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Technical Information

PKA Immunoglobulin

Chromogenic assay for the determination of Prekallikrein Activator (PKA) in Human Immunoglobulin Products according to the European Pharmacopoeia.

Cat. No.:	PW302EP		
	PW51005	Just Positive PKA Control	5x0.5ml
	PW52005	High Positive PKA Control	5x0.5ml
Method:	**Chrom. Assay**		
Tests:	50		
Range:	1.56 – 25 IU/ml PreKallikrein Activator		
Sensitivity:	2.25 IU/ml (for standard protocol but higher if required)		
Calibration:	Calibrated 2nd International reference preparation (NIBSC)		
Incubation time:	45 minutes		
Sample volume:	100 µl (dilute 1:2)		
Sample type:	Plasma, serum, and fractionated plasma concentrates/finished preparation with level adjusted to below 50 IU/ml by dilution in albumin.		
Sample preparation:	Plasma should be prepared as soon as possible following collection. And if not tested immediately should be stored for 6 months at –20 °C or lower and should not be frozen/thawed again.		
Species:	Human and other mammalian species		

Intended use:

The fractionation of Human plasma to produce Human Albumin and Immunoglobulin preparations for substitution therapy concentrates not only the preparations but also PKA which if present at high enough levels can release kallikrein and cause patients to go into shock. PKA is normally removed by post fractionation chromatography but this has to be validated so all Blood Product licensing authorities require manufacturers to measure PKA levels in each batch of final product before it can be released for patient care.
In the EU the requirements for this testing are outlined in the general monograph 'Human plasma for fractionation (0853)' of the European Pharmacopoeia (Ph. Eur.) and in the specific monograph 0255 Albumin solution and monograph 01/2006:0918 for Human immunoglobulin fractions. Further details are outlined within the framework of Article 114 Paragraph 2 of Directive 2001/83/EC and Article 1, paragraph 78 of the amending Directive 2004/27/EC and following the current Guideline on EC Administrative Procedure for Official Control Authority Batch Release.

The test involves the PKA present in the blood product being tested, activating Prekallikrein to release the enzyme Kallikrein. The Kallikrein released is measured using a synthetic peptide substrate for the enzyme which releases a chromogen that can be quantified using a microtitre plate reader. The critical components of the test are the Prekallikrein preparation which must not be activated before testing and the specificity of the chromogenic substrate for Kallikrein.

For further information please contact / Für weitere Informationen wenden Sie sich bitte an / Pour plus d´informations, veuillez contacter:

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