

	ANALYSENZERTIFIKAT CERTIFICATE OF ANALYSIS	8PT71BL
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HFP: ECAT ADAMTS-13 INH Plasma low

REF	5450443	LOT	8PT71BL
	07-Apr-2017		30-Apr-2019

Analytische Verfahren Analytical Procedures		Anforderung Requirement	Ergebnis Result		
Type of material		Plasma	Plasma	OK	
Reconstituted volume		= 0.5 mL	0.5 mL	OK	
Virologie / Virology HBsAg / HBsAg HIV-Ak / HIV-Ab HCV-AK / HCV-Ab The testing methods applied were FDA-approved or cleared in compliance with the European Directive 98/79/EC, Annex II, List A.		Negative Negative Negative	Negative Negative Negative	OK	
Homogenität n=10 Homogeneity n=10 according to ISO13528:2005 Annex B	Intra-part	ADAMTS-13 INH ELISA	≤ 12.50 %	7.78 %	OK
	Inter-part	n.z.	≤ n.z. %	n.z. %	OK
Richtwert n=10 Expected value n=10	ADAMTS-13 INH ELISA		2.5 - 5.0 U/mL	4.1 U/mL	OK
			CV ≤ 12.5 %	7.8 %	
Lösungsstabilität n=2, 2 Stunden bei 18-25°C In use stability n=2, 2 hours at 18-25°C	ADAMTS-13 INH ELISA		≤ 12.5 %	6.1 %	OK
			mean value at baseline	6.7	
		mean value after stressing	6.3		
Lagerstabilität n=2, 1 Woche bei 37°C Storage Stability n=2, 1 week at 37°C	ADAMTS-13 INH ELISA		≤ 12.5 %	7.8 %	OK
			mean value at baseline	6.7	
		mean value after stressing	7.2		



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CERTIFICATE OF ANALYSIS**

8PT71BL

Durchgeführt von
Prepared by

Fikret NASUFI *Fikret Nasufi*

20. APR. 2017

Datum / Date:

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Approved by

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20. APR. 2017

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