



Stability Test report of Fragmin 5000 IU/0.2ml Disposable Syringe

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1. Study information

Study Number	Man Lot Number	Storage Condition	Storage Period	Container	Closure	Lot Quantity	Start Date	Manufacturing Date	Manufacturing Place
ST07272LF	74311-53	25°C ± 2°C – 60% RH ± 5% RH	36 MONTHS	Glass syringe	RUBBER PLUNGER	138944	14/09/2007	25/06/2007	VETTER
ST08114LF	74434-53	25°C ± 2°C – 60% RH ± 5% RH	36 MONTHS	Glass syringe	RUBBER PLUNGER	178816	18/07/2008	19/05/2008	VETTER
ST09039LF	74541-51	25°C ± 2°C – 60% RH ± 5% RH	36 MONTHS	Glass syringe	RUBBER PLUNGER	175171	30/03/2009	20/01/2009	VETTER

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2. Schedule

		ABSORBANCE AT 405 NM	ANTI FACTOR IIA ACTIVITY	ANTI FACTOR XA ACTIVITY	CLARITY	DESCRIPTION	EJECTABLE AMOUNT	HEPARIN FRAGMENTS MOLECULAR WEIGHT LESS THAN 3000	HEPARIN FRAGMENTS MOLECULAR WEIGHT MORE THAN 8000	MOLECULAR WEIGHT NUMBER AVERAGE	MOLECULAR WEIGHT WEIGHT AVERAGE	PH	RATIO ANTI-FACTOR XA/IIA	STERILITY	ENDOTOXINS	VISUAL INSPECTION
ST07272LF	00 MONTHS	X	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	X
ST08114LF	00 MONTHS	X	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	X
ST09039LF	00 MONTHS	X	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	X

3. Currently registered procedures and limits on stability

Test	Test method	Limits
Description	Visual	A clear , colorless or straw colored solution
pH	Ph. Eur.	5.0 to 7.5
Visual Inspection	Ph. Eur.	Clear and practically free from particles
Clarity	T627	Not more opalescent than reference suspension I
Anti-Factor Xa activity	H236	22500 to 27500 IU/ml
Anti-Factor IIa activity	S643	7700 to 11900 IU/ml
Ratio Anti-Factor Xa/IIa	H236 / S643	1.9 to 3.2
Molecular Weight Number Average	M602	4500 to 5300
Molecular Weight Weight Average	M602	5600 to 6400
Heparin Fragments Molecular Weight Less Than 3000	M602	5.0 to 13.0 %
Heparin Fragments Molecular Weight More Than 8000	M602	15.0 to 25.0 %
Absorbance at 405 nm	UV/VIS	Not more than 0.40
Ejectable Amount		4000 to 6000 IU/syringe
Sterility	Ph. Eur.	Sterile: Meets test
Endotoxins	Ph. Eur.	Not More Than 2.5 EU/1000 IU.

4. Stability Test results at 25°C ± 2°C – 60% RH ± 5% RH

DESCRIPTION

	ST07272LF	ST08114LF	ST09039LF
00 MONTHS	MEETS TEST	MEETS TEST	MEETS TEST
12 MONTHS	MEETS TEST	MEETS TEST	MEETS TEST
24 MONTHS	MEETS TEST	MEETS TEST	MEETS TEST
36 MONTHS	MEETS TEST	MEETS TEST	MEETS TEST

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

pH

	ST07272LF	ST08114LF	ST09039LF
00 MONTHS	6.4	6.4	6.4
12 MONTHS	6.0	6.0	5.8
24 MONTHS	5.7	6.0	5.8
36 MONTHS	5.6	5.6	5.4

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

VISUAL INSPECTION

	ST07272LF	ST08114LF	ST09039LF
00 MONTHS	MEETS TEST	MEETS TEST	MEETS TEST
12 MONTHS	MEETS TEST	MEETS TEST	MEETS TEST
24 MONTHS	MEETS TEST	MEETS TEST	MEETS TEST
36 MONTHS	MEETS TEST	MEETS TEST	MEETS TEST

