Master Product Code: 811243-01
Master Release Date: July 7th, 2016

CERTIFICATE OF ANALYSIS

Product	: **DRIED SODIUM HYALURONATE FERMENTED SOURCE, Injectable Grade - HYAL**
FIDIA batch number	: A19270
FIDIA code number	: 811243
Manufacturing date	: September, 2017
Assay date	: October, 2019.
Expiry date	: September, 2020
Analysis record number	: 040000001834 – 16000000034 - 040000008031

TESTS	SPECIFICATIONS	RESULTS
CHARACTERS	White or almost white, very hygroscopic odorless powder or fibrous aggregates	**complies**
IDENTIFICATION: *(Ph. Eur.)* - IR spectrum - Reaction of Sodium	 Conforms to Sodium Hyaluronate RS Gives reaction (a) of Sodium	 **complies** **complies**
pH (0.5% w/v) *(Ph. Eur.)*	5.0 – 8.5	**6.6**
LOSS ON DRYING (105°C, 6 h) *(Ph. Eur.)*	≤ 10.0%	**3.0**
APPEARANCE OF SOLUTION *(Ph. Eur.)* $A^{0.33\%}_{1cm}$ at 600 nm	The solution is clear ≤ 0.01 AU	**0.00**
INTRINSIC VISCOSITY *(Ph. Eur.)*	18 – 24 dl/g	**19**
ASSAY *(Ph. Eur.)*	95.0 – 105.0% on dried basis	**100.0**
PROTEINS (Lowry method) *(Ph. Eur.)*	≤ 0.1% as albumin	**0.0**
NUCLEIC ACIDS *(Ph. Eur.)* specific absorbance $A^{0.33\%}_{1\ cm}$ at 260 nm	 ≤ 0.5 AU	**0.0**
SULPHATED ASH *(Ph. Eur.)*	15.0 – 19.0 %	**17.2**
CHLORIDES (Titration method) *(in-house)*	≤ 0.5%	**0.0**
CALCIUM (ICP) *(in-house method)*	≤ 50 ppm	**2**
IRON (ICP) *(in-house method)*	≤ 80 ppm	**8**
HEAVY METALS *(USP – Method II)*	≤ 10 ppm	**complies**
RESIDUAL SOLVENTS (GC) *(in-house method)*: – Ethanol – Acetone – Isopropanol	 ≤ 2000 ppm ≤ 500 ppm ≤ 500 ppm	 **68** **56** **0**
BACTERIAL ENDOTOXINS *(Ph. Eur.)*	< 0.05 EU/mg	**complies**
MICROBIOLOGICAL LIMITS *(Ph. Eur.)*: – Total aerobic microbial count – Total combined moulds and yeast count – Common pathogens	 ≤ 10^2 cfu/g ≤10^1 cfu/g Absent/1 g	 **1** **1** **absent/1 g**

NOTE The product should be stored in an airtight container, protected from light and moisture at 5°C ± 3°C

☒ **CONFORM** ☐ **NOT CONFORM**

Dr. Luca Pirrone
FIDIA Farmaceutici S.p.A.
Head, Quality Control Department

Date November 13, 2019

REGENYAL / P.O. 307

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