PRODUCT DATA SHEET

VISCOLMA® COLLAGEN SUSPENSION MEDICAL GRADE

Product Description

Viscolma® Collagen Suspension medical grade is a concentrated suspension of bovine collagen type I fibers diluted in HCI. The insoluble collagen fibers retain their highly native structure and exhibit excellent biocompatibility and biodegradability.

The fibrillar collagen suspension with its putty-like consistency contains up to 15% collagen in water. It is produced from bovine skin from New Zealand in a highly standardized industrial process.

Viscolma® is delivered frozen and non-sterile as 15 kg or 1 kg packaging unit.



Viscolma® fibrillary collagen suspension

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PRODUCT SPECIFICATIONS

Parameter	Viscolma® Collagen Suspension (medical grade)
Source	bovine dermis from New Zealand, age ≤ 30 months
Appearance	white collagen viscous suspension
Form	acid suspension
Collagen type I concentration*	10 – 15%
На	2.2 - 3.0

^{*}Please note: Dry substance content correlates to collagen concentration. Pure collagen represents more than 90% of the dry substance of Viscolma® collagen suspension. Dry substance content of a specific lot is provided in the Certificate of Analysis supplied with the purchase of each product.

APPLICATONS

The native fiber structure represents a natural 3D-scaffold for cells, promoting attachment, growth and differentiation which is ideal for the development of medical devices in tissue engineering.

Viscolma® medical grade can be used for individual research applications such as the development of 3D-scaffolds, as a material for coating of implantable medical devices or as raw material for collagen sponges or bioinks.

BENEFITS

- Ultrapure collagen suspension in medical quality for universal use
- Unique nativity and intactness of collagen fibers and small fiber bundles for optimal biocompatibility
- High concentration and homogeneity for flexible use
- Broad range of applications, e.g., coating of medical devices, development of 2D- & 3D-scaffolds
- Master File Application at the FDA (application number MAF #3471)



INTENDED USE

Viscolma® Collagen Suspension medical grade is not a medical device. The collagen suspension is an in-process product developed and manufactured according to DIN EN ISO 13485:2016. It can be used as biomaterial for research activities and manufacturing or for covering of implants. It is not intended for direct clinical use and, if used for manufacturing or covering of implants, it remains in the responsibility of the said manufacturer to ensure compliance with country-specific regulations.

QUALITY & SAFETY

The raw material used for Viscolma® medical grade is obtained solely from veterinary-controlled herds in countries classified for negligible BSE risk. Viscolma® is manufactured in accordance with the principles of Good Manufacturing Practice and within a DIN EN ISO 13485 certified quality management system.

STORAGE

Viscolma® should be stored at -19 ± 4°C for long-term storage and has a shelf life of 36 months when stored as indicated. For short-term storage (up to 7 days) the collagen suspension should be stored between +2°C and +8°C in closed packaging. Do not freeze Viscolma® Collagen Suspension once thawed.

HANDLING & PROCESSING

Viscolma® Collagen Suspension is delivered at an acidic pH. It should be handled wearing protective equipment such as gloves to avoid direct contact of the collagen mass with the skin. Viscolma® can be diluted in aqueous solutions with a pH between pH 2.2 – 3.2 at temperatures between +4°C and +25°C.

CONTACT

For technical or sales support, please contact us:

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Technical support

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Corresponding documents

 Product Flyer Viscolma®

For lot-specific information regarding product quality please refer to:

 Certificate of Analysis
 Viscolma® Collagen
 Suspension medical
 grade

Disclaimer

All data and recommenddations correspond to the present state of our knowledge; they are published without engagement. We reserve the right to make alterations and additions in line with technical developments without prior notice.

The customer is obliged to check whether our products meet the technical requirements.

Please contact us for questions or support.

