KRAEBER & CO GMBH
PHARMAZEUTISCHE ROHSTOFFE

SPECIFICATION

Product : PROTAMINE SULFATE
tested to Ph. Eur.

Origin : fish spermatozoa (salmon milt) **Page : 1/1**
Product no. : 5611100900 **Version : 2**
Valid from : 11/07

CAS-No. : 9009-65-8

Controls	Specification	Method
Appearance	white or almost white powder, hygroscopic	complies
Appearance of solution	not more opalescent than reference suspension II, and not more intensely coloured than reference solution BY_6 or Y_6	2.2.1.+ 2.2.2 II
Loss on drying (at 105° C for 3 h)	< 5,0 %	2.2.32
Sulfate (dried substance)	16,0 - 24,0 %	2.3.1
Nitrogen content (dried substance)	21,0 - 26,0 %	2.5.9.
Assay	> 100 I.U. of Heparin Sodium/mg	according to Ph.Eur.
Solubility	sparingly soluble in water, practically insoluble in alcohol	according to Ph.Eur.
Heavy metals	< 20 ppm	2.4.8.
Iron	< 10 ppm	2.4.9
Mercury	< 10 ppm	according to Ph.Eur.
Abnormal toxicity	within the limit	2.6.9
UV Absorbance (at 260 to 280 nm)	< 0,1 %	2.2.25
Specific optical rotation (dried substance)	-65° - -85°	2.2.7
Bacterial endotoxins	< 7,0 I.U./mg	2.6.14

Primary packing : tamper-proof container
Storage : airtight, well closed, at room temperature
Shelf life : 3 years

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