



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 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

Christoph ENNE

30. MRZ. 2018
Datum / Date:

Freigabe von
Approved by

Eva Maria HAGER

30. MRZ. 2018
Datum / Date: