

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

Zola Predosa, 18/05/2020

Ref. Your Order del 2020

Test Report N° 20-0508-04

DETERMINATION OF A POPULATION OF MICROORGANISMS ON PRODUCTS – VALIDATION OF METHOD

Sample description

Denomination: 3ply-adult
Code: ID2
Lot: FM2003
Sterilization: No
N° of tested samples: 5
Receipt number: 15769
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

Sterile samples have been contaminated with a know concentration of Staphylococcus aureus ATCC 6538 and Candida albicans ATCC 10231. Micro-organisms were extracted from samples using sterile physiological saline containing 0,05 % of Tween 80 in mechanical agitation. The extract obtained from each sample was filtrated through a 0,45 µm sterile membrane filter. One half of the filter was incubated on Tryptone Soya Agar (TSA) culture medium for 72 hours at 32°C ± 2°C to evaluate aerobic microorganisms. The other half was incubated on Potato Dextrose Agar (POT) culture medium for 5 days at 22 ± 2°C to evaluate recovered yeasts and moulds . Then was calculated the correction factor for each microorganism.

Results

Staphylococcus aureus ATCC 6538

Sample	Contamination (cfu/sample)	Recovered micro-organism (cfu/sample)	Recovery (%)
1	74	48	64.9
2	74	68	91.9
3	74	64	86.5
4	74	52	70.3
5	74	60	81.1
Mean value		58.4	78.9
Correction factor		1.27	

Candida albicans ATCC 10231

Sample	Contamination (cfu/sample)	Recovered micro-organism (cfu/sample)	Recovery (%)
1	425	362	85.2
2	425	322	75.8
3	425	286	67.3
4	425	370	87.1
5	425	286	67.3
Mean value		325.2	76.5
Correction factor		1.31	

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 authorized by:
Head of Laboratory, Giovanni Bassini, Ch.Eng.

END OF TEST REPORT