

Stability Test report of FRAGMIN 10000IU/1.0 ML Disposable Syringe
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Name	Job title	Signature and date

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Stability Report: P4392001003EU	Pfizer Puurs Belgium STABILITY	
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1. Study information

Study Number	Man Lotnumber	Storage Condition	Storage Period	Container	Closure	Lot Quantity	Start Date	Manufacturing Date	Manufacturing Place
ST04146LF	96136-51	25DEGC / 60% RH	36 MONTHS	GLASS SYRINGE	RUBBER PLUNGER	99492	10/06/2004	25/02/2004	VETTER
ST05320LF	96154-51	25DEGC / 60% RH	36 MONTHS	GLASS SYRINGE	RUBBER PLUNGER	98648	08/12/2005	21/09/2005	VETTER
ST08115LF	96196-51	25DEGC / 60% RH	24 MONTHS	GLASS SYRINGE	RUBBER PLUNGER	98693	18/07/2008	07/05/2008	VETTER

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2. Schedule

		ABSORBANCE AT 405 NM	ANTI FACTOR IIA ACTIVITY	ANTI FACTOR XA ACTIVITY	CLARITY	DESCRIPTION	EJECTABLE VOLUME	HEPARIN.FRAGMENT MOLECULAR WEIGHT LT 3000	HEPARIN.FRAGMENT MOLECULAR WEIGHT MT 8000	MOLECULAR WEIGHT: NUMBER AVERAGE	MOLECULAR WEIGHT: PEAK MOLECULAR WEIGHT	MOLECULAR WEIGHT: WEIGHT AVERAGE	PH	RATIO ANTI-FACTOR.XA/IIA	STERILITY
ST04146LF	00 MONTHS	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	06 MONTHS	X	X	X	X	X	X	X	X	X	X	X	X	X	
	12 MONTHS	X	X	X	X	X	X	X	X	X	X	X	X	X	
	24 MONTHS	X	X	X	X	X	X	X	X	X	X	X	X	X	
	36 MONTHS	X	X	X	X	X	X	X	X	X	X	X	X	X	X
ST05320LF	00 MONTHS	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	12 MONTHS	X	X	X	X	X	X	X	X	X	X	X	X	X	
	24 MONTHS	X	X	X	X	X	X	X	X	X	X	X	X	X	
	36 MONTHS	X	X	X	X	X	X	X	X	X	X	X	X	X	X
ST08115LF	00 MONTHS	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	12 MONTHS	X	X	X	X	X	X	X	X	X	X	X	X	X	
	24 MONTHS	X	X	X	X	X	X	X	X	X	X	X	X	X	
	36 MONTHS	X	X	X	X	X	X	X	X	X	X	X	X	X	X

3. Currently registered procedures and limits on stability

Test	Test method	Limits
DESCRIPTION	VISUAL	A CLEAR , COLORLESS OR STRAW COLOURED SOLUTION
STERILITY	PH.EUR.	MEETS TEST
EJECTABLE VOLUME	PH.EUR.	1.02 TO 1.07 ML PER SINGLE DOSE SYRINGE
PH	PH.EUR.	5.0 TO 7.5
CLARITY	T627	NMT I
ANTI-FACTOR IIA ACTIVITY	S643	3080 TO 4760 IU/ML
ABSORBANCE AT 405 NM		NOT MORE THAN 0.10
ANTI-FACTOR XA ACTIVITY	H236	9000 TO 11000 IU/ML
HEPARIN FRAGMENT MOLECULAR WEIGHT LT 3000	M602	5.0 TO 13.0 %
HEPARIN FRAGMENT MOLECULAR WEIGHT MT 8000	M602	15.0 TO 25.0 %
MOLECULAR WEIGHT: NUMBER AVERAGE	M602	4500 TO 5300
MOLECULAR WEIGHT: WEIGHT AVERAGE	M602	5600 TO 6400
MOLECULAR WEIGHT: PEAK MOLECULAR WEIGHT	M602	4300 TO 5500
RATIO ANTI-FACTOR XA/IIA	H236 / S643	1.9 TO 3.2

4. Stability Test results at 25°C – 60% RH

Note: Test results of studies that are still in progress are reported as To Be Determined (TBD)
Not scheduled test periods are reported as Not Scheduled (NS)

DESCRIPTION

	ST04146LF	ST05320LF	ST08115LF
00 MONTHS	MEETS TEST	MEETS TEST	MEETS TEST
06 MONTHS	MEETS TEST	NS	NS
12 MONTHS	MEETS TEST	MEETS TEST	MEETS TEST
24 MONTHS	MEETS TEST	MEETS TEST	MEETS TEST
36 MONTHS	MEETS TEST	MEETS TEST	TBD

All results within limits up to testing period: no problems reported.

pH

	ST04146LF	ST05320LF	ST08115LF
00 MONTHS	6.4	6.7	6.4
06 MONTHS	6.2	NS	NS
12 MONTHS	6.1	6.1	6.0
24 MONTHS	6.0	5.9	5.9
36 MONTHS	5.9	5.9	TBD

All results within limits up to testing period: no problems reported.

