

Sanofi Winthrop Industrie
Le Trait
France

3.2.P.8.3 STABILITY DATA

Enoxaparin sodium 100 mg/mL

Solution for injection in pre-filled syringes

20 mg/0.2 mL, 40 mg/0.4 mL, 60 mg/0.6 mL, 80 mg/0.8 mL and 100 mg/1.0 mL

Study type:	Long term conditions
Objective:	Assessment of the stability profile of enoxaparin sodium 100 mg/mL solution for injection in pre-filled syringes at Le Trait site.
Total duration of investigation:	36 months at 25°C/60%RH

Date: April 2017

Total number of pages:

13

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Stability Data

Enoxaparin sodium 100 mg/mL solution – solution for injection in pre-filled syringe - 20 mg/0.2 mL, 40 mg/0.4 mL, 60 mg/0.6 mL, 80 mg/0.8 mL and 100 mg/1.0 mL

Table 1: Long term stability 20 mg/0.2 mL – Batch no. : 952002

Drug product:	Enoxaparin sodium 100 mg/mL solution for injection in pre-filled syringes	Batch no.:	952002			
Dosage strength:	20 mg/0.2 mL	Batch size (L):	120			
Manufacturing date:	04/05/2012	Manufacturing site:	Le Trait			
Study activation date:	07/02/2013					
Container/closure type:	Plunger stopper chlorobutyl black					
Primary Packaging type:	Syringe type I clear glass					
Storage condition:	+ 25 ± 2°C/60 ± 5 % RH					
Test item	Acceptance criteria	Time				
		Initial	6 months	12 months	24 months	36 months
- Characters						
Clarity	Clear	Complies	Complies	Complies	Complies	Complies
Color	Colorless to pale yellow solution	Complies	Complies	Complies	Complies	Complies
- Clarity	Not more than reference suspension I	Complies	Complies	Complies	Complies	Complies
- Coloration of solution						
Degree of coloration	Not more colored than 4	7	6	5	5	4
Shade of coloration	Y or BY	BY	BY	BY	BY	BY
- pH	5.5 to 7.5	6.2	6.1	6.0	5.9	5.7
- Free sulfates (%)	Not more than 0.12 %	0.03	0.03	0.03	0.03	0.03
- Extractable volume on 5 syringes (mL)						
Minimum volume	Greater than or equal to 0.20 mL	0.21	Not performed	0.21	0.21	0.20
Maximum volume	Less than or equal to 0.22 mL	0.21	Not performed	0.22	0.21	0.21
- Anti-Xa activity (IU/0.2 mL)	1800 to 2200 IU/0.2 mL	1992	1994	2000	2001	2026
- Anti-IIa activity (IU/0.2 mL)	400 to 700 IU/0.2 mL	503	492	498	497	493
- Anti Xa/anti IIa ratio	3.3 to 5.3	4.0	4.1	4.0	4.1	4.1
- Particulate matter						
Particles ≥ to 10 µm	Not more than 6000	105	Not performed	38	114	117
Particles ≥ to 25 µm	Not more than 600	1	Not performed	0	0	1
- Bacterial endotoxins	Less than 100 EU/mL	Complies	Not performed	Not performed	Complies	Complies
- Sterility (Ph. Eur)	Conforms	Conforms	Not performed	Not performed	Conforms	Conforms

Stability Data

Enoxaparin sodium 100 mg/mL solution – solution for injection in pre-filled syringe - 20 mg/0.2 mL, 40 mg/0.4 mL, 60 mg/0.6 mL, 80 mg/0.8 mL and 100 mg/1.0 mL

