%
SULFATE (DRIED BASIS) (USP)	16 %	22 %	18%
METHYLMERCURY (USP)		10 ppm	<10 ppm
RESIDUAL SOLVENTS (USP)	TO PASS TEST		
CLASS 3, ETHANOL		5000 ppm	1292 ppm
IDENTIFICATION (USP)			
A : RETENTION TIME	TO PASS TEST		PASSES TEST
B : SULFATES	TO PASS TEST		PASSES TEST
C : BIOIDENTITY	100 USP Heparin Units		141 USP Heparin Units
ULTRAVIOLET ABSORBANCE (USP/EP)	TO PASS TEST		PASSES TEST
IRON (USP/EP)		10 ppm	<10 ppm
BACTERIAL ENDOTOXIN (USP/EP)		7.0 USP EU / mg	<7.0 USP EU / mg
APPEARANCE OF SOLUTION (EP)	TO PASS TEST		PASSES TEST
NITROGEN (EP)	21.0%	26.0%	23.4%
LOSS ON DRYING (EP)		5.0%	1.2%
MERCURY (EP)		10 ppm	<10 ppm
ASSAY (Dried substance) (EP)	100 IU / mg		142 IU / mg
IDENTIFICATION (EP)			
A : SPECIFIC OPTICAL ROTATION	-85°	-65°	-76°
B : QUALITATIVE REACTION Ⅰ	FORMS A PRECIPITATE		PASSES TEST
C : SAKAGUCHI REACTION	AN INTENSE RED COLOR IS PRODUCED		PASSES TEST
D : QUALITATIVE REACTION Ⅱ	TO PASS TEST		PASSES TEST
E : SULFATES	TO PASS TEST		PASSES TEST
ELEMENTAL IMPURITIES			
CADMIUM		0.2 µg/g	NOT DETECTED (< 0.1 µg/g)
LEAD		0.5 µg/g	NOT DETECTED (< 0.25 µg/g)
INORGANIC ARSENIC		1.5 µg/g	NOT DETECTED (< 0.75 µg/g)
INORGANIC MERCURY		0.3 µg/g	NOT DETECTED (< 0.15 µg/g)
NICKEL		2 µg/g	NOT DETECTED (< 1 µg/g)
EXPIRATION DATE			22-FEB-2019

DATE OF MANUFACTURE			23-FEB-2016

RESIDUAL SOLVENTS: USP, Chapter <467> limits the residual solvent content of a drug product to the permitted daily exposure (PDE) level given in that chapter. This Spectrum Certificate of Analysis reports any residual solvents that are likely to be present in the material as a result of manufacturing and/or processing. Residual solvents of Class 1 are identified and quantified when present in the material. Residual solvents of Class 2 or Class 3 are identified and the maximum limit is reported unless Class 2 solvents are present at levels greater than Option 1 limits or Class 3 solvents are present at levels greater than 0.5%. It is the responsibility of the producer of a finished dosage form to ensure that the aggregate residual solvent content meets applicable requirements set forth in USP, Chapter <467>.

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