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

CLARITY

	ST07272LF	ST08114LF	ST09039LF
00 MONTHS	MEETS TEST	MEETS TEST	MEETS TEST
12 MONTHS	MEETS TEST	MEETS TEST	MEETS TEST
24 MONTHS	MEETS TEST	MEETS TEST	MEETS TEST
36 MONTHS	MEETS TEST	MEETS TEST	MEETS TEST

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

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ANTI-FACTOR XA ACTIVITY

	ST07272LF	ST08114LF	ST09039LF
00 MONTHS	24500	25300	25000
12 MONTHS	23900	25100	25200
24 MONTHS	23500	25200	24900
36 MONTHS	24000	25100	24100

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

ANTI-FACTOR IIA ACTIVITY

	ST07272LF	ST08114LF	ST09039LF
00 MONTHS	9500	10050	9950
12 MONTHS	9350	10150	9750
24 MONTHS	9300	9900	9850
36 MONTHS	9400	10000	9600

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

RATIO ANTI-FACTOR XA/IIA

	ST07272LF	ST08114LF	ST09039LF
00 MONTHS	2.6	2.5	2.5
12 MONTHS	2.6	2.5	2.6
24 MONTHS	2.5	2.5	2.5
36 MONTHS	2.6	2.5	2.5

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

MOLECULAR WEIGHT NUMBER AVERAGE

	ST07272LF	ST08114LF	ST09039LF
00 MONTHS	4910	4890	4766
12 MONTHS	4821	4831	4691
24 MONTHS	4783	4858	4676
36 MONTHS	4760	4798	4645

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

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MOLECULAR WEIGHT WEIGHT AVERAGE

	ST07272LF	ST08114LF	ST09039LF
00 MONTHS	6120	6110	6009
12 MONTHS	6003	6063	5928
24 MONTHS	5951	6080	5940
36 MONTHS	5927	6025	5904

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

HEPARIN FRAGMENTS MOLECULAR WEIGHT LESS THAN 3000

	ST07272LF	ST08114LF	ST09039LF
00 MONTHS	9.4	9.2	10.9
12 MONTHS	9.3	9.7	11.5
24 MONTHS	9.6	9.3	11.7
36 MONTHS	9.8	10.0	12.0

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

HEPARIN FRAGMENTS MOLECULAR WEIGHT MORE THAN 8000

	ST07272LF	ST08114LF	ST09039LF
00 MONTHS	21.1	20.6	19.9
12 MONTHS	19.4	20.0	19.1
24 MONTHS	18.9	20.1	19.0
36 MONTHS	18.7	19.4	18.8

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

ABSORBANCE AT 405 NM

	ST07272LF	ST08114LF	ST09039LF
00 MONTHS	0.04	0.02	0.03
12 MONTHS	0.11	0.06	0.06
24 MONTHS	0.15	0.06	0.09
36 MONTHS	0.20	0.09	0.12

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

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EJECTABLE AMOUNT

	ST07272LF	ST08114LF	ST09039LF
00 MONTHS	5268	5313	5250
12 MONTHS	5019	5271	5355
24 MONTHS	4935	5292	5478
36 MONTHS	5124	5271	5061

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

STERILITY

	ST07272LF	ST08114LF	ST09039LF
00 MONTHS	MEETS TEST	MEETS TEST	MEETS TEST
36 MONTHS	MEETS TEST	MEETS TEST	MEETS TEST

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

ENDOTOXINS

	ST07272LF	ST08114LF	ST09039LF
00 MONTHS	MEETS TEST	MEETS TEST	MEETS TEST
36 MONTHS	MEETS TEST	MEETS TEST	MEETS TEST

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

5. Conclusion

The results show that Fragmin 5000 IU/0.2ml disposable syringe is stable up to testing period when stored at 25°C ± 2°C – 60% RH ± 5% RH.

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