Table 2: Long term stability 20 mg/0.2 mL – Batch no. : 962001

Drug product:	Enoxaparin sodium 100 mg/mL solution for injection in pre-filled syringes	Batch no.:	962001			
Dosage strength:	20 mg/0.2 mL	Batch size (L):	170			
Manufacturing date:	08/01/2013	Manufacturing site:	Le Trait			
Study activation date:	26/04/2013					
Container/closure type:	Plunger stopper chlorobutyl black					
Primary Packaging type:	Syringe type I clear glass					
Storage condition:	+ 25 ± 2°C/60 ± 5 % RH					
Test item	Acceptance criteria	Time				
		Initial	6 months	12 months	24 months	36 months
- Characters						
Clarity	Clear	Complies	Complies	Complies	Complies	Complies
Color	Colorless to pale yellow solution	Complies	Complies	Complies	Complies	Complies
- Clarity	Not more than reference suspension I	Complies	Complies	Complies	Complies	Complies
- Coloration of solution						
Degree of coloration	Not more colored than 4	7	7	6	5	4
Shade of coloration	Y or BY	BY	BY	BY	BY	BY
- pH	5.5 to 7.5	6.5	6.3	6.2	6.0	5.9
- Free sulfates (%)	Not more than 0.12 %	0.03	0.03	0.03	0.03	0.03
- Extractable volume on 5 syringes (mL)						
Minimum volume	Greater than or equal to 0.20 mL	0.22	Not performed	0.21	0.20	0.198*
Maximum volume	Less than or equal to 0.22 mL	0.21	Not performed	0.21	0.21	0.21
- Anti-Xa activity (IU/0.2 mL)	1800 to 2200 IU/0.2 mL	1998	2019	1995	2037	2033
- Anti-IIa activity (IU/0.2 mL)	400 to 700 IU/0.2 mL	512	522	516	519	520
- Anti Xa/anti IIa ratio	3.3 to 5.3	3.9	3.9	3.9	3.9	3.9
- Particulate matter						
Particles ≥ to 10 µm	Not more than 6000	180	Not performed	100	84	320
Particles ≥ to 25 µm	Not more than 600	2	Not performed	0	1	2
- Bacterial endotoxins	Less than 100 EU/mL	Complies	Not performed	Not performed	Complies	Complies
- Sterility (Ph. Eur)	Conforms	Conforms	Not performed	Not performed	Conforms	Conforms

* Out-of-specification result for volume (0.198 mL). The biological activity has been assessed to evaluate the impact of this low volume on patient. The out-of-specification result for the volume has no impact on patient since the biological activity remains within specifications.

Stability Data

Enoxaparin sodium 100 mg/mL solution – solution for injection in pre-filled syringe - 20 mg/0.2 mL, 40 mg/0.4 mL, 60 mg/0.6 mL, 80 mg/0.8 mL and 100 mg/1.0 mL

Table 3: Long term stability 20 mg/0.2 mL – Batch no. : 962609

Drug product:	Enoxaparin sodium 100 mg/mL solution for injection in pre-filled syringes	Batch no.:	962609			
Dosage strength:	20 mg/0.2 mL	Batch size (L):	150			
Manufacturing date:	02/04/2013	Manufacturing site:	Le Trait			
Study activation date:	21/06/2013					
Container/closure type:	Plunger stopper chlorobutyl black					
Primary Packaging type:	Syringe type I clear glass					
Storage condition:	+ 25 ± 2°C/60 ± 5 % RH					
Test item	Acceptance criteria	Time				
		Initial	6 months	12 months	24 months	36 months
- Characters						
Clarity	Clear	Complies	Complies	Complies	Complies	Complies
Color	Colorless to pale yellow solution	Complies	Complies	Complies	Complies	Complies
- Clarity	Not more than reference suspension I	Complies	Complies	Complies	Complies	Complies
- Coloration of solution						
Degree of coloration	Not more colored than 4	7	6	6	5	5
Shade of coloration	Y or BY	BY	BY	BY	BY	BY
- pH	5.5 to 7.5	6.5	6.5	6.4	6.3	6.2
- Free sulfates (%)	Not more than 0.12 %	0.02	0.02	0.02	0.03	0.03
- Extractable volume on 5 syringes (mL)						
Minimum volume	Greater than or equal to 0.20 mL	0.20	Not performed	0.21	0.20	0.20
Maximum volume	Less than or equal to 0.22 mL	0.21	Not performed	0.21	0.21	0.21
- Anti-Xa activity (IU/0.2 mL)	1800 to 2200 IU/0.2 mL	2060	2089	2116	2094	2088
- Anti-IIa activity (IU/0.2 mL)	400 to 700 IU/0.2 mL	582	587	575	575	580
- Anti Xa/anti IIa ratio	3.3 to 5.3	3.5	3.6	3.7	3.6	3.6
- Particulate matter						
Particles ≥ to 10 µm	Not more than 6000	17	Not performed	8	5	13
Particles ≥ to 25 µm	Not more than 600	0	Not performed	0	0	0
- Bacterial endotoxins	Less than 100 EU/mL	Complies	Not performed	Not performed	Complies	Complies
- Sterility (Ph. Eur)	Conforms	Conforms	Not performed	Not performed	Conforms	Conforms

