



Certificate of Analysis

PFIZER MANUFACTURING BELGIUM NV
RIJKSWEIG 12
B-2870 PUURS (BELGIUM)
TEL: +32 (0)3 890.92.11
FAX: +32 (0)3 889.65.32

Page 1 of 2

Puurs Batch Number: EF8571

Date Generated: 10-2020

Product Name: FRAGMIN SS 2500IU 10X0.2ML SYRINGE

(DALTEPARIN SODIUM)

Material Number: F000036952

Date of Manufacture: 07-2020

Expiration Date: 06-2023

Specification Name: P5340001002EU

TEST	RESULT	UNIT	LIMITS
ABSORBANCE AT 405 NM	0.01	AU	NMT 0.20
ANTI-FACTOR IIA ACTIVITY	5300	IU/ML	3850 TO 5950 IU/ML
ANTI-FACTOR XA ACTIVITY	12300	IU/ML	11250 TO 13750 IU/ML
CLARITY	MEETS TEST		NOT MORE OPALESCENT THAN REFERENCE SUSPENSION I
DESCRIPTION	MEETS TEST		A CLEAR, COLORLESS OR STRAW COLORED SOLUTION
EJECTABLE AMOUNT, IU (ANTI-FACTOR XA) / SINGLE DOSE SYRINGE	2706	IU/CONT	2000 TO 3000 IU (ANTI-FACTOR XA) PER SINGLE DOSE SYRINGE
ENDOTOXINS	MEETS TEST		NMT 2.5 EU/1000IU
EXTRACTABLE VOLUME	0.22	ML/CONT	0.20 TO 0.23 ML/SYRINGE
HEPARIN FRAGMENT MATERIAL LOWER THAN 3000 (IN %)	9.1	%	5.0 TO 13.0 %
HEPARIN FRAGMENT MATERIAL HIGHER THAN 8000 (IN %)	20.8	%	15.0 TO 25.0 %
MOLECULAR WEIGHT : NUMBER AVERAGE	4971		4500 TO 5300
MOLECULAR WEIGHT: WEIGHT AVERAGE	6151		5600 TO 6400
PARTICULATES NLT 10 MCM	10	PART/CONT	NMT 6000 PARTICLES/CONTAINER
PARTICULATES NLT 25 MCM	0	PART/CONT	NMT 600 PARTICLES/CONTAINER
PH	6.5		5.0 TO 7.5
QUOTIENT ANTI-FACTOR XA/ ANTI-FACTOR IIA	2.3		1.9 TO 3.2
STERILITY	MEETS TEST		STERILE: MEETS TEST
VISUAL INSPECTION	MEETS TEST		CLEAR AND PRACTICALLY FREE FROM PARTICLES

BATCH: EA4691



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I HEREBY CERTIFY THAT THE ABOVE INFORMATION IS AUTHENTIC AND ACCURATE.
THIS BATCH OF PRODUCT HAS BEEN FABRICATED/MANUFACTURED, INCLUDING PACKAGING AND QUALITY
CONTROL IN FULL COMPLIANCE WITH THE GMP REQUIREMENTS OF THE LOCAL REGULATORY AUTHORITY
AND WITH THE SPECIFICATIONS IN THE MARKETING AUTHORISATION OF THE IMPORTING COUNTRY:

CHILE - CL

THE BATCH PROCESSING/PACKAGING AND ANALYSIS WERE
REVIEWED AND FOUND TO BE IN COMPLIANCE WITH GMP.

BATCH NUMBER API: DN0153 / DN0154

ALL ACTIVITIES ARE PERFORMED BY QUALIFIED PEOPLE, UNDER THE SUPERVISION OF THE QUALIFIED PERSON.

Electronic Signature: JEROEN DYCK Lot Release Local Timestamp: 23-OCT-2020 12:42:37 Server Timestamp:
23-OCT-2020 12:42:30