

Technoview Arixtra CON H



Attachment 17 DQ2600.02

Temp.: TFG336.05

3V41C00.02

REF	5090014-RUO
LOT	3V41C00.02
⌚	2026-05-31

Analytical Procedures		Requirement	Result	
visual inspection	Cap color	red	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
	Batch table	present	confirmed	OK
	Appearance before reconstitution	buff colored plug of lyophilized material	confirmed	OK
	Appearance after reconstitution	amber colored liquid	confirmed	OK
Virology	HBsAg / HBsAg HIV-Ak / HIV-Ab HCV-AK / HCV-Ab The testing methods applied were FDA-approved or CE marked.	Negative Negative Negative	Negative Negative Negative	OK
Recovery of control		0.97 - 1.61 µg/mL	1.37 µg/mL	OK

Prepared by Lucas HOLOWCZ

23. NOV. 2024
Date

Approved by Mavis FAUSCHER

29. NOV. 2024
Date