



ANALYSENZERTIFIKAT CERTIFICATE OF ANALYSIS

DQP000.02

Alt.20

P981B00.01

Technoview® Edoxaban CONT High 5x1mL

REF

5090253

LOT

P981B00.01



2020-03-31

Analytische Verfahren Analytical Procedures		Anforderung Requirement	Ergebnis Result	
visuelle Kontrolle 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	buff colored liquid	confirmed	OK	
Virologie / Virology	HBsAg / HBsAg HIV-Ak / HIV-Ab HCV-AK / HCV-Ab	Negative Negative Negative	Negative Negative Negative	OK
The testing methods applied were FDA-approved or CE marked.				
Kontrollwiederfindung am Ceveron® Alpha Recovery of controls on Ceveron® Alpha	Technochrom® anti-Xa LOT 0872B00	275.0 - 459.0 ng/mL	362.6 ng/mL	OK

Durchgeführt von

Prepared by

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30. MRZ. 2018

Datum / Date:

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30. MRZ. 2018

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