Stability Data

Enoxaparin sodium 100 mg/mL solution – solution for injection in pre-filled syringe - 20 mg/0.2 mL, 40 mg/0.4 mL, 60 mg/0.6 mL, 80 mg/0.8 mL and 100 mg/1.0 mL

Table 4: Long term stability 40 mg/0.4 mL – Batch no. : 958446

Drug product:	Enoxaparin sodium 100 mg/mL solution for injection in pre-filled syringes	Batch no.:	958446			
Dosage strength:	40 mg/0.4 mL	Batch size (L):	250			
Manufacturing date:	30/11/2012	Manufacturing site:	Le Trait			
Study activation date:	23/01/2013					
Container/closure type:	Plunger stopper chlorobutyl black					
Primary Packaging type:	Syringe type I clear glass					
Storage condition:	+ 25 ± 2°C/60 ± 5 % RH					
Test item	Acceptance criteria	Time				
		Initial	6 months	12 months	24 months	36 months
- Characters						
Clarity	Clear	Complies	Complies	Complies	Complies	Complies
Color	Colorless to pale yellow solution	Complies	Complies	Complies	Complies	Complies
- Clarity	Not more than reference suspension I	Complies	Complies	Complies	Complies	Complies
- Coloration of solution						
Degree of coloration	Not more colored than 4	7	6	6	5	4
Shade of coloration	Y or BY	BY	BY	BY	BY	BY
- pH	5.5 to 7.5	6.5	6.3	6.2	6.0	5.8
- Free sulfates (%)	Not more than 0.12 %	0.03	0.03	0.03	0.03	0.03
- Extractable volume on 5 syringes (mL)						
Minimum volume	Greater than or equal to 0.40 mL	0.41	Not performed	0.41	0.41	0.40
Maximum volume	Less than or equal to 0.44 mL	0.42	Not performed	0.41	0.41	0.41
- Anti-Xa activity (IU/0.4 mL)	3600 to 4400 IU/0.4 mL	3983	4070	3970	4035	4012
- Anti-IIa activity (IU/0.4 mL)	800 to 1400 IU/0.4 mL	1075	1075	1002	1047	1033
- Anti Xa/anti IIa ratio	3.3 to 5.3	3.7	3.8	4.0	3.9	3.9
- Particulate matter						
Particles ≥ to 10 µm	Not more than 6000	30	Not performed	198	381	914
Particles ≥ to 25 µm	Not more than 600	2	Not performed	7	6	29
- Bacterial endotoxins	Less than 100 EU/mL	Complies	Not performed	Not performed	Complies	Complies
- Sterility (Ph. Eur)	Conforms	Conforms	Not performed	Not performed	Conforms	Conforms

Stability Data

Enoxaparin sodium 100 mg/mL solution – solution for injection in pre-filled syringe - 20 mg/0.2 mL, 40 mg/0.4 mL, 60 mg/0.6 mL, 80 mg/0.8 mL and 100 mg/1.0 mL

