

Certificate of Analysis

Consignee:	DOMES PHARMA SC F-63370 Lempdes - France Rue des Bardines	Your Contact:	Quality Phone: ++ 49 30 33 0 93-0 Fax: ++ 49 30 33 0 93-201	BUECKEM
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Product: Viskyal eye.drops [10ml]
Batch number: 321

Product No.: 0981B2FR
Date of manufacture: 06.10.2021
Release date: 20.12.2021
Expiry date: 09.2023

Test Parameters	Specifications	Results of Testing
Colour (Ph. Eur. current Ed., 2.2.2.)	not more intensely coloured than reference solution Y6	Y6
Visible particles (Ph. Eur. current Ed., 2.9.20.)	practically free from visible particles	complies
Opalescence (Ph. Eur. current Ed., 2.2.1.)	not more opalescent than reference suspension II	complies
pH-Value (Ph. Eur. current Ed., 2.2.3.)	7.1 - 7.6	7.3
Osmolality (Ph. Eur. current Ed., 2.2.35.)	250 - 300 mosmol/kg	281 mosmol/kg
Viscosity (Ph. Eur. current Ed., 2.2.8.)	>= 2 mPa s	7 mPa s
Identity Hyaluronic acid sodium salt (HPLC)	positive	complies
Assay Hyaluronic acid sodium salt (HPLC)	1.35 - 1.65 mg/ml (90 - 110 %)	1.58 mg/ml
Antimicrobial effectiveness testing (DIN EN ISO 14730)	must comply	complies
Sterility (Ph. Eur. current Ed., 2.6.1.)	sterile	complies

Analysis date: 26.11.2021
Place of analysis: Dr. Gerhard Mann Chem.-pharm. Fabrik GmbH
Brunsbütteler Damm 165 / 173
13581 Berlin
Germany

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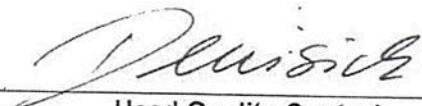
Amtsgericht
Charlottenburg
HRB 25425
St.-Nr. 37/004/49749
USt-IdNr. DE136572946

Citigroup Global Markets Deutschland AG
BLZ 50210900
Kto.-Nr. 214113007
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The product was tested according to the current procedure and complies with the specifications.
The batch was released.

20.12.2021

Date


Head Quality Control

***** End of Certificate of Analysis *****

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