



Str-005354 v.1.0

CHEMISTRY MANUFACTURING CONTROL

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Title Certificate of Analysis, Dalteparin Sodium Drug Substance		
Batch/Lot No. 47180-51	Article No. 608196	Complies with Spec. No. S-40000781
Manufacturing date 2010-03-08		Expiry date 2013-03-08

TESTS	RESULTS	ACCEPTANCE CRITERIA
Number Average, Da, M602	4839	4500-5300
Weight Average, Da, M602	6026	5600-6400
Peak Molecular Weight, Da, M602	4542	4300-5500
Proportion of Heparin fragment material higher than molecular weight 8 000 Da (%>8 000), M602	19.7	15.0-25.0
Proportion of Heparin fragment material lower than molecular weight 3 000 Da (%<3 000), M602	9.3	5.0-13.0
Quotient Anti-Factor Xa/Anti-Factor IIa	2.6	1.9-3.2
Sodium Identity, Ph.Eur	Positive	Positive
Anti-Factor Xa activity, IU/mg, H236	157	110-210
Anti-Factor IIa activity, IU/mg, S643	61	35-100
pH (1 % w/v solution), Ph.Eur	7.3	5.5-8.0
Nitrogen content, % w/w, Ph.Eur	1.9	1.5-2.5
Heavy metals, ppm, Ph.Eur	<30	≤ 30
Sodium, % w/w, Ph.Eur	11.7	9.5-12.5
Loss on drying, % w/w, Ph.Eur	0.6	≤ 5.0
Molar Ratio of Sulphate to Carboxylate ions, Ph.Eur	2.3	≥ 1.8
Boron, ppm, B220	<1	≤ 1
Nitrite, ppm, F609	<1	≤ 5



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Title
Certificate of Analysis, Dalteparin Sodium Drug Substance
Batch/Lot No.
47180-51

TESTS	RESULTS	ACCEPTANCE CRITERIA
Ethanol, % w/w, E600	3	≤ 5
Clarity of Solution, Ph.Eur	Approved	Approved
Colour of Solution, Ph.Eur	Approved	Approved
Bacterial Endotoxin test, EU/1000 IU, Ph Eur	<0.1	< 2.5
Bacteriological test, CFU/g, S695	0	≤ 100

Description: A white or yellowish white powder, moderately hygroscopic, freely soluble in water.

Franklin Heparin Lot number: 80923A and 80925A : NMR-result; Pass.

Strängnäs date 2012-01-18
Pfizer global Supply
Quality Organisation, QA

Anna Nordin
CMC Manager

Karin Mouille
Quality Assurance Release Officer



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Title Certificate of Analysis, Dalteparin Sodium Drug Substance		
Batch/Lot No. 48454-51	Article No. 608196	Complies with Spec. No S-40000781
Manufacturing date 2011-05-08		Expiry date 2014-05-08

TESTS	RESULTS	ACCEPTANCE CRITERIA
Number Average, Da, M602	4943	4500-5300
Weight Average, Da, M602	6158	5600-6400
Peak Molecular Weight, Da, M602	4728	4300-5500
Proportion of Heparin fragment material higher than molecular weight 8 000 Da (%>8 000), M602	21.1	15.0-25.0
Proportion of Heparin fragment material lower than molecular weight 3 000 Da (%<3 000), M602	8.4	5.0-13.0
Quotient Anti-Factor Xa/Anti-Factor IIa	2.5	1.9-3.2
Sodium Identity, Ph.Eur	Positive	Positive
Anti-Factor Xa activity, IU/mg, H236	159	110-210
Anti-Factor IIa activity, IU/mg, S643	64	35-100
pH (1 % w/v solution), Ph.Eur	7.2	5.5-8.0
Nitrogen content, % w/w, Ph.Eur	2.0	1.5-2.5
Heavy metals, ppm, Ph.Eur	<30	≤ 30
Sodium, % w/w, Ph.Eur	11.7	9.5-12.5
Loss on drying, % w/w, Ph.Eur	1.7	≤ 5.0
Molar Ratio of Sulphate to Carboxylate ions, Ph.Eur	2.1	≥ 1.8
Boron, ppm, B220	<1	≤ 1
Nitrite, ppm, F609	<1	≤ 5



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Title

Certificate of Analysis, Dalteparin Sodium Drug Substance

Batch/Lot No.

48454-51

TESTS	RESULTS	ACCEPTANCE CRITERIA
Ethanol, % w/w, E600	2	≤ 5
Clarity of Solution, Ph.Eur	Approved	Approved
Colour of Solution, Ph.Eur	Approved	Approved
Bacterial Endotoxin test, EU/1000 IU, Ph Eur	<0.1	< 2.5
Bacteriological test, CFU/g, S695	0	≤ 100

Description: A white or yellowish white powder, moderately hygroscopic, freely soluble in water.

Franklin Heparin Lot number: 81579A and 81596A : NMR-result; Pass.

Strängnäs date 2012-01-18
Pfizer global Supply
Quality Organisation, QA,

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Title Certificate of Analysis, Dalteparin Sodium Drug Substance		
Batch/Lot No. 48581-51	Article No. 608196	Complies with Spec. No S-40000781
Manufacturing date 2011-06-17		Expiry date 2014-06-17

TESTS	RESULTS	ACCEPTANCE CRITERIA
Number Average, Da, M602	4999	4500-5300
Weight Average, Da, M602	6262	5600-6400
Peak Molecular Weight, Da, M602	4787	4300-5500
Proportion of Heparin fragment material higher than molecular weight 8 000 Da (%>8 000), M602	22.0	15.0-25.0
Proportion of Heparin fragment material lower than molecular weight 3 000 Da (%<3 000), M602	8.1	5.0-13.0
Quotient Anti-Factor Xa/Anti-Factor IIa	2.5	1.9-3.2
Sodium Identity, Ph.Eur	Positive	Positive
Anti-Factor Xa activity, IU/mg, H236	154	110-210
Anti-Factor IIa activity, IU/mg, S643	62	35-100
pH (1 % w/v solution), Ph.Eur	7.3	5.5-8.0
Nitrogen content, % w/w, Ph.Eur	2.1	1.5-2.5
Heavy metals, ppm, Ph.Eur	<30	≤ 30
Sodium, % w/w, Ph.Eur	11.8	9.5-12.5
Loss on drying, % w/w, Ph.Eur	2.9	≤ 5.0
Molar Ratio of Sulphate to Carboxylate ions, Ph.Eur	2.3	≥ 1.8
Boron, ppm, B220	<1	≤ 1
Nitrite, ppm, F609	<1	≤ 5



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Title
Certificate of Analysis, Dalteparin Sodium Drug Substance
Batch/Lot No.
48581-51

TESTS	RESULTS	ACCEPTANCE CRITERIA
Ethanol, % w/w, E600	3	≤ 5
Clarity of Solution, Ph.Eur	Approved	Approved
Colour of Solution, Ph.Eur	Approved	Approved
Bacterial Endotoxin test, EU/1000 IU, Ph Eur	<0.1	< 2.5
Bacteriological test, CFU/g, S695	0	≤ 100

Description: A white or yellowish white powder, moderately hygroscopic, freely soluble in water.

Franklin Heparin Lot number: 81631A : NMR-result; Pass.

Strängnäs date 2012-01-18
Pfizer global Supply
Quality Organisation, QA

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Title Certificate of Analysis, Dalteparin Sodium Drug Substance		
Batch/Lot No. 48586-51	Article No. 608196	Complies with Spec. No. S-40000781
Manufacturing date 2011-06-26		Expiry date 2014-06-26

TESTS	RESULTS	ACCEPTANCE CRITERIA
Number Average, Da, M602	4904	4500-5300
Weight Average, Da, M602	6154	5600-6400
Peak Molecular Weight, Da, M602	4719	4300-5500
Proportion of Heparin fragment material higher than molecular weight 8 000 Da (%>8 000), M602	21.0	15.0-25.0
Proportion of Heparin fragment material lower than molecular weight 3 000 Da (%<3 000), M602	9.1	5.0-13.0
Quotient Anti-Factor Xa/Anti-Factor IIa	2.4	1.9-3.2
Sodium Identity, Ph.Eur	Positive	Positive
Anti-Factor Xa activity, IU/mg, H236	158	110-210
Anti-Factor IIa activity, IU/mg, S643	65	35-100
pH (1 % w/v solution), Ph.Eur	7.3	5.5-8.0
Nitrogen content, % w/w, Ph.Eur	2.0	1.5-2.5
Heavy metals, ppm, Ph.Eur	<30	≤ 30
Sodium, % w/w, Ph.Eur	11.8	9.5-12.5
Loss on drying, % w/w, Ph.Eur	2.0	≤ 5.0
Molar Ratio of Sulphate to Carboxylate ions, Ph.Eur	2.1	≥ 1.8
Boron, ppm, B220	<1	≤ 1
Nitrite, ppm, F609	<1	≤ 5



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Title
Certificate of Analysis, Dalteparin Sodium Drug Substance
Batch/Lot No.
48586-51

TESTS	RESULTS	ACCEPTANCE CRITERIA
Ethanol, % w/w, E600	3	≤ 5
Clarity of Solution, Ph.Eur	Approved	Approved
Colour of Solution, Ph.Eur	Approved	Approved
Bacterial Endotoxin test, EU/1000 IU, Ph Eur	<0.1	< 2.5
Bacteriological test, CFU/g, S695	0	≤ 100

Description: A white or yellowish white powder, moderately hygroscopic, freely soluble in water.

Franklin Heparin Lot number: 81639A : NMR-result; Pass.

Strängnäs date 2012-01-18
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