Table 5: Long term stability 40 mg/0.4 mL – Batch no. : 968451

Drug product:	Enoxaparin sodium 100 mg/mL solution for injection in pre-filled syringes	Batch no.:	968451			
Dosage strength:	40 mg/0.4 mL	Batch size (L):	250			
Manufacturing date:	21/01/2013	Manufacturing site:	Le Trait			
Study activation date:	07/02/2013					
Container/closure type:	Plunger stopper chlorobutyl black					
Primary Packaging type:	Syringe type I clear glass					
Storage condition:	+ 25 ± 2°C/60 ± 5 % RH					
Test item	Acceptance criteria	Time				
		Initial	6 months	12 months	24 months	36 months
- Characters						
Clarity	Clear	Complies	Complies	Complies	Complies	Complies
Color	Colorless to pale yellow solution	Complies	Complies	Complies	Complies	Complies
- Clarity	Not more than reference suspension I	Complies	Complies	Complies	Complies	Complies
- Coloration of solution						
Degree of coloration	Not more colored than 4	7	6	6	5	5
Shade of coloration	Y or BY	BY	BY	BY	BY	BY
- pH	5.5 to 7.5	6.6	6.4	6.3	6.2	6.0
- Free sulfates (%)	Not more than 0.12 %	0.03	0.03	0.03	0.03	0.03
- Extractable volume on 5 syringes (mL)						
Minimum volume	Greater than or equal to 0.40 mL	0.41	Not performed	0.41	0.41	0.41
Maximum volume	Less than or equal to 0.44 mL	0.42	Not performed	0.42	0.41	0.41
- Anti-Xa activity (IU/0.4 mL)	3600 to 4400 IU/0.4 mL	4112	4012	4005	3972	4163
- Anti-IIa activity (IU/0.4 mL)	800 to 1400 IU/0.4 mL	1053	1029	1031	1028	1042
- Anti Xa/anti IIa ratio	3.3 to 5.3	3.9	3.9	3.9	3.9	4.0
- Particulate matter						
Particles ≥ to 10 µm	Not more than 6000	58	Not performed	188	500	1345
Particles ≥ to 25 µm	Not more than 600	1	Not performed	3	15	59
- Bacterial endotoxins	Less than 100 EU/mL	Complies	Not performed	Not performed	Complies	Complies
- Sterility (Ph. Eur)	Conforms	Conforms	Not performed	Not performed	Conforms	Conforms

Stability Data

Enoxaparin sodium 100 mg/mL solution – solution for injection in pre-filled syringe - 20 mg/0.2 mL, 40 mg/0.4 mL, 60 mg/0.6 mL, 80 mg/0.8 mL and 100 mg/1.0 mL

Table 6: Long term stability 40 mg/0.4 mL – Batch no. : 964307

Drug product:	Enoxaparin sodium 100 mg/mL solution for injection in pre-filled syringes	Batch no.:	964307			
Dosage strength:	40 mg/0.4 mL	Batch size (L):	250			
Manufacturing date:	11/02/2013	Manufacturing site:	Le Trait			
Study activation date:	25/04/2013					
Container/closure type:	Plunger stopper chlorobutyl black					
Primary Packaging type:	Syringe type I clear glass					
Storage condition:	+ 25 ± 2°C/60 ± 5 % RH					
Test item	Acceptance criteria	Time				
		Initial	6 months	12 months	24 months	36 months
- Characters						
Clarity	Clear	Complies	Complies	Complies	Complies	Complies
Color	Colorless to pale yellow solution	Complies	Complies	Complies	Complies	Complies
- Clarity	Not more than reference suspension I	Complies	Complies	Complies	Complies	Complies
- Coloration of solution						
Degree of coloration	Not more colored than 4	7	6	6	6	4
Shade of coloration	Y or BY	BY	BY	BY	BY	BY
- pH	5.5 to 7.5	6.6	6.5	6.4	6.2	6.1
- Free sulfates (%)	Not more than 0.12 %	0.03	0.03	0.03	0.03	0.03
- Extractable volume on 5 syringes (mL)						
Minimum volume	Greater than or equal to 0.40 mL	0.41	Not performed	0.41	0.41	0.41
Maximum volume	Less than or equal to 0.44 mL	0.42	Not performed	0.42	0.41	0.41
- Anti-Xa activity (IU/0.4 mL)	3600 to 4400 IU/0.4 mL	4085	4072	4169	4177	4166
- Anti-IIa activity (IU/0.4 mL)	800 to 1400 IU/0.4 mL	1115	1106	1133	1153	1141
- Anti Xa/anti IIa ratio	3.3 to 5.3	3.7	3.7	3.7	3.6	3.7
- Particulate matter						
Particles ≥ to 10 µm	Not more than 6000	3	Not performed	20	50	235
Particles ≥ to 25 µm	Not more than 600	0	Not performed	0	0	1
- Bacterial endotoxins	Less than 100 EU/mL	Complies	Not performed	Not performed	Complies	Complies
- Sterility (Ph. Eur)	Conforms	Conforms	Not performed	Not performed	Conforms	Conforms

