



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 | | |
|-------------------|-------------------|--------------------|----------------|--|------------|
| | | | P081B00 | | |
| 1x | 1mL | Edoxaban CAL 1 | P281B00 | | 2020-03-31 |
| 1x | 1mL | Edoxaban CAL 2 | P381B00 | | 2020-03-31 |
| 1x | 1mL | Edoxaban CAL 3 | 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 | Technoview® Edoxaban CONT Low LOT P781B00 | 21.0 - 39.0 ng/mL | 29.1 ng/mL | OK |
| Recovery of controls on Ceveron® Alpha | Technoview® Edoxaban CONT Medium LOT P81B00 | 81.0 - 135.0 ng/mL | 107.4 ng/mL | OK |

Durchgeführt von
Prepared by

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30. MRZ. 2018

Datum / Date:

Freigabe von
Approved by

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30. MRZ. 2018

Datum / Date: