



CERTIFICATE OF ANALYSIS

Work Order : MF2011565-AB
Amendment : 1
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Fascimile : ---
Page : 1 of 5
Date Samples Received : 30-Jun-2020 5:00 PM
Date Analysis Commenced : 03-Jul-2020
Issue Date : 13-Jul-2020
No. of Samples Received : 3
No. of Samples Analysed : 3

This Certificate of Analysis contains the following information:

- General Comments
• Workorder Specific Comments
• Analytical Results

Signatories

This laboratory is accredited under STANDARDS MALAYSIA. The tests reported herein have been performed in accordance with laboratory's Terms of Accreditation. This document has been electronically signed by authorized signatories indicated below.

Signatories



Handwritten signature of Nurnadira Binti Abdul Rashid

Nurnadira Binti Abdul Rashid
Microbiologist (MJMM No: 0290)
BSc. (Hons) Microbiology

*Please direct all technical queries to the laboratory (Reports.MF@alsglobal.com)

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• This report shall not be reproduced except in full without the written approval of the laboratory •

General Comments

This report supersedes any previous report(s) with this reference. Results apply to the sample(s) as submitted. All pages of this report have been checked and approved for release.

The analytical procedures used by the Food & Pharmaceutical Division have been developed from established internationally recognized procedures such as those published by the FDA BAM, AOAC, ISO, GB, USP, BP and BS EN. In house developed procedures are employed in the absence of documented standards or by client request.

Where a reported less than (<) result is higher than the LOR, this may be due to primary sample extract/digested dilution and/or insufficient sample for analysis.

Where the LOR of a reported result differs from standard LOR, this may be due to high moisture content, insufficient sample (reduced weight employed) or matrix interference.

Key: LOR = Limit of reporting CFU = Colony Forming Unit MPN = Most Probable Number PN = Probable Number
∅ = ALS is not accredited for these tests

Work Order Specific Comments

- ALS TECHNICHEM prepares this Test Report based on the tests requested and on the specific sample(s) submitted for analysis. The significance of this Report is subject to the adequacy and representative character of the sample(s) and to the comprehensiveness of the tests requested or made. ALS TECHNICHEM assumes no responsibility for variations in quality or other characteristic of the product produced or supplied under conditions over which ALS TECHNICHEM has no control.
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- Result < LOR = Not Detected (ND)
- **This analysis is performed in ALS Shah Alam, Malaysia.**

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Analytical Results

Sample ID: MF2011565-002

A20 - 120 micron PE Film

Microbial Challenge Test									
Method: USP <51>									
Test Organism		Incubation at 35°C							
		Inoculum Count (cfu/ml)	Test	Contact Time: 1 hour			Contact Time: 4 hours		
				Result (cfu/film)	Percentage of Microorganism Reduced (%)	Log Reduction	Result (cfu/film)	Percentage of Microorganism Reduced (%)	Log Reduction
<i>Escherichia coli</i> ATCC 8739	Viable Count (cfu)	8.2 x 10 ⁵	1	2.3 x 10 ⁵	71.95		1.4 x 10 ⁵	82.93	
	Log ₁₀	5.91		5.36		0.55	5.15		0.76
	Viable Count (cfu)	8.2 x 10 ⁵	2	2.5 x 10 ⁵	69.51		1.5 x 10 ⁵	81.71	
	Log ₁₀	5.91		5.40		0.51	5.18		0.73
	Viable Count (cfu)	8.2 x 10 ⁵	3	2.1 x 10 ⁵	74.39		1.2 x 10 ⁵	85.37	
	Log ₁₀	5.91		5.32		0.59	5.08		0.83
<i>Staphylococcus aureus</i> ATCC 6538	Viable Count (cfu)	5.0 x 10 ⁵	1	3.4 x 10 ⁵	32.00		5.5 x 10 ⁴	89.00	
	Log ₁₀	5.70		5.53		0.17	4.74		0.96
	Viable Count (cfu)	5.0 x 10 ⁵	2	3.7 x 10 ⁵	26.00		5.7 x 10 ⁴	88.60	
	Log ₁₀	5.70		5.57		0.13	4.76		0.94
	Viable Count (cfu)	5.0 x 10 ⁵	3	3.6 x 10 ⁵	28.00		5.3 x 10 ⁴	89.40	
	Log ₁₀	5.70		5.56		0.14	4.72		0.98
<i>Pseudomonas aeruginosa</i> ATCC 9027	Viable Count (cfu)	5.9 x 10 ⁵	1	3.6 x 10 ⁵	38.98		1.3 x 10 ⁵	77.97	
	Log ₁₀	5.77		5.56		0.21	5.11		0.66
	Viable Count (cfu)	5.9 x 10 ⁵	2	3.2 x 10 ⁵	45.76		1.1 x 10 ⁵	81.36	
	Log ₁₀	5.77		5.51		0.26	5.04		0.73
	Viable Count (cfu)	5.9 x 10 ⁵	3	3.3 x 10 ⁵	44.07		1.0 x 10 ⁵	83.05	
	Log ₁₀	5.77		5.52		0.25	5.00		0.77

Remark:

- 1) Film size – 10cm x 10cm
 - 2) Initial Bacteria Count – Concentration of bacteria spiked onto 10cm x 10cm of the film
 - 3) Contact Time – The duration from the time the bacteria was spiked onto the film until it was recovered back by swabbing.
 - 4) Uninoculated film sample wiped using 70% IPA before spiking showed no growth after incubation.
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