

Messrs. PFC Pharma Manufacturing SL Calle Osona, 2 08820, Prat de Llobregat (EI), Barcelona Cataluña, España

Zola Predosa, 18/05/2020

Ref. Your Order del 2020

Test Report N°20-0508-05

DETERMINATION OF A POPULATION OF MICROORGANISMS ON PRODUCTS

Sample description

Denomination: 3ply-adult
Code: ID2
Lot: FM2003
Sterilization: No
N° of tested samples: 5
Receipt number: 15770
Receipt date: 06/05/2020
Sampling carried out by: PERFECT CARE DISTRIBUTION SRL

The test was started on 12/05/2020 and was completed on 18/05/2020.

Test method

ISO 11737-1:2018

Summary of practice

Samples were aseptically treated. Micro-organisms were extracted from samples using sterile physiological saline containing 0,05 % of Tween 80 in mechanical agitation. The extract was collected and filtered through a 0,45 μ m sterile membrane filter. One half of the filter was incubated on Triptone Soya Agar (TSA) culture medium for 72 hours at 32 ± 2°C in order to evaluate non-selective aerobic bac teria. The other half was incubated on Potato Dextrose Agar (POT) culture medium for 5 days at 22 ± 2°C in order to evaluate yeasts and moulds. Results were multiplied by correction factor (1.27 – 1.31) obtained from the method validation (see test report N°20-0 508-04).

Mod.BiobFiltrazRv20



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VIA BENINI 13- 40069 ZOLA PREDOSA BO - TEL +39-051755295 - FAX +39-051754622 www.biochem-bcm.com E-mail: info@biochem-bcm.com - C.F. e P.IVA IT 03531810376 - R.E.A. BO-297535



Results

| Sample | Non-selective aerobic bacteria (cfu/sample) | Moulds (cfu/sample) | Yeast (cfu/sample) |
|-------------------|---|------------------------|--------------------|
| 1 | 12 | 2 | <2 |
| 2 | 16 | 4 | <2 |
| 3 | 6 | 2 | <2 |
| 4 | 6 | 2 | <2 |
| 5 | 10 | 2 | <2 |
| Mean value | 10.0 | 2.4 | <2.0 |
| Correction factor | 1.27 | 1.31 | 1.31 |
| Corrected value | 12.7 | 3.1 | <2.6 |
| Value per gram | 4.0 | 2 | <2 |

The present test report exclusively refers to the referenced test sample.

If the sample has been sampled by the Customer, the results are referred to the sample as received. The present test report may not be partially reproduced without Biochem authorization.

(#)Data provided by the Customer. The laboratory declines responsibility for such data.

Test verified by: Buriani Giampaolo, Phd.

Issue authorised by: Head of Laboratory Dr. Giovanni Bassini

END OF TEST REPORT

Mod.BiobFiltrazRv20



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