CERTIFICATE OF ANALYSIS Factor VII immunads





Attachment 03

DQ470D.03

4721C0E.02

REF

5144015-RUO

LOT

4721C0E.02

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2026-08-31

Analytical Procedures		Requirement			Result			
	Cap color	blue		confir	med	ОК		
	Vial type	C	clear glass vial		confir	med	ОК	
	Vial label	accordi	according to packaging SOP		confir	med	ОК	
	Vial barcode	according to packaging SOP		confir	med	ок		
visual inspection	Box label	according to packaging SOP		confir	med	ОК		
	Box barcode	according to packaging SOP		confir	med	ОК		
	Package insert	present		confir	med	ОК		
	Appearance before reconstitution	buff colored plug of lyophilized material		confir	med	ок		
	Appearance after reconstitution	amber colored liquid		confir	med	ОК		
	HBsAg / HBsAg	Negative		Negative Negative				
Virology	HIV-Ak / HIV-Ab	Negative						
	HCV-AK / HCV-Ab	Negative		Negative		ОК		
The testing methods a	applied were FDA-approved or CE marked.							
	Control N	74.5						
Recovery of controls	LOT 1P31C01	71.3	5	118.8	%	103.9	%	ОК
F VII	Control A	1	**		%		10000	ОК
	LOT 3P42C00	33.0		55.0		43.6	%	

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