Technoview Arixtra CON H



Attachment 17

DQ2600.02

Temp.:

3V41C01.02

REF

5090014-RUO

LOT

3V41C01.02

 \mathbf{Z}

2027-06-30

Analytical Procedures		Requirement		Result			
	Cap color	red			confi	rmed	ОК
visual inspection	Vial type	clear glass vial		confi	rmed	ОК	
	Vial label	according to packaging SOP		confi	rmed	ОК	
	Vial barcode	according to packaging SOP		confi	rmed	ок	
	Box label	according to packaging SOP		confi	rmed	ОК	
	Box barcode	according to packaging SOP		confi	rmed	ок	
	Package insert	present		confi	rmed	ок	
	Batch table	present		confi	rmed	ок	
	Appearance before reconstitution	buff colored plug of lyophilized material		confi	irmed	ок	
	Appearance after reconstitution	amber colored liquid			confi	irmed	ОК
	HBsAg / HBsAg	Negative		Neg	ative		
Virology	HIV-Ak / HIV-Ab	Negative		Neg	ative		
	HCV-AK / HCV-Ab	Negative		Neg	ative	OK	
The testing methods a	applied were FDA-approved or CE marked.						
Recovery of control	0.97 -	1.61	µg/mL	1.57	μg/mL	ОК	

	Mayle RAUSCHER
Prepared by	- 1. Karli
	Cours/
Approved by	Lucas MVOVICZ

13. AUG. 2025

Date

13, AUG. 2025

Date