January 26, 2021 UTC+08

CERTIFICATE OF ANALYSIS

Enoxaparin Sodium (Suitable for all markets except Canada)

SG205F

Batch number : **20QEEA1174**

Manufacturing date	: November 18, 2020		
Expiry date	: November 17, 2023	Retest date	: N/A
Analytical method	: JUR-SPEC-0091/V2		
Storage conditions	: Hygroscopic. Storage: controlled room temperature (up to 25°C).		
Inspection lot number	: 6992466		
Compliance	: This batch is accepted and complies with the specifications.		

Tests	Analytical results	Specifications
Appearance	Complies	White to almost white fine powder
Identification- Protamine Sulphate	Complies	White to creamy white precipitate
Identification - 1,6 Anhydro ring structure by LC	21	15 to 25 %
Loss on drying	6.8	5.5 to 10.0 % w/w
Specific absorbance at 231nm (on dried basis)	14.9	14.0 to 20.0
Aqueous Solution (1g in 10 ml) - Clarity (opalescence) by EP	< standard 1	<=Standard 1
Aqueous Solution (1g in 10 ml) - Colour by EP	< degree 7	<=Degree 6
Molecular mass distribution: Fraction <2000Da	14.0	12.0 to 20.0 %
Molecular mass distribution: Fractions >8000Da	13.5	<= 18.0 %
Molecular mass distribution: fraction between 2000 and 8000 Da	72.5	68.0 to 82.0 %
Average molecular mass	4800	3800 to 5000 Da
pH (10% w/v aqueous solution)	7.0	6.2 to 7.7
Heavy Metals (as Pb)	< 0.0030	<=0.0030 % w/w
Residual Benzethonium (as benzethonium chloride)	< 0.0050	<=0.0050 % w/w
Benzyl Alcohol	0.0101	<= 0.1000 % w/w
Residual Solvents - Methanol	< 0.0100	<=0.0100 % w/w

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SG205F

Batch number : **20QEEA1174**

Tests	Analytical results	Specifications
Residual Solvents - Methylene Chloride	Not detected	<=0.0100 % w/w
Total Nitrogen (on dried basis)	2.0	1.8 to 2.5 % w/w
Sodium (on dried basis)	13.1	11.3 to 13.5 % w/w
Sulphate to Carboxylate Ratio	2.2	1.8 to 2.3
Anti-Xa Activity (as it is), IU/mg	105.096	Not applicable
Anti-Xa Activity (on dried basis)	113	90 to 125 IU/mg
Anti-lla Activity (as it is), IU/mg	31.077	Not applicable
Anti-lla Activity (On dried basis)	33.3	20.0 to 35.0 IU/mg
Anti-Xa to Anti IIa Activity Ratio	3.4	3.3 to 5.3
Total Viable Count (Aerobic)	< 1	<= 100 cfu/g
Moulds and Yeasts	< 1	<= 10 cfu/g
Specified Micro-organisms: Salmonella species	Absent	Absent
Specified Micro-organisms: Staphylococcus Aureus	Absent	Absent
Specified Micro-organisms: Pseudomonas Aeruginosa	Absent	Absent
Specified Micro-organisms: Escherichia coli	Absent	Absent
Bacterial Endotoxins	< 0.01 EU/IU of Anti-XA activity	<0.01 EU/IU of Anti-XA activity

This batch was tested using analytical method reference A58387/current approved version.
Analytical Standard for Biological Control: Batch No. E00850-WS-01.
This batch has been manufactured in compliance with the current Good Manufacturing Practice requirements and complies with the specification of the relevant marketing authorization.

The certificate of analysis has been produced by a validated Laboratory Information Management System and signed electronically the December 16, 2020 at 19:27:14 UTC+8 by Ameliah Basir Snr QA Executive

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January 26, 2021 UTC+08

CERTIFICATE OF ANALYSIS

Enoxaparin Sodium (Suitable for all markets except Canada)

SG205F

Batch number : **20QEEA1175**

Manufacturing date	: November 19, 2020		
Expiry date	: November 18, 2023	Retest date	: N/A
Analytical method	: JUR-SPEC-0091/V2		
Storage conditions	: Hygroscopic. Storage: controlled room temperature (up to 25°C).		
Inspection lot number	: 6992867		
Compliance	: This batch is accepted and complies with the specifications.		

Tests	Analytical results	Specifications
Appearance	Complies	White to almost white fine powder
Identification- Protamine Sulphate	Complies	White to creamy white precipitate
Identification - 1,6 Anhydro ring structure by LC	21	15 to 25 %
Loss on drying	6.7	5.5 to 10.0 % w/w
Specific absorbance at 231nm (on dried basis)	15.3	14.0 to 20.0
Aqueous Solution (1g in 10 ml) - Clarity (opalescence) by EP	< standard 1	<=Standard 1
Aqueous Solution (1g in 10 ml) - Colour by EP	< degree 7	<=Degree 6
Molecular mass distribution: Fraction <2000Da	15.0	12.0 to 20.0 %
Molecular mass distribution: Fractions >8000Da	13.5	<= 18.0 %
Molecular mass distribution: fraction between 2000 and 8000 Da	71.5	68.0 to 82.0 %
Average molecular mass	4700	3800 to 5000 Da
pH (10% w/v aqueous solution)	7.2	6.2 to 7.7
Heavy Metals (as Pb)	< 0.0030	<=0.0030 % w/w
Residual Benzethonium (as benzethonium chloride)	< 0.0050	<=0.0050 % w/w
Benzyl Alcohol	0.0116	<= 0.1000 % w/w
Residual Solvents - Methanol	< 0.0100	<=0.0100 % w/w

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Enoxaparin Sodium (Suitable for all markets except Canada)

