

Stability Test report of Fragmin 2500 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
ST06214LF	74221-01	25°C ± 2°C – 60% RH ± 5% RH	36 MONTHS	Glass syringe	RUBBER PLUNGER	138474	10/10/2006	21/07/2006	VETTER
ST07238LF	74302-53	25°C ± 2°C – 60% RH ± 5% RH	36 MONTHS	Glass syringe	RUBBER PLUNGER	148652	02/08/2007	25/05/2007	VETTER
ST09046LF	74571-01	25°C ± 2°C – 60% RH ± 5% RH	36 MONTHS	Glass syringe	RUBBER PLUNGER	40953	16/04/2009	13/03/2009	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
ST06214LF	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
ST07238LF	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
ST09046LF	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	11250 to 13750 IU/ml
Anti-Factor IIa activity	S643	3850 to 5950 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 0.20
Ejectable Amount		2000 to 3000 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

	ST06214LF	ST07238LF	ST09046LF
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

	ST06214LF	ST07238LF	ST09046LF
00 MONTHS	6.8	6.4	6.8
12 MONTHS	6.1	6.1	6.1
24 MONTHS	6.0	5.9	5.9
36 MONTHS	5.7	5.8	5.7

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

VISUAL INSPECTION

	ST06214LF	ST07238LF	ST09046LF
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

	ST06214LF	ST07238LF	ST09046LF
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

	ST06214LF	ST07238LF	ST09046LF
00 MONTHS	12000	12100	12300
12 MONTHS	11900	12100	12200
24 MONTHS	12000	12100	12400
36 MONTHS	11900	12100	11800

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

ANTI-FACTOR IIA ACTIVITY

	ST06214LF	ST07238LF	ST09046LF
00 MONTHS	4770	4770	4990
12 MONTHS	4580	4720	4820
24 MONTHS	4530	4720	4760
36 MONTHS	4580	4700	4840

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

RATIO ANTI-FACTOR XA/IIA

	ST06214LF	ST07238LF	ST09046LF
00 MONTHS	2.5	2.5	2.5
12 MONTHS	2.6	2.6	2.5
24 MONTHS	2.6	2.6	2.6
36 MONTHS	2.6	2.6	2.4

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

MOLECULAR WEIGHT NUMBER AVERAGE

	ST06214LF	ST07238LF	ST09046LF
00 MONTHS	4896	4918	4849
12 MONTHS	4765	4753	4730
24 MONTHS	4746	4784	4718
36 MONTHS	4768	4730	4679

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

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MOLECULAR WEIGHT WEIGHT AVERAGE

	ST06214LF	ST07238LF	ST09046LF
00 MONTHS	6113	6146	6065
12 MONTHS	5986	5930	5965
24 MONTHS	5925	5985	5932
36 MONTHS	5918	5898	5898

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

HEPARIN FRAGMENTS MOLECULAR WEIGHT LESS THAN 3000

	ST06214LF	ST07238LF	ST09046LF
00 MONTHS	9.6	9.4	9.9
12 MONTHS	10.9	10.2	10.9
24 MONTHS	10.3	9.8	10.9
36 MONTHS	9.9	10.3	11.4

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

HEPARIN FRAGMENTS MOLECULAR WEIGHT MORE THAN 8000

	ST06214LF	ST07238LF	ST09046LF
00 MONTHS	21.2	21.5	20.4
12 MONTHS	20.1	18.9	19.3
24 MONTHS	18.9	19.1	18.9
36 MONTHS	18.6	18.5	18.7

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

ABSORBANCE AT 405 NM

	ST06214LF	ST07238LF	ST09046LF
00 MONTHS	0.02	0.02	0.02
12 MONTHS	0.04	0.06	0.03
24 MONTHS	0.05	0.10	0.07
36 MONTHS	0.08	0.06	0.05

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

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EJECTABLE AMOUNT

	ST06214LF	ST07238LF	ST09046LF
00 MONTHS	2592	2589	2706
12 MONTHS	2499	2541	2440
24 MONTHS	2520	2541	2604
36 MONTHS	2499	2541	2478

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

STERILITY

	ST06214LF	ST07238LF	ST09046LF
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

	ST06214LF	ST07238LF	ST09046LF
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 2500 IU/0.2ml disposable syringe is stable up to testing period when stored at 25°C ± 2°C – 60% RH ± 5% RH.