CLARITY

	ST04146LF	ST05320LF	ST08115LF
00 MONTHS	MEETS TEST	MEETS TEST	MEETS TEST
06 MONTHS	MEETS TEST	NS	NS
12 MONTHS	MEETS TEST	MEETS TEST	MEETS TEST
24 MONTHS	MEETS TEST	MEETS TEST	MEETS TEST
36 MONTHS	MEETS TEST	MEETS TEST	TBD

All results within limits up to testing period: no problems reported

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ANTI FACTOR XA ACTIVITY

	ST04146LF	ST05320LF	ST08115LF
00 MONTHS	10300	9900	10000
06 MONTHS	10000	NS	NS
12 MONTHS	10100	9500	10000
24 MONTHS	9800	9500	10200
36 MONTHS	9700	9600	TBD

All results within limits up to testing period: no problems reported

ANTI-FACTOR IIA ACTIVITY

	ST04146LF	ST05320LF	ST08115LF
00 MONTHS	4100	4240	4010
06 MONTHS	4180	NS	NS
12 MONTHS	4090	3820	3990
24 MONTHS	3730	3680	4010
36 MONTHS	3530	3660	TBD

All results within limits up to testing period: no problems reported.

RATIO ANTI-FACTOR XA/IIA

	ST04146LF	ST05320LF	ST08115LF
00 MONTHS	2.5	2.3	2.5
06 MONTHS	2.4	NS	NS
12 MONTHS	2.5	2.5	2.5
24 MONTHS	2.6	2.6	2.5
36 MONTHS	2.7	2.6	TBD

All results within limits up to testing period: no problems reported.

MOLECULAR WEIGHT : NUMBER AVERAGE

	ST04146LF	ST05320LF	ST08115LF
00 MONTHS	4788	4764	4896
06 MONTHS	4735	NS	NS
12 MONTHS	4713	4666	4809
24 MONTHS	4723	4667	4833
36 MONTHS	4687	4625	TBD

All results within limits up to testing period: no problems reported.

MOLECULAR WEIGHT : PEAK MOLECULAR WEIGHT

	ST04146LF	ST05320LF	ST08115LF
00 MONTHS	4574	4490	4662
06 MONTHS	4553	NS	NS
12 MONTHS	4527	4434	4573
24 MONTHS	4516	4445	4616
36 MONTHS	4495	4358	TBD

All results within limits up to testing period: no problems reported

MOLECULAR WEIGHT : WEIGHT AVERAGE

	ST04146LF	ST05320LF	ST08115LF
00 MONTHS	6044	6023	6089
06 MONTHS	5996	NS	NS
12 MONTHS	5970	5918	6009
24 MONTHS	5959	5911	6026
36 MONTHS	5928	5821	TBD

All results within limits up to testing period: no problems reported.

HEPARIN FRAGMENT MOLECULAR WEIGHT LT 3000

	ST04146LF	ST05320LF	ST08115LF
00 MONTHS	11.0	11.3	9.0
06 MONTHS	11.6	NS	NS
12 MONTHS	11.7	12.0	9.7
24 MONTHS	11.6	12.1	9.4
36 MONTHS	11.9	11.9	TBD

All results within limits up to testing period: no problems reported.

HEPARIN FRAGMENT MOLECULAR WEIGHT MT 8000

	ST04146LF	ST05320LF	ST08115LF
00 MONTHS	20.7	20.4	20.4
06 MONTHS	20.3	NS	NS
12 MONTHS	20.0	19.7	19.5
24 MONTHS	20.0	19.5	19.6
36 MONTHS	19.8	18.1	TBD

All results within limits up to testing period: no problems reported.

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ABSORBANCE AT 405 nm

	ST04146LF	ST05320LF	ST08115LF
00 MONTHS	0.02	0.01	0.01
06 MONTHS	0.03	NS	NS
12 MONTHS	0.04	0.03	0.03
24 MONTHS	0.04	0.04	0.02
36 MONTHS	0.05	0.06	TBD

All results within limits up to testing period: no problems reported.

EJECTABLE VOLUME

	ST04146LF	ST05320LF	ST08115LF
00 MONTHS	1.05	1.05	1.04
06 MONTHS	1.04	NS	NS
12 MONTHS	1.04	1.04	1.04
24 MONTHS	1.05	1.04	1.03
36 MONTHS	TEST NOT RUN	1.03	TBD

Due to shortage of samples the test Ejectable volume was not performed at 36 months for study ST04146LF

All other results within limits up to testing period: no problems reported

STERILITY

	ST04146LF	ST05320LF	ST08115LF
00 MONTHS	MEETS TEST	MEETS TEST	MEETS TEST
36 MONTHS	MEETS TEST	MEETS TEST	TBD

All results within limits up to testing period: no problems reported.

5. Conclusion

The results show that Fragmin 10000IU/1.0ml Disposable Syringe is stable up to testing period when stored at 25°C – 60% RH.

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