Stability Data

Enoxaparin sodium 100 mg/mL solution – solution for injection in pre-filled syringe - 20 mg/0.2 mL, 40 mg/0.4 mL, 60 mg/0.6 mL, 80 mg/0.8 mL and 100 mg/1.0 mL

Table 7: Long-term stability 60 mg/0.6 mL – Batch no. : 958603

Drug product:	Enoxaparin sodium 100 mg/mL solution for injection in pre-filled syringes	Batch no.:	958603			
Dosage strength:	60 mg/0.6 mL	Batch size (L):	170			
Manufacturing date:	27/11/2012	Manufacturing site:	Le Trait			
Study activation date:	30/01/2013					
Container/closure type:	Plunger stopper chlorobutyl black					
Primary Packaging type:	Syringe type I clear glass					
Storage condition:	+ 25 ± 2°C/60 ± 5 % RH					
Test item	Acceptance criteria	Time				
		Initial	6 months	12 months	24 months	36 months
- Characters						
Clarity	Clear	Complies	Complies	Complies	Complies	Complies
Color	Colorless to pale yellow solution	Complies	Complies	Complies	Complies	Complies
- Clarity	Not more than reference suspension I	Complies	Complies	Complies	Complies	Complies
- Coloration of solution						
Degree of coloration	Not more colored than 4	7	6	6	5	4
Shade of coloration	Y or BY	BY	BY	BY	BY	BY
- pH	5.5 to 7.5	6.5	6.3	6.1	6.0	5.9
- Free sulfates (%)	Not more than 0.12 %	0.03	0.03	0.03	0.03	0.04
- Extractable volume on 5 syringes (mL)	Not less than 0.60 mL	0.61	Not performed	0.61	0.61	0.61
- Anti-Xa activity (IU/mL)	9000 to 11000 IU/mL	9980	10104	9987	10062	9995
- Anti-IIa activity (IU/mL)	2000 to 3500 IU/mL	2658	2648	2595	2628	2648
- Anti Xa/anti IIa ratio	3.3 to 5.3	3.8	3.8	3.8	3.8	3.8
- Particulate matter						
Particles ≥ to 10 µm	Not more than 6000	368	Not performed	170	208	264
Particles ≥ to 25 µm	Not more than 600	2	Not performed	2	1	1
- Bacterial endotoxins	Less than 100 EU/mL	Complies	Not performed	Not performed	Complies	Complies
- Sterility (Ph. Eur)	Conforms	Conforms	Not performed	Not performed	Conforms	Conforms

Stability Data

Enoxaparin sodium 100 mg/mL solution – solution for injection in pre-filled syringe - 20 mg/0.2 mL, 40 mg/0.4 mL, 60 mg/0.6 mL, 80 mg/0.8 mL and 100 mg/1.0 mL

