	ANALYSENZERTIFIKAT CERTIFICATE OF ANALYSIS	8PT83BV
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HFP: ECAT ADAMTS-13 INH Plasma very high

REF	5450447	LOT	8PT83BV
	2018-03-09		2020-03-31

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 *LOT-size too small for Intra-part of homogeneity testing	Intra-part	ADAMTS-13 INH ELISA	≤ 5.00 %	n.a. % *
	Inter-part	ADAMTS-13 INH ELISA	≤ 5.00 %	13.50 % ***
Richtwert n=10 Expected value n=10	ADAMTS-13 INH ELISA		15.0 - 25.0 U/mL	17.5 U/mL
			CV ≤ 5.0 %	14.7 %
Lösungsstabilität n=2, 2 Stunden bei 18-25°C In use stability n=2, 2 hours at 18-25°C	ADAMTS-13 INH ELISA		≤ 5.0 %	0.2 %
			mean value at baseline	18.1
			mean value after stressing	18.1
Lagerstabilität n=2, 1 Woche bei 37°C Storage Stability n=2, 1 week at 37°C	ADAMTS-13 INH ELISA		≤ 5.0 %	3.0 %
			mean value at baseline	19.0
			mean value after stressing	19.5


Rev.01
 ***) Sonderfreigabe ***) Special Release



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CERTIFICATE OF ANALYSIS**

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Durchgeführt von
Prepared by

Michael KAFKA 

04. APR. 2018

Datum / Date:

Freigabe von
Approved by

Fikret NASUFI 

04. APR. 2018

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