

	ANALYSENZERTIFIKAT CERTIFICATE OF ANALYSIS	8PT81BL
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HFP: ECAT ADAMTS-13 INH Plasma low

REF	5450443	LOT	8PT81BL
	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	≤ 12.50 %	n.a. % *
	Inter-part	ADAMTS-13 INH ELISA	≤ 12.50 %	7.10 % OK
Richtwert n=10 Expected value n=10	ADAMTS-13 INH ELISA		2.5 - 5.0 U/mL CV ≤ 12.5 %	3.8 U/mL 24.7 % OK
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 % mean value at baseline mean value after stressing	49.2 % 4.0 2.0 ***
Lagerstabilität n=2, 1 Woche bei 37°C Storage Stability n=2, 1 week at 37°C	ADAMTS-13 INH ELISA		≤ 12.5 % mean value at baseline mean value after stressing	11.1 % 4.4 3.9 OK

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



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Durchgeföhrt von
Prepared by

Michael KAFKA 

04. APR. 2018

Datum / Date:

Freigabe von
Approved by

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04. APR. 2018

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