

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

TEST	SPECIFICATION
EXPIRATION DATE	
MANUFACTURE DATE	
APPEARANCE	
ASSAY (DRIED BASIS) (USP)	90.0% - 110.0%
CHROMATOGRAPHIC PURITY (USP)	92% --
SULFATE (DRIED BASIS) (USP)	16% - 22%
METHYLMERCURY (USP)	-- 10 ppm
RESIDUAL SOLVENTS (USP)	
CLASS 3, ETHANOL	-- 5000 ppm
IDENTIFICATION (USP)	
A: RETENTION TIME	TO PASS TEST
B: SULFATES	TO PASS TEST
C: BIOIDENTITY	100 USP Heparin Units --
ULTRAVIOLET ABSORBANCE (USP/EP)	TO PASS TEST
IRON (USP/EP)	-- 10 ppm
BACTERIAL ENDOTOXIN (USP/EP)	-- 7.0 USP EU / mg
APPEARANCE OF SOLUTION (EP)	TO PASS TEST
NITROGEN (EP)	21.0% - 26.0%
LOSS ON DRYING (EP)	-- 5.0%
MERCURY (EP)	-- 10 ppm
ASSAY (Dried substance) (EP)	100 IU / mg --
IDENTIFICATION (EP)	
A: SPECIFIC OPTICAL ROTATION	-85° TO -65°
B: QUALITATIVE REACTION I	FORMS A PRECIPITATE

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

TEST	SPECIFICATION
C: SAKAGUCHI REACTION	AN INTENSE RED COLOR IS PRODUCED
D: QUALITATIVE REACTION II	TO PASS TEST
E: SULFATES	TO PASS TEST
ELEMENTAL IMPURITIES	
CADMIUM	-- 0.2 ug/g
INORGANIC ARSENIC	-- 1.5 ug/g
INORGANIC MERCURY	-- 0.3 ug/g
LEAD	-- 0.5 ug/g
NICKEL	-- 2 ug/g