Table 8: Long-term stability 60 mg/0.6 mL – Batch no. : 968605

Drug product:	Enoxaparin sodium 100 mg/mL solution for injection in pre-filled syringes	Batch no.:	968605			
Dosage strength:	60 mg/0.6 mL	Batch size (L):	170			
Manufacturing date:	06/02/2013	Manufacturing site:	Le Trait			
Study activation date:	07/03/2013					
Container/closure type:	Plunger stopper chlorobutyl black					
Primary Packaging type:	Syringe type I clear glass					
Storage condition:	+ 25 ± 2°C/60 ± 5 % RH					
Test item	Acceptance criteria	Time				
		Initial	6 months	12 months	24 months	36 months
- Characters						
Clarity	Clear	Complies	Complies	Complies	Complies	Complies
Color	Colorless to pale yellow solution	Complies	Complies	Complies	Complies	Complies
- Clarity	Not more than reference suspension I	Complies	Complies	Complies	Complies	Complies
- Coloration of solution						
Degree of coloration	Not more colored than 4	6	6	6	5	4
Shade of coloration	Y or BY	BY	BY	BY	BY	BY
- pH	5.5 to 7.5	6.6	6.4	6.3	6.1	6.0
- Free sulfates (%)	Not more than 0.12 %	0.03	0.03	0.03	0.03	0.03
- Extractable volume on 5 syringes (mL)	Not less than 0.60 mL	0.62	Not performed	0.61	0.61	0.61
- Anti-Xa activity (IU/mL)	9000 to 11000 IU/mL	10043	9883	9883	9993	9993
- Anti-IIa activity (IU/mL)	2000 to 3500 IU/mL	2608	2581	2528	2573	2526
- Anti Xa/anti IIa ratio	3.3 to 5.3	3.9	3.8	3.9	3.9	4.0
- Particulate matter						
Particles ≥ to 10 µm	Not more than 6000	436	Not performed	273	304	400
Particles ≥ to 25 µm	Not more than 600	7	Not performed	4	3	2
- Bacterial endotoxins	Less than 100 EU/mL	Complies	Not performed	Not performed	Complies	Complies
- Sterility (Ph. Eur)	Conforms	Conforms	Not performed	Not performed	Conforms	Conforms

Stability Data

Enoxaparin sodium 100 mg/mL solution – solution for injection in pre-filled syringe - 20 mg/0.2 mL, 40 mg/0.4 mL, 60 mg/0.6 mL, 80 mg/0.8 mL and 100 mg/1.0 mL

Table 9: Long-term stability 60 mg/0.6 mL – Batch no. : 966213

Drug product:	Enoxaparin sodium 100 mg/mL solution for injection in pre-filled syringes	Batch no.:	966213			
Dosage strength:	60 mg/0.6 mL	Batch size (L):	250			
Manufacturing date:	22/05/2013	Manufacturing site:	Le Trait			
Study activation date:	17/06/2013					
Container/closure type:	Plunger stopper chlorobutyl black					
Primary Packaging type:	Syringe type I clear glass					
Storage condition:	+ 25 ± 2°C/60 ± 5 % RH					
Test item	Acceptance criteria	Time				
		Initial	6 months	12 months	24 months	36 months
- Characters						
Clarity	Clear	Complies	Complies	Complies	Complies	Complies
Color	Colorless to pale yellow solution	Complies	Complies	Complies	Complies	Complies
- Clarity	Not more than reference suspension I	Complies	Complies	Complies	Complies	Complies
- Coloration of solution						
Degree of coloration	Not more colored than 4	7	6	6	5	4
Shade of coloration	Y or BY	BY	BY	BY	BY	BY
- pH	5.5 to 7.5	6.8	6.6	6.5	6.3	6.2
- Free sulfates (%)	Not more than 0.12 %	0.02	0.02	0.02	0.03	0.03
- Extractable volume on 5 syringes (mL)	Not less than 0.60 mL	0.62	Not performed	0.61	0.61	0.61
- Anti-Xa activity (IU/mL)	9000 to 11000 IU/mL	9904	10016	10197	10092	10231
- Anti-IIa activity (IU/mL)	2000 to 3500 IU/mL	2878	2886	2858	2853	2883
- Anti Xa/anti IIa ratio	3.3 to 5.3	3.4	3.5	3.6	3.5	3.5
- Particulate matter						
Particles ≥ to 10 µm	Not more than 6000	6	Not performed	9	21	7
Particles ≥ to 25 µm	Not more than 600	0	Not performed	0	2	0
- Bacterial endotoxins	Less than 100 EU/mL	Complies	Not performed	Not performed	Complies	Complies
- Sterility (Ph. Eur)	Conforms	Conforms	Not performed	Not performed	Conforms	Conforms

Stability Data

Enoxaparin sodium 100 mg/mL solution – solution for injection in pre-filled syringe - 20 mg/0.2 mL, 40 mg/0.4 mL, 60 mg/0.6 mL, 80 mg/0.8 mL and 100 mg/1.0 mL

Table 10: Long-term stability 100 mg/1.0 mL – Batch no. : 951213

Drug product:	Enoxaparin sodium 100 mg/mL solution for injection in pre-filled syringes	Batch no.:	951213			
Dosage strength:	100 mg/1.0 mL	Batch size (L):	250			
Manufacturing date:	11/06/2012	Manufacturing site:	Le Trait			
Study activation date:	04/09/2012					
Container/closure type:	Plunger stopper chlorobutyl black					
Primary Packaging type:	Syringe type I clear glass					
Storage condition:	+ 25 ± 2°C/60 ± 5 % RH					
Test item	Acceptance criteria	Time				
		Initial	6 months	12 months	24 months	36 months
- Characters						
Clarity	Clear	Complies	Complies	Complies	Complies	Complies
Color	Colorless to pale yellow solution	Complies	Complies	Complies	Complies	Complies
- Clarity	Not more than reference suspension I	Complies	Complies	Complies	Complies	Complies
- Coloration of solution						
Degree of coloration	Not more colored than 4	7	7	6	5	5
Shade of coloration	Y or BY	BY	BY	BY	BY	BY
- pH	5.5 to 7.5	6.6	6.5	6.5	6.3	6.2
- Free sulfates (%)	Not more than 0.12 %	0.03	0.03	0.03	0.03	0.03
- Extractable volume on 5 syringes (mL)	Not less than 1.00 mL	1.03	Not performed	1.00	1.00	1.01
- Anti-Xa activity (IU/mL)	9000 to 11000 IU/mL	10106	10000	9938	10273	10047
- Anti-IIa activity (IU/mL)	2000 to 3500 IU/mL	2715	2644	2738	2751	2666
- Anti Xa/anti IIa ratio	3.3 to 5.3	3.7	3.8	3.6	3.7	3.8
- Particulate matter						
Particles ≥ to 10 µm	Not more than 6000	13	Not performed	Not performed	2519	2635
Particles ≥ to 25 µm	Not more than 600	0	Not performed	Not performed	7	41
- Bacterial endotoxins	Less than 100 EU/mL	Complies	Not performed	Not performed	Complies	Complies
- Sterility (Ph. Eur)	Conforms	Conforms	Not performed	Not performed	Conforms	Conforms

Stability Data

Enoxaparin sodium 100 mg/mL solution – solution for injection in pre-filled syringe - 20 mg/0.2 mL, 40 mg/0.4 mL, 60 mg/0.6 mL, 80 mg/0.8 mL and 100 mg/1.0 mL

Table 11: Long-term stability 100 mg/1.0 mL – Batch no. : 958103

Drug product:	Enoxaparin sodium 100 mg/mL solution for injection in pre-filled syringes	Batch no.:	958103			
Dosage strength:	100 mg/1.0 mL	Batch size (L):	170			
Manufacturing date:	19/11/2012	Manufacturing site:	Le Trait			
Study activation date:	30/01/2013					
Container/closure type:	Plunger stopper chlorobutyl black					
Primary Packaging type:	Syringe type I clear glass					
Storage condition:	+ 25 ± 2°C/60 ± 5 % RH					
Test item	Acceptance criteria	Time				
		Initial	6 months	12 months	24 months	36 months
- Characters						
Clarity	Clear	Complies	Complies	Complies	Complies	Complies
Color	Colorless to pale yellow solution	Complies	Complies	Complies	Complies	Complies
- Clarity	Not more than reference suspension I	Complies	Complies	Complies	Complies	Complies
- Coloration of solution						
Degree of coloration	Not more colored than 4	7	6	5	5	4
Shade of coloration	Y or BY	BY	BY	BY	BY	BY
- pH	5.5 to 7.5	6.5	6.3	6.2	6.0	5.9
- Free sulfates (%)	Not more than 0.12 %	0.03	0.03	0.03	0.03	0.03
- Extractable volume on 5 syringes (mL)	Not less than 1.00 mL	1.02	Not performed	1.01	1.01	1.01
- Anti-Xa activity (IU/mL)	9000 to 11000 IU/mL	10021	10114	10106	9981	9912
- Anti-IIa activity (IU/mL)	2000 to 3500 IU/mL	2673	2622	2684	2696	2606
- Anti Xa/anti IIa ratio	3.3 to 5.3	3.7	3.9	3.8	3.7	3.8
- Particulate matter						
Particles ≥ to 10 µm	Not more than 6000	645	Not performed	409	876	637
Particles ≥ to 25 µm	Not more than 600	4	Not performed	3	4	3
- Bacterial endotoxins	Less than 100 EU/mL	Complies	Not performed	Not performed	Complies	Complies
- Sterility (Ph. Eur)	Conforms	Conforms	Not performed	Not performed	Conforms	Conforms

Stability Data

Enoxaparin sodium 100 mg/mL solution – solution for injection in pre-filled syringe - 20 mg/0.2 mL, 40 mg/0.4 mL, 60 mg/0.6 mL, 80 mg/0.8 mL and 100 mg/1.0 mL

Table 12: Long-term stability 100 mg/1.0 mL – Batch no. : 968113

Drug product:	Enoxaparin sodium 100 mg/mL solution for injection in pre-filled syringes	Batch no.:	968113			
Dosage strength:	100 mg/1.0 mL	Batch size (L):	170			
Manufacturing date:	19/02/2013	Manufacturing site:	Le Trait			
Study activation date:	25/04/2013					
Container/closure type:	Plunger stopper chlorobutyl black					
Primary Packaging type:	Syringe type I clear glass					
Storage condition:	+ 25 ± 2°C/60 ± 5 % RH					
Test item	Acceptance criteria	Time				
		Initial	6 months	12 months	24 months	36 months
- Characters						
Clarity	Clear	Complies	Complies	Complies	Complies	Complies
Color	Colorless to pale yellow solution	Complies	Complies	Complies	Complies	Complies
- Clarity	Not more than reference suspension I	Complies	Complies	Complies	Complies	Complies
- Coloration of solution						
Degree of coloration	Not more colored than 4	7	6	6	5	4
Shade of coloration	Y or BY	BY	BY	BY	BY	BY
- pH	5.5 to 7.5	6.5	6.3	6.2	6.0	5.9
- Free sulfates (%)	Not more than 0.12 %	0.03	0.03	0.03	0.03	0.03
- Extractable volume on 5 syringes (mL)	Not less than 1.00 mL	1.02	Not performed	1.02	1.02	1.02
- Anti-Xa activity (IU/mL)	9000 to 11000 IU/mL	9867	9909	9956	9969	9954
- Anti-IIa activity (IU/mL)	2000 to 3500 IU/mL	2528	2524	2529	2521	2525
- Anti Xa/anti IIa ratio	3.3 to 5.3	3.9	3.9	3.9	4.0	3.9
- Particulate matter						
Particles ≥ to 10 µm	Not more than 6000	499	Not performed	281	282	427
Particles ≥ to 25 µm	Not more than 600	2	Not performed	5	2	1
- Bacterial endotoxins	Less than 100 EU/mL	Complies	Not performed	Not performed	Complies	Complies
- Sterility (Ph. Eur)	Conforms	Conforms	Not performed	Not performed	Conforms	Conforms