

Certificate of Analysis

Consignee:	DOMES PHARMA SC F-63370 Lempdes - France Rue des Bardines	Your Contact:	SYSUSER
		Phone:	Quality ++ 49 30 33 0 93-0
		Fax:	++ 49 30 33 0 93-201

Product: Viskyal eye drops [10ml]
Batch number: 382

Product No.: 0981B2FR
 Date of manufacture: 29.12.2022
 Release date: 14.02.2023
 Expiry date: 11.2024

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
Sub-visible particles $\geq 10 \mu\text{m}$ (Ph. Eur. current Ed., 2.9.53., method 1)	≤ 1000	6
Sub-visible particles $\geq 25 \mu\text{m}$ (Ph. Eur. current Ed., 2.9.53., method 1)	≤ 100	0
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	278 mosmol/kg
Viscosity (Ph. Eur. current Ed., 2.2.8.)	$\geq 2 \text{ mPa s}$	6 mPa s
Identity Hyaluronic acid sodium salt (HPLC)	positive	complies
Assay Hyaluronic acid sodium salt (HPLC)	1.35 - 1.65 mg/ml (90 - 110 %)	1.59 mg/ml
Antimicrobial effectiveness testing (DIN EN ISO 14730)	must comply	complies
Sterility (Ph. Eur. current Ed., 2.6.1.)	sterile	complies

Analysis date: 13.02.2023

No.: 23000319

Dr. Gerhard Mann
 chem.-pharm. Fabrik GmbH
 Drunbüttelei Damm 165/173
 13581 Berlin

T +49 (0)30 33093-0
 F +49 (0)30 33093-201
 e-mail: dmp@bausch.com
 www.bausch.com

Geschäftsführer
 Eberhard Kühne
 Manoj Kumar Panda

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

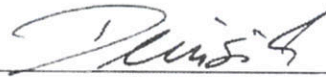
Citigroup Global Markets Deutschland AG
 BLZ 50210900
 Kto.-Nr. 214113007
 SWIFT CITIEFF
 IBAN DE 54 50210900 0214 1130 07

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

The product was tested according to the current procedure and complies with the specifications.
The batch was released.

14.02.2023

Date



Head Quality Control

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