mp.: TF0326.06

3U41C01.01

REF

5090012-RUO

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2027-06-30

Analytical Procedures		Requirement	Result	
visual inspection	Cap color	red	confirmed	ОК
	Vial type	clear glass vial	confirmed	ОК
	Vial label	according to packaging SOP	confirmed	ОК
	Vial barcode	according to packaging SOP	confirmed	ОК
	Box label	according to packaging SOP	confirmed	ОК
	Box barcode	according to packaging SOP	confirmed	ОК
	Package insert	present	confirmed	ОК
	Batch table	present	confirmed	ОК
	Appearance before reconstitution	buff colored plug of lyophilized material	confirmed	ок
	Appearance after reconstitution	amber colored liquid	confirmed	ОК
	HBsAg / HBsAg	Negative	Negative	ОК
Virology	HIV-Ak / HIV-Ab	Negative	Negative	
	HCV-AK / HCV-Ab	Negative	Negative	
The testing methods ap	plied were FDA-approved or CE marked.			
Recovery of control		0.35 - 0.65 μg/ml	. 0.51 μg/ml	ОК

Prepared by	Mayns RAUSCHER	<b>3 0</b> . JULI 2025
	4	Date
Approved by	Lucas HOLOVICZ	3 1. JULI <b>2025</b>
		Date