

	ANALYSENZERTIFIKAT CERTIFICATE OF ANALYSIS	DQ7G00AZ LOT 7G51B00
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TECHNOTHROMBIN® TGA Reagent RD

REF 5006148
LOT 7G51B00
 30-Jan-2015
 31-Jan-2017

Analytische Verfahren Analytical Procedure		Anforderung Requirement	Ergebnis Result	
pH		6.5 – 7.5	6.8	OK
Restfeuchte Residual moisture		≤1%	0.95 %	OK
Homogenität Homogeneity	TGA Control High (nM Peak Thrombin) LOT 1B41B00	CV ≤ 5%	4.3 %	OK
Lösungsstabilität 8 Stunden bei RT	TGA Control High (nM Peak Thrombin) LOT 1B41B00	< 10%	1.3 %	OK
Reconstituted stability 8 hours at RT	TGA Control Low (nM Peak Thrombin) LOT 2B43B00	< 10%	2.6 %	OK
Kontrollwiederfindung	TGA Control High (nM Peak Thrombin) LOT 1B41B00	161 – 299	192.8	OK
Recovery of controls	TGA Control Low (nM Peak Thrombin) LOT 2B43B00	239 – 443	250.3	OK
Lagerstabilität 4 Wochen bei 37°C Storage stability 4 weeks at 37°C	TGA Control High (nM Peak Thrombin) LOT 1B41B00	< 10%	0.7	OK



ANALYSENZERTIFIKAT
CERTIFICATE OF ANALYSIS

DQ7G00AZ

LOT 7G51B00

Durchführung von
Prepared by

Fikret NASUFI *Fikret Nasufi*

16-MAR-2015
Datum / Date:

Freigabe von
Approved by

Michael RIHA *Michael Riha*

16 MAR-2015
Datum / Date: