

# NEOSILK

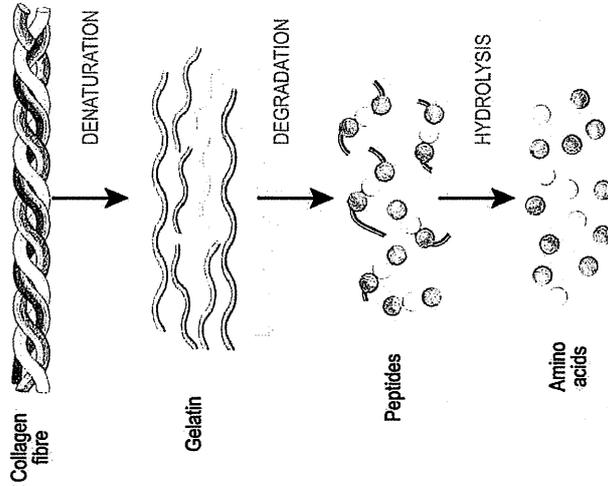
Essential for Beauty & Health.

## R-polypeptide $\alpha 1$ chain

Mechanisms of action in comparison



## Collagen



In the case of the triple helix, the process involves the denaturation of the fibers up to the formation of the amino acids essential for regeneration; Neosilk® directly stimulates new growth of collagen, simplifying and accelerating the regenerative process

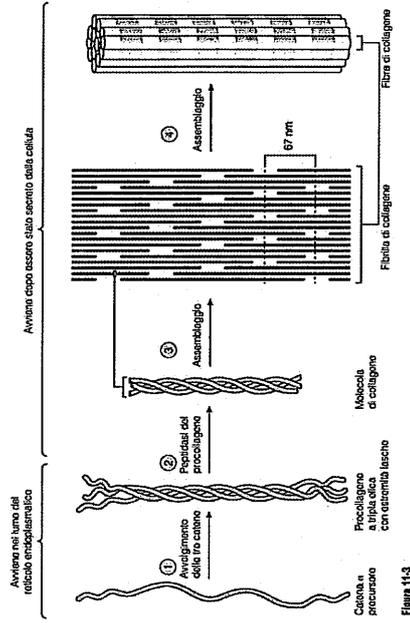


Figura 11-3





ANALYTICAL PROCEDURE N° QC017

Rev. 0 of 20/12/2020

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Product code:

ANALYTICAL CONTROL OF THE MEDICAL DEVICE

INTRA-ARTICULAR GEL WITH COLLAGEN

**NEOIAL**

### CONTROLS ON THE FINISHED PRODUCT

| CONTROLS                                  | SPECIFICATION  |
|---|--|
| Appearance of the gel                     | Clear light yellow gel to yellow,<br>without foreign particles |
| pH  | 6.5 - 7.5  |
| Extractable volume 2 mL                   | 2,00 – 2,30 ml   |
| Extractable volume 4 mL                   | 4,00 – 4,30 ml   |
| Osmolality                                | 270 – 420 mOsm/Kg  |
| Rotational Viscosity )<br>Internal method | 3000 cP - 15000 cP   |
| Sterility                                 | Sterile  |
| Bacterial endotoxins                      | ≤ 5 EU/ml  |
| Control on final packaging                | In compliance  |

- **APPEARANCE AND COLOUR OF GEL:**

This control is operated on all syringes of the batch on a light plan with the aid of a magnifier, both on white background and on black background. The gel must be clear and with pale yellow colour to yellow without foreign particulate matter.

- **pH:**

This control is performed using HANNA pH-meter. Dip the probe in gel and read the value.

RANGE: 6.50 – 7.50.

- **EXTRACTABLE VOLUME:**

Empty as much as possible 20 syringes, collecting separately the extracted the gels in dried and weighed containers. Determinate the weight of the extracted gels, obtaining the gel volume by the formula  $V=W/D$  (where V=volume, W=weight and D=density).

RANGE 2 mL: each volume must be between 2,00 – 2,30 mL

RANGE 4 mL: each volume must be between 4,00 – 4,30 mL

- **OSMOLALITY:**

Osmolality test is performed with the osmometer “Astori” in compliance with Ph.Eur.

RANGE: 270 -420 mOsm/Kg.

- **VISCOSITY:**

Using adapter for small sample for rotational viscosimeter, put 8-9 mL of gel. Using the correct spindle test the viscosity.

T: 20 °C

Spindle: S34

RPM: 1

RANGE: 3000 cP- 15000 cP

- **STERILITY:**

The control of sterility is performed on the finished product in conformity with the European Pharmacopoeia.

Specifications: The product must be sterile.

- **BACTERIAL ENDOTOXINS:**

The assay for endotoxin is performed on the finished product in conformity with the European Pharmacopoeia

Specifications: < 5 EU/ml.

- **CONTROL ON FINAL PACKAGING:**

Packaging controls include:

- *Folding box*
- *Leaflet*
- *Envelope bag containing: Vials syringe and Labels*
- *Final packaging (carton box)*

Sampling:

The sampling is performed by the packaging department. During packaging is taken a complete package every 30 minutes.

*Folding box*

Appearance: the folding box should have no tearing and must be clean.

Closing: the closing flaps must be well-fitted and the operation of opening shall be smooth without causing tearing.

Words: the product name on the box must match the content and the name on the leaflet.

Stamping: the lot number and expiration date must match those on the batch record. All these should be marked with clear characters, aligned and centered.

*Leaflet*

The leaflet must be present in every case. Check that it is of the expected type.

*Vial-syringes*

Check that the package contains 1 vial-syringe, inserted in the blister. The vials must be well labeled bearing the name of the product, lot number and expiration date. The bag must have not tearing and must be clean and well closed.

*Labels*

The bag also contains 2 two self-adhesive labels with lot number, expiry date and name of the product.

*Carton box*

The carton boxes placed on the pallets must contain the expected number of packages and be properly labeled.

