




HFP: Technoclot PT Plus 10mL

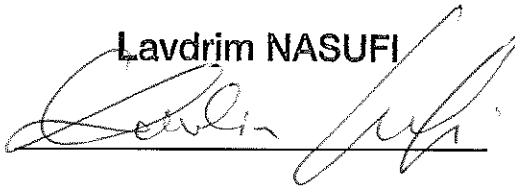
REF 5003140
 LOT 6C47BB0
 08-Sep-2014
 30-Sep-2016

Analytische Verfahren Analytical Procedure		Anforderung Requirement	Ergebnis Result		
Restfeuchte Residual moisture		≤3%	1.00	OK	
Kontrollwiederfindung Recovery of controls	CCN LOT 1P44B00	85.0 – 107.0% INR: 0.90 – 1.14	91.9 1.06	OK	
	CCA LOT 3P38B00	15.9 – 20.1% INR: 2.47 – 3.11	16.1 2.65	OK	
Homogenität Homogeneity VK / CV sec	Intra-Tasse 1	CCN LOT 1P44B00	CV ≤ 3%	1.54	OK
		CCA LOT 3P38B00	CV ≤ 3%	1.06	OK
	Inter-Tassen	CCN LOT 1P44B00	CV ≤ 3%	1.46	OK
		CCA LOT 3P38B00	CV ≤ 3%	1.07	OK
FVII Verwendbarkeit / FVII usability	CCN LOT 1P44B00	87.8 – 146.3%	121.9	OK	
	CCA LOT 3P38B00	33.8 – 56.3%	50.9	OK	
Sensitivität Heparin sensitivity heparin	0.5 E/mL UFH	< 10%	0.6	OK	
ISI		Ceveron® Alpha	0.99		
		KC10	1.00		
		Thrombotrack	0.99		
		Thrombotimer	1.00		
		Thrombolyser	0.96		

	ANALYSENZERTIFIKAT CERTIFICATE OF ANALYSIS	DQ6C0BAZ.03 [LOT] 6C47BB0
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Analytische Verfahren Analytical Procedure			Anforderung Requirement	Ergebnis Result	
Lösungsstabilität 5 Tage on board Reconstituted stability 5 days on board	CCN, [LOT] 1P44B00	Change from storage at 2-8°C	< 10%	3.8	OK
	CCA, [LOT] 3P38B00	Change from storage at 2-8°C		9.0	OK
Lagerstabilität 4 Wochen bei 37°C Storage stability 4 weeks at 37°C	CCN, INR [LOT] 1P44B00	Change from storage at 2-8°C	< 10%	0.9	OK
	CCA, INR [LOT] 3P38B00	Change from storage at 2-8°C		5.4	OK

Durchführung von
Prepared by

Lavdrim NASUFI


22-Oct-2014
Datum / Date:

Freigabe von
Approved by

Alessandro BENIGNI


22-Oct-2014
Datum / Date:

Ceveron® alpha

S. SCHWINGENSCHLÖGL


22-Oct-2014
Datum / Date: