

	ANALYSENZERTIFIKAT CERTIFICATE OF ANALYSIS	8PT72BM
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HFP: ECAT ADAMTS-13 INH Plasma medium

REF 5450446
 07-Apr-2017

LOT 8PT72BM
 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 $\leq 7.00 \%$	6.48%	OK
	Inter-part	n.z.	$\leq n.z. \%$ $n.z. \%$	OK
Richtwert n=10 Expected value n=10	ADAMTS-13 INH ELISA $7.5 - 12.5 \text{ U/mL}$ $CV \leq 7.0 \%$		7.6 U/mL 6.5%	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 $\leq 7.0 \%$ mean value at baseline mean value after stressing		9.0% 13.2 12.0	*)
Lagerstabilität n=2, 1 Woche bei 37°C Storage Stability n=2, 1 week at 37°C	ADAMTS-13 INH ELISA $\leq 7.0 \%$ mean value at baseline mean value after stressing		1.3% 13.2 13.4	OK

*) Sonderfreigabe
 *) Special release



**ANALYSENZERTIFIKAT
CERTIFICATE OF ANALYSIS**

8PT72BM

Durchgeführt von
Prepared by

Fikret NASUFI *Fikret Nasufi*

20. APR. 2017

Datum / Date:

Freigabe von
Approved by

Michael KAFKA *Michael Kafka*

20. APR. 2017

Datum / Date: