

	<b>ANALYSENZERTIFIKAT</b> <b>CERTIFICATE OF ANALYSIS</b>	8PT73BV
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## HFP: ECAT ADAMTS-13 INH Plasma very high

REF	5450447	LOT	8PT73BV
	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	<b>ADAMTS-13 INH ELISA</b>  ≤ 5.00 %	6.35 %	*)
	Inter-part	n.z.  ≤ n.z. %	n.z. %	OK
Richtwert n=10 Expected value n=10	<b>ADAMTS-13 INH ELISA</b>	15.0 - 20.0 U/mL  CV ≤ 5.0 %	17.4 U/mL  6.4 %	OK
Lösungsstabilität n=2, 2 Stunden bei 18-25°C In use stability n=2, 2 hours at 18-25°C	<b>ADAMTS-13 INH ELISA</b>	≤ 5.0 %  mean value at baseline mean value after stressing	1.7 %  24.3 23.9	OK
Lagerstabilität n=2, 1 Woche bei 37°C Storage Stability n=2, 1 week at 37°C	<b>ADAMTS-13 INH ELISA</b>	≤ 5.0 %  mean value at baseline mean value after stressing	3.8 %  25.5 26.5	OK

\*) Sonderfreigabe  
 \*) Special release



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Durchgeföhrt von  
Prepared by

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20. APR. 2017

Datum / Date:

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20. APR. 2017

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