

## CERTIFICATE OF ANALYSIS

**Product name:** WAZELINA ŻÓŁTA

**Inspection No:** H07906/0920/536      **Customer:** Fagron PL

**Batch No:** 081076      **Batch size:** 3 000 x 100 g

**Expiry date:** 28.02.2023

**Analyzed according to:** Ph. Eur. 07/2008:1554, corr. 6.8

Tests	Requirements:	Results:
Appearance	Yellow, translucent, unctuous mass, slightly fluorescent in daylight when melted.	conform
Solubility	Practically insoluble in water, slightly soluble in methylene chloride, practically insoluble in ethanol 96% and in glycerol.	conform
Identification		
Identification A	40 – 60 [ °C]	57 °C
Identification B	complies with Ph. Eur.	conform
Identification D	complies with Ph. Eur.	conform
Tests		
Appearance	complies with Ph. Eur.	conform
Acidity or alkalinity	complies with Ph. Eur.	conform
Consistency	100 – 300	114
Polycyclic aromatic hydrocarbons	complies with Ph. Eur.	conform
Sulfated ash	≤ 0,05 [%]	0,00 %
Microbiology	complies with Ph. Eur.	conform
TAMC	≤ 10 <sup>3</sup> [CFU/g]	conform
TYMC	≤ 10 <sup>2</sup> [CFU/g]	conform

The product conforms to Ph. Eur. 07/2008:1554, corr. 6.8

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: Ivana Urbánková, QP

Date and signature:

7.9.2020 