CHEMISTRY MANUFACTURING CONTROL

Title

Certificate of Analysis, Dalteparin Sodium Drug Substance

Batch/Lot No.	Article No.	Complies with Spec. No
48586-51	608196	S-40000781

Manufacturing date	Expiry date
2011-06-26	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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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
Pfizer global Supply
Quality Organisation, QA

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