



Micro Quality Labs

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Westwood Laboratories
Attn: Monica Schick.
710 South Ayon Ave
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Report Date: 04/15/15
Date Received: 03/09/15
Date Completed: 03/27/15
P.O. #: N/A
Reference #: 8276

SAMPLE DESCRIPTION:

ACCESSION

ML Project #8276

SAMPLE

Curx Ointment

Product Code/ Batch & Date

Formula#GM05 15A23A
(Initial)

TEST PERFORMED:

United States Pharmacopeia

ML METHOD

TM-03

METHOD REFERENCE#

USP 37-2014 Antimicrobial
Effectiveness Testing <51>

Procedure Summary:

1. 5 different organism were inoculated having an inoculums level of 1×10^6 colony forming units (CFU) per gram for bacteria and 1×10^5 (CFU) per gram for yeast & mold.
2. The inoculated test samples were stored at 20-25°C for 28days.
3. The population of each challenge microorganism was determined by plate count method at Day 2, 7, 14, 21, and 28.
4. The plate counts were performed at a 1:10 initial dilution using Modified Lethen Broth the diluents and Tryptic Soy and Sabouraud Dextrose agar, as determined by the plate count validation for this product.

Initial results:

Accession#: 8276

<i>Initial Aerobic Plate Count</i>	<i>Initial Yeast-Mold Count</i>
CFU/g	CFU/g
<10	<10



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RESULTS:

TABLE SUMMARY

Organism	Inoculum / g	Preservative Testing Colony Forming Units / gram				
		Day 2	Day 7	Day 14	Day 21	Day 28
<i>Staphylococcus aureus</i> (bacteria) (ATCC# 6538)	1.00 x10 ⁶	<10	<10	<10	<10	<10
<i>Pseudomonas aeruginosa</i> (bacteria) (ATCC# 9027)	1.00 x10 ⁶	<10	<10	<10	<10	<10
<i>Escherichia coli</i> (bacteria) (ATCC# 8739)	1.00 x10 ⁶	<10	<10	<10	<10	<10
<i>Candida albicans</i> (yeast) (ATCC# 10231)	1.00 x10 ⁵	<10	<10	<10	<10	<10
<i>Asperigillus niger</i> (mold) (ATCC# 16404)	1.00 x10 ⁵	<10	<10	<10	<10	<10

LOG REDUCTION CALCULATION FROM INITIAL INOCULUM

	<u>14 DAYS</u>	<u>28 DAYS</u>
<i>Asperigillus niger</i>	<u>4.00</u>	<u>4.00</u>
<i>Candida albicans</i>	<u>4.00</u>	<u>4.00</u>
<i>Pseudomonas aeruginosa</i>	<u>5.00</u>	<u>5.00</u>
<i>Escherichia coli</i>	<u>5.00</u>	<u>5.00</u>
<i>Staphylococcus aureus</i>	<u>5.00</u>	<u>5.00</u>



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SAMPLE DESCRIPTION:

<u>ACCESSION #</u> MQL Project #8276	<u>SAMPLE</u> Curx Ointment	<u>Product Code/ Batch & Date</u> Formula#GM05 15A23A (Initial)
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<u>TEST PERFORMED:</u> United States Pharmacopeia	<u>MQL METHOD #</u> TM-03	<u>METHOD REFERENCE#</u> USP 37-2014 Antimicrobial Effectiveness Testing <51>
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PLATING MEDIA:
 Microbial Content Test Agar (Bacteria)
 Sabouraud Dextrose Agar (Yeast and Mold)

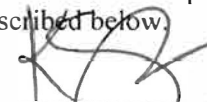
RESULTS:


Preservative Testing Validation					
Organism	Inoculum	Dilution	Microbial Recovery	Diluent	Percent Recovery
<i>Staphylococcus aureus</i>	76cfu/plate	1:10	69cfu/plate	LB	<u>87%</u>
<i>Pseudomonas aeruginosa</i>	83cfu/plate	1:10	81cfu/plate	LB	<u>97%</u>
<i>Escherichia coli</i>	68cfu/plate	1:10	58cfu/plate	LB	<u>85%</u>
<i>Candida albicans</i>	63cfu/plate	1:10	50cfu/plate	LB	<u>79%</u>
<i>Asperigillus niger</i>	60cfu/plate	1:10	60cfu/plate	LB	<u>100%</u>

CFU = colony forming units LB = Lethen Broth
 Diluent: Lethen broth Dilution: 1:10

CONCLUSION:

The antimicrobial preservative properties present in the sample can be neutralized under the test conditions described below.


 Approved: Karine Aylozyan Date: APR 15 2015
 Senior Microbiologist/Q.A. Coordinator


 Chineche DeLaRosa Date: APR 15 2015
 Microbiologist



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- THE EUROPEAN MARKET ACCEPTANCE CRITERIA

Topical Preparations A2

Log 10 Reduction		2d	7d	14d	28d
<i>Bacteria</i>	A	2	3	-	NI
	B	-	-	3	NI
<i>Yeast/Mold</i>	A	-	-	2	NI
	B	-	-	1	NI

NI = No Increase NR = No Recovery log1 = 90% log 2 = 95% log 3 = 99.9%

Category 2 – Topical preparations (made with aqueous base, on-sterile nasal products, emulsions, including those applied to mucous membrane).

The A criteria express the recommended efficacy to be achieved. In justified cases where the A criteria cannot be attained, for example for reasons of an increased risk of adverse reactions, the B criteria must be satisfied (EP-4th edition).

- THE UNITED STATES PHARMACOPEIA ACCEPTANCE CRITERIA

Topical Preparations A2

Log 10 Reduction		7d	14d	21d	28d
<i>Bacteria</i>	-	-	2	-	NI
<i>Yeast/Mold</i>	-	-	NI	-	NI

NI = No Increase NR = No Recovery log1=90% log2=95% log3=99.9%

The A-2 criteria express the recommended efficacy to be achieved. (USP-27/CTFA)

- THE J.P. MARKET ACCEPTANCE CRITERIA

CATEGORY 1B
Topically used products.
Products with aqueous base

Log 10 Reduction		6 h	24 h	7 d	14d	28d
<i>Bacteria</i>	A	N/A	N/A	N/A	.1% of inoculum or less	Same or less than level after 14 days
<i>Yeast/Mold</i>	B	N/A	N/A	N/A	Same or less than inoculum count	Same or less than inoculum count

NI = No Increase NR = No Recovery log1 = 90% log 2 = 95% log 3 = 99.9%




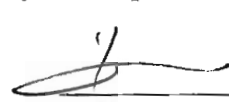
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Cosmetic Preservative efficacy. The above guidelines for interpretation of results apply to cosmetic product before the time of use. Cosmetics contain antimicrobial preservatives and thus are expected to withstand a certain amount of abuse by users. Formerly, there were no validated tests for cosmetic preservative efficacy (3), although the test for pharmaceutical preservative efficacy in the U.S. Pharmacopoeia (2) or the cosmetic test in the technical guidelines of Cosmetic, Toiletry and Fragrance Association (CTFA)(1) were used. Recently, the CTFA test has been AOAC validated for use with liquid cosmetics. A test for solid cosmetic preservative efficacy has been proposed.(6). Cosmetics is reusable test kits such as those in retail stores, can be microbiologically evaluated semiquantitatively by a sterile swab test (5)

Preservative Challenge Results:

Based on the results, the preservative is effective in exerting its antimicrobial effectiveness. The preservative is effective in maintaining the sterility of the product.

 APR 15 2015
Approved: Karine Aylozyan Date:
Senior Microbiologist/Q.A. Coordinator

 APR 15 2015
Chineche DeLaRosa Date:
Microbiologist

***References**

- 1) Anonymous.1985. Preservation testing of aqueous liquid and semi-liquid eye cosmetics. In: CTFA Technical Guidelines. The Cosmetic, Toiletry and Fragrance Association,Inc.,
- 2) Anonymous. 1990. Antimicrobial preservatives-effectiveness. In: United States Pharmacopeia, 22nd Revision,p.1478. U.S. Pharmacopeial Convention, Rockville, MD.
- 3)Hitchins,A.D.1993 Cosmetic Preservation and safety:FDA Status.J.Assoc. Food Drug Official 57:42-49
- 4) Dunningan,A.P. 1968 Microbiological control of Cosmetics.Drug Cosmet. Ind.102:43-45,152-158
- 5)Tran,T.T.,A.D. Hitchins, and S.W. Collier.1990.Direct contact membrane method for evaluating preservative efficacy in solid cosmetics. Int.J. Cosmet.Sc. 12:175-183
- 6) Tran,T.T., A.D Hitchins.1194. Microbiological survey of shared-use cosmetic test kits available to the public, J. Ind. Microbial.13:389-391