

F XI Mangelplasma nativ, 5x1mL

REF 5184004-RUO
LOT 4E12C00.02
⌚ 2023-09-30

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 The testing methods applied were FDA-approved or CE marked.	Negative Negative Positive	Negative Negative Positive	OK
Kontrollwiederfindung F XI am Ceveron® Alpha	Control N LOT 1P02C01	72.0 - 120.0 %	102.9 %	OK
Recovery of controls F XI on Ceveron® Alpha	Control A LOT 3P02C00	36.8 - 61.3 %	60.0 %	OK

Durchgeführt von

Prepared by


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20. OKT. 2021

Datum / Date:

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20. OKT. 2021

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