SG205F

Batch number : **20QEEA1175**

Tests	Analytical results	Specifications
Residual Solvents - Methylene Chloride	Not detected	<=0.0100 % w/w
Total Nitrogen (on dried basis)	2.0	1.8 to 2.5 % w/w
Sodium (on dried basis)	12.9	11.3 to 13.5 % w/w
Sulphate to Carboxylate Ratio	2.2	1.8 to 2.3
Anti-Xa Activity (as it is), IU/mg	102.632	Not applicable
Anti-Xa Activity (on dried basis)	110	90 to 125 IU/mg
Anti-lla Activity (as it is), IU/mg	30.585	Not applicable
Anti-lla Activity (On dried basis)	32.8	20.0 to 35.0 IU/mg
Anti-Xa to Anti IIa Activity Ratio	3.4	3.3 to 5.3
Total Viable Count (Aerobic)	< 1	<= 100 cfu/g
Moulds and Yeasts	< 1	<= 10 cfu/g
Specified Micro-organisms: Salmonella species	Absent	Absent
Specified Micro-organisms: Staphylococcus Aureus	Absent	Absent
Specified Micro-organisms: Pseudomonas Aeruginosa	Absent	Absent
Specified Micro-organisms: Escherichia coli	Absent	Absent
Bacterial Endotoxins	< 0.01 EU/IU of Anti-XA activity	<0.01 EU/IU of Anti-XA activity

This batch was tested using analytical method reference A58387/current approved version.
Analytical Standard for Biological Control: Batch No. E00850-WS-01.
This batch has been manufactured in compliance with the current Good Manufacturing Practice requirements and complies with the specification of the relevant marketing authorization.

The certificate of analysis has been produced by a validated Laboratory Information Management System and signed electronically the December 16, 2020 at 19:28:02 UTC+8 by Ameliah Basir Snr QA Executive

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January 26, 2021 UTC+08

CERTIFICATE OF ANALYSIS

Enoxaparin Sodium (Suitable for all markets except Canada)

SG205F

Batch number : **20QEEA1176**

Manufacturing date	: November 20, 2020		
Expiry date	: November 19, 2023	Retest date	: N/A
Analytical method	: JUR-SPEC-0091/V2		
Storage conditions	: Hygroscopic. Storage: controlled room temperature (up to 25°C).		
Inspection lot number	: 6993010		
Compliance	: This batch is accepted and complies with the specifications.		

Tests	Analytical results	Specifications
Appearance	Complies	White to almost white fine powder
Identification- Protamine Sulphate	Complies	White to creamy white precipitate
Identification - 1,6 Anhydro ring structure by LC	20	15 to 25 %
Loss on drying	6.7	5.5 to 10.0 % w/w
Specific absorbance at 231nm (on dried basis)	15.6	14.0 to 20.0
Aqueous Solution (1g in 10 ml) - Clarity (opalescence) by EP	< standard 1	<=Standard 1
Aqueous Solution (1g in 10 ml) - Colour by EP	< degree 7	<=Degree 6
Molecular mass distribution: Fraction <2000Da	15.0	12.0 to 20.0 %
Molecular mass distribution: Fractions >8000Da	13.0	<= 18.0 %
Molecular mass distribution: fraction between 2000 and 8000 Da	72.0	68.0 to 82.0 %
Average molecular mass	4700	3800 to 5000 Da
pH (10% w/v aqueous solution)	7.1	6.2 to 7.7
Heavy Metals (as Pb)	< 0.0030	<=0.0030 % w/w
Residual Benzethonium (as benzethonium chloride)	< 0.0050	<=0.0050 % w/w
Benzyl Alcohol	0.0128	<= 0.1000 % w/w
Residual Solvents - Methanol	< 0.0100	<=0.0100 % w/w

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CERTIFICATE OF ANALYSIS

Enoxaparin Sodium (Suitable for all markets except Canada)

SG205F

Batch number : **20QEEA1176**

Tests	Analytical results	Specifications
Residual Solvents - Methylene Chloride	Not detected	<=0.0100 % w/w
Total Nitrogen (on dried basis)	2.0	1.8 to 2.5 % w/w
Sodium (on dried basis)	12.8	11.3 to 13.5 % w/w
Sulphate to Carboxylate Ratio	2.2	1.8 to 2.3
Anti-Xa Activity (as it is), IU/mg	102.531	Not applicable
Anti-Xa Activity (on dried basis)	110	90 to 125 IU/mg
Anti-lla Activity (as it is), IU/mg	30.054	Not applicable
Anti-lla Activity (On dried basis)	32.2	20.0 to 35.0 IU/mg
Anti-Xa to Anti IIa Activity Ratio	3.4	3.3 to 5.3
Total Viable Count (Aerobic)	< 1	<= 100 cfu/g
Moulds and Yeasts	< 1	<= 10 cfu/g
Specified Micro-organisms: Salmonella species	Absent	Absent
Specified Micro-organisms: Staphylococcus Aureus	Absent	Absent
Specified Micro-organisms: Pseudomonas Aeruginosa	Absent	Absent
Specified Micro-organisms: Escherichia coli	Absent	Absent
Bacterial Endotoxins	< 0.01 EU/IU of Anti-XA activity	<0.01 EU/IU of Anti-XA activity

This batch was tested using analytical method reference A58387/current approved version.
Analytical Standard for Biological Control: Batch No. E00850-WS-01.
This batch has been manufactured in compliance with the current Good Manufacturing Practice requirements and complies with the specification of the relevant marketing authorization.

The certificate of analysis has been produced by a validated Laboratory Information Management System and signed electronically the December 16, 2020 at 19:28:44 UTC+8 by Ameliah Basir Snr QA Executive

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