

	ANALYSENZERTIFIKAT CERTIFICATE OF ANALYSIS	DQ3400.01 LOT 3451B00
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Rivaroxaban Control Low 1 mL

REF 5090190
LOT 3451B00
 05-Feb-2015
 28-Feb-2019

Analytische Verfahren Analytical Procedure			Anforderung Requirement	Ergebnis Result	
pH			7.4 – 7.8	7.7	OK
Restfeuchte Residual moisture			≤1%	0.41	OK
OD _{320nm}			≤10	6.9	OK
Virologie Virology	HBsAg / HBsAg HIV-AK / HIV-Ab HCV-AK / HCV-Ab		Negative Negative Negative	Negative Negative Negative	OK
Homogenität Homogeneity Intra-Test			CV ≤ 7%	3.4	OK
Homogenität Homogeneity Inter-Test			CV ≤ 7%	3.7	OK
Lösungsstabilität 4 Tage bei RT Reconstituted stability 4 days at RT	Anti Xa (Rivaroxaban)	Change from storage at 2-8°C	< 10%	1.6	OK
Chargenspezifische Kalibrationswerte Lot specific calibration values			53.9 – 80.9 ng/mL	67.4	OK
Lagerstabilität 8 Wochen bei 37°C Storage stability 8 weeks at 37°C	Anti Xa (Rivaroxaban)	Change from storage at 2-8°C	< 10%	0.3	OK

Durchführung von
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15-Apr-2015
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