

TEST REPORT N. 20133/21

Ascoli Piceno 07/09/2021

Company: REGENYAL Laboratories S.r.l.
Via Valtellina 19/21/23 63074 San Benedetto del Tronto (AP)

Receive date: 24/08/21 **Test initial date:** 24/08/21 **Test final date:** 07/09/21
Category product: MEDICAL DEVICES
Product declared: Various
Sample description: **HYALURONIC ACID LOT SI0821071A3 1ML**
(Test carried out on two samples of sterile finished product)
Sampling modality: Samples sent by express courier **Opening date of sample:** 24/08/21
Date of sampling: 24/08/21

Test and Analytical Method	U M	Value	Limit	Annotation	Notes
Sterility EU PHARMA 04/2011: 20601 corrected 7.7		Sterile			

The Analyst
Dr. Giosia Laura

The Responsible
Dott. Bruno Bucciarelli



This report relates only to the sample subjected to testing and it cannot be partially reproduced, unless prior written approval by this Laboratory. The laboratory assumes responsibility for all information presented in the report, except when it is provided by the client and except when the information provided by the client can influence the test results.

In the test report, the data relating to the description of the sample are provided by the customer.

In the event that the laboratory is not responsible for the sampling phase, the results refer to the sample as received.

The uncertainty of measurement is calculated in a 95% confidence interval and with a coverage factor of $k = 2$. For microbiological tests the uncertainty is calculated by means of the standard deviation of intralaboratory reproducibility multiplied by $K = 2$ which corresponds to a confidence level of 95%.

Recovery between 70% -120%. Incorrect result for the recovery value

The decision-making rule for issuing conformity judgments does not envisage taking into account the contribution of measurement uncertainty to the result. The laboratory issues conformity assessments on the basis of the legal limits in force and / or on the basis of the limits agreed with the customer on the self-control manual.

Test records are kept for ten years.

Note: (+) Above the Limit (-) Below the Limit LDR = Detection limit NR = Not Detectable (<detection limit LOD) UM = Unit of Measurement
END OF TEST REPORT