

	ANALYSENZERTIFIKAT CERTIFICATE OF ANALYSIS	DQP000.02
		Att.17
		P081B00.01


Technoview® Edoxaban CAL Set 5x1mL

REF	5090250
LOT	P081B00.01
	2020-03-31

Inhalt Content	Volumen volume	Reagenz Reagent	LOT	
1x	1mL	Edoxaban CAL 1	P081B00	
1x	1mL	Edoxaban CAL 2	P281B00	2020-03-31
1x	1mL	Edoxaban CAL 3	P381B00	2020-03-31
1x	1mL	Edoxaban CAL 4	P481B00	2020-03-31
1x	1mL	Edoxaban CAL 4	P581B00	2020-03-31
1x	1mL	Edoxaban CAL 5	P681B00	2020-03-31

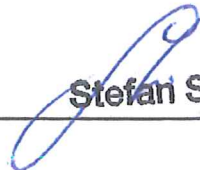
Analytische Verfahren Analytical Procedures		Anforderung Requirement	Ergebnis Result	
visuelle Kontrolle visual inspection	Content	according to packaging SOP	confirmed	OK
	Vial label	according to packaging SOP	confirmed	OK
	Vial barcode	according to packaging SOP	confirmed	OK
	Box label	according to packaging SOP	confirmed	OK
	Box barcode	according to packaging SOP	confirmed	OK
	Package insert	present	confirmed	OK
	Batch table	present	confirmed	OK
Kontrollwiederfindung am Ceveron® Alpha Recovery of controls on Ceveron® Alpha	Technoview® Edoxaban CONT Low LOT P781B00	21.0 - 39.0 ng/mL	29.1 ng/mL	OK
	Technoview® Edoxaban CONT Medium LOT P81B00	81.0 - 135.0 ng/mL	107.4 ng/mL	OK

Durchgeführt von
Prepared by


Christoph ENNE

30. MRZ. 2018
Datum / Date:

Freigabe von
Approved by


Stefan STEINER

30. MRZ. 2018
Datum / Date: