technoclone	ANALYSENZERTIFIKAT CERTIFICATE OF ANALYSIS	DQ3V00AZ.01 LOT 3V31B00

ARIXTRA Control High

REF 5090032

LOT 3V31B00

18-APR-2013

30-APR-2015

Analytische Verfahren **Analytical Procedure**			**Anforderung** **Requirement**	**Ergebnis** **Result**	
pH			7.4 – 7.8	7.6	OK
Restfeuchte Residual moister			≤1%	0.05%	OK
OD_{320nm}			≤10	6.8	OK
Virologie Virology	HBsAg / HBsAg HIV-AK / HIV-Ab HCV-AK / HCV-Ab		Negative Negative Negative	Negative Negative Negative	OK
Homogenität Homogeneity			CV ≤ 7%	2.03%	OK
Lösungsstabilität 5 Stunden bei RT Reconstituted stability 5 hours at RT	Anti Xa (AT-)	Change from storage at 2-8°C	< 10%	7.5%	OK
Chargenspezifische Kalibrationswerte Lot specifc calibration values			0.71 – 1.07 µg/ml	0.89 µg/mL	OK
Lagerstabilität 4 Wochen bei 37°C Storage stability 4 weeks at 37°C	Anti Xa (AT-)	Change from storage at 2-8°C	< 10%	1.7%	OK

Durchführung von
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29-MAI-2013
Datum / Date:

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Approved by

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31. MAI 2013
Datum / Date