

FAGRON a.s.

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CERTIFICATE OF ANALYSIS

Product name:

MAŚĆ CHOLESTEROLOWA

Inspection No:

108964/1021/536

Batch No:

088670

Batch size: 805 x 500 g

Expiry date:

31.10.2023

Analysed according to:

FP XI, FAPL 022 v. 1

Tests	Requirements:	Results:
Appearance and properties	White, translucent, homogenous, soft mass	conform
Solubility	Practically insoluble in water, soluble in	conform
	chloroform and ethyl ether, very slightly soluble	
	in ethanol (96 %)	
Identification	complies with FP	conform
Appearance after melting	Transparent and colourless liquid	conform
Water-absorption capacity	Complies with FP	39 g water / 10 g Cholesteroli Ung.
Microbiology (2.6.12)		
TAMC	_ ≤ 10 ³ [CFU/g]	< 10 CFU/g
TYMC	$\leq 10^2 [CFU/g]$	< 10 CFU/g

The product conforms to FP XI, specification FAPL 022 v. 1

Conclusion: I certify that the above-mentioned batch of pharmaceutical raw material has been manufactured and tested in accordance with the requirements of Marketing Authorization (License) and requirements of Good Manufacturing Practice.

Approved by:

MVDr. Zdenka Borská, QP

Date and signature:

29 11. 2021 Bef