Micro Quality Labs

3200 N. San Fernando Blvd., Burbank, California 91504
(818) 845-0070 • Fax: (818) 845-0030

E-Mail: MicroQualityLabs@sbcglobal.net

Westwood Laboratories
Attn: Monica Schick.
710 South Ayon Ave
Azusa, CA 91702

Report Date: 09/26/16
Date Received: 03/09/15
Date Completed: 03/27/15
P.O. #: N/A
Reference #: 8276 – Revision 1

SAMPLE DESCRIPTION:

ACCESSION #	SAMPLE	Product Code/ Batch & Date
MQL Project #8276	Curex Ointment	Formula#GM05 15A23A (Intial)

TEST PERFORMED:	MQL METHOD #	METHOD REFERENCE#
United States Pharmacopeia	TM-03	USP 37-2014 Antimicrobial Effectiveness Testing <51>

Procedure Summary:

1. 5 different organism were inoculated having an inoculums level of 1x 10^6 colony forming units (CFU) per gram for bacteria and 1x 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 Letheen Broth the diluents and Tryptic Soy and Sabouraud Dextrose agar, as determined by the plate count validation for this product.

Initial results:

Accession#: 8276

Initial Aerobic Plate Count CFU/g	*Initial Yeast –Mold Count* CFU/g
<10	<10

Micro Quality Labs

3200 N. San Fernando Blvd., Burbank, California 91504
(818) 845-0070 • Fax: (818) 845-0030
E-Mail: MicroQualityLabs@sbcglobal.net

Westwood Laboratories
Attn: Monica Schick.
710 South Ayon Ave
Azusa, CA 91702

Report Date: 09/26/16
Date Received: 03/09/15
Date Completed: 03/27/15
P.O. #: N/A
Reference #: 8276 – Revision 1

SAMPLE DESCRIPTION:

ACCESSION #	SAMPLE	Product Code/ Batch & Date
MQL Project #8276	Curex Ointment	Formula#GM05 15A23A (Intial)

TEST PERFORMED:	MQL METHOD #	METHOD REFERENCE#
United States Pharmacopeia	TM-03	USP 37-2014 Antimicrobial Effectiveness Testing <51>

RESULTS:

TABLE SUMMARY

	Preservative Testing Colony Forming Units / gram					
Organism	Inoculum / g	Day 2	Day 7	Day 14	Day 21	Day 28
Staphylococcus aureus (bacteria) (ATCC# 6538)	***1.26×10^6***	<10	<10	<10	<10	<10
Pseudomonas aeruginosa (bacteria) (ATCC# 9027)	***1.16×10^6***	<10	<10	<10	<10	<10
Escherichia coli (bacteria) (ATCC# 8739)	***1.30×10^6***	<10	<10	<10	<10	<10
Candida albicans (yeast) (ATCC# 10231)	***1.21×10^5***	<10	<10	<10	<10	<10
Asperigillus niger (mold) (ATCC# 16404)	***1.12×10^5***	<10	<10	<10	<10	<10

LOG REDUCTION CALCULATION FROM INITIAL INOCULUM

	14 DAYS	28 DAYS
Asperigillus niger	4.00	4.00
Candida albicans	4.00	4.00
Pseudomonas aeruginosa	5.00	5.00
Escherichia coli	5.00	5.00
Staphylococcus aureus	5.00	5.00

3200 N. San Fernando Blvd., Burbank, California 91504
(818) 845-0070 • Fax: (818) 845-0030
E-Mail: MicroQualityLabs@sbcglobal.net

Westwood Laboratories
Attn: Monica Schick.
710 South Ayon Ave
Azusa, CA 91702

Report Date: 09/26/16
Date Received: 03/09/15
Date Completed: 03/27/15
P.O. #: N/A
Reference #: 8276 – Revision 1

SAMPLE DESCRIPTION:

ACCESSION #	SAMPLE	Product Code/ Batch & Date
MQL Project #8276	Curex Ointment	Formula#GM05 15A23A (Intial)

TEST PERFORMED:	MQL METHOD #	METHOD REFERENCE#
United States Pharmacopeia	TM-03	USP 37-2014 Antimicrobial Effectiveness Testing <51>

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
Staphylococcus aureus	**76cfu/plate**	1:10	**69cfu/plate**	LB	**87%**
Pseudomonas aeruginosa	**83cfu/plate**	1:10	**81cfu/plate**	LB	**97%**
Escherichia coli	**68cfu/plate**	1:10	**58cfu/plate**	LB	**85%**
Candida albicans	**63cfu/plate**	1:10	**50cfu/plate**	LB	**79%**
Asperigillus niger	**60cfu/plate**	1:10	**60cfu/plate**	LB	**100%**

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

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

SEP 2 6 2016

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

SEP 2 6 2016

Michelle Luu Date:
Microