

F VII Mangelplasma immunads, 5x1mL

REF

5144015-RUO

LOT

4731C0D.02



2025-08-31

Analytische Verfahren Analytical Procedures		Anforderung Requirement	Ergebnis Result	
visuelle Kontrolle visual inspection	Cap color	blue	confirmed	OK
	Vial type	clear glass vial	confirmed	OK
	Vial label	according to packaging SOP	confirmed	OK
	Vial barcode	according to packaging SOP	confirmed	OK
	Box label	according to packaging SOP	confirmed	OK
	Box barcode	according to packaging SOP	confirmed	OK
	Package insert	present	confirmed	OK
	Appearance before reconstitution	buff colored plug of lyophilized material	confirmed	OK
	Appearance after reconstitution	buff colored liquid without visible particles	confirmed	OK
Virologie / Virology	HBsAg / HBsAg HIV-Ak / HIV-Ab HCV-AK / HCV-Ab	Negative Negative Negative	Negative Negative Negative	OK
The testing methods applied were FDA-approved or CE marked.				
Kontrollwiederfindung FVII am Ceveron® Alpha	Control N LOT 1P31C00	71.3 - 118.8 %	95.3 %	OK
Recovery of controls FVII on Ceveron® Alpha	Control A LOT 3P41C00	33.0 - 55.0 %	42.6 %	OK

Durchgeführt von

Prepared by

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02. OKT. 2024

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