FAGRON a.s.
Inspectional laboratory no. 536
Holická 1098/31m, 779 00 Olomouc
tel. 585222590, fax 585226521
email: orj@fagron.cz

CERTIFICATE OF ANALYSIS

Product name: **LANOLINA**

Inspection No: **H07901/0920/536** **Customer:** **Fagron PL**

Batch No: **081079** **Batch size:** **100 x 500 g**

Expiry date: **31.03.2022**

Analysed according to: **Ph. Eur. 04/2012:0134**

Tests	Requirements:	Results:
Appearance	Yellow, unctuous substance. When melted, it is a clear or almost clear, yellow liquid. A solution in light petroleum in opalescent.	conform
Solubility	Practically insoluble in water, slightly soluble in boiling anhydrous ethanol.	conform
Odour	Characteristic odour.	conform
Identification		
Identification A	green	conform
Identification B	red colour, fluorescence	conform
Tests		
Water-soluble acid or alk. subs.	complies with Ph. Eur.	conform
Water-absorption capacity	≥ 20 [ml]	35 ml
Acid value	≤ 1,0	0,70
Peroxide value	≤ 20	7,4
Saponification value	90 - 105	101
Water-soluble oxidisable subs.	complies with Ph. Eur.	conform
Paraffins	≤1,0 [%]	0,20 %
Pesticides residues	complies with Ph. Eur.	conform
Chlorides	≤150 [ppm]	conform
Loss on drying	≤ 0,5 [%]	0,01 %
Sulfated ash	≤ 0,15 [%]	0,065 %

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Expiry date: **31.03.2022**

Analysed according to: **Ph. Eur. 04/2012:0134**

Tests	Requirements:	Results:
Microbiology	complies with Ph. Eur.	conform
TAMC	≤ 10^3 [CFU/g]	conform
TYMC	≤ 10^2 [CFU/g]	conform
TSE/BSE	No contamination with TSE/BSE-risk materials.	conform
Drop point	38 – 44 [°C]	43 °C

The product conforms to Ph. Eur. 04/2012:0134

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: 1.9.2020 .....