

	ANALYSENZERTIFIKAT CERTIFICATE OF ANALYSIS	DQ7F00AZ.02 LOT 7F51B00
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TECHNOTHROMBIN[®] TGA Reagent C high (RCH)

REF 5006145
LOT 7F51B00
 14-Apr-2015
 30-Apr-2017

Analytische Verfahren Analytical Procedure		Anforderung Requirement	Ergebnis Result		
pH		7.0 – 7.6	7.35	OK	
Restfeuchte Residual moisture		≤ 3%	0.12	OK	
Homogenität Homogeneity	TGA Control High (nM Peak Thrombin)	CV ≤ 10%	8.36	OK	
Kontrollwiederfindung Recovery of controls		TGA Control High (nM Peak Thrombin) LOT 1B41B00	276 – 512	471.4	OK
		TGA Control Low (nM Peak Thrombin) LOT 2B43B00	137 – 255	143.1	OK
Lösungsstabilität 8 Stunden bei RT Reconstituted stability 8 hours at RT	TGA Control High LOT 1B41B00	≤ 15%	11.9	OK	
Lagerstabilität 4 Wochen bei 37°C Storage stability 4 weeks at 37°C	TGA Control High LOT 1B41B00	≤ 15%	1.1	OK	

Durchführung von
Prepared by

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13-May-2015
Datum / Date:

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