Technoview Arixtra CON L

technoclone

Attachment 18 DQ2600.02

Temp.: TF0326.06

3U41C00.02

REF	5090012-RUO
LOT	3U41C00.02
	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 The testing methods applied were FDA-approved or CE marked.	HBsAg / HBsAg HIV-Ak / HIV-Ab HCV-AK / HCV-Ab	Negative Negative Negative	Negative Negative Negative	OK
Recovery of control		0.35 - 0.65 µg/mL	0.59 µg/mL	OK

Prepared by Lucas HOLZKNECHT 25. NOV. 2024
Date

Approved by Stefan BRUCKBERGER 29. NOV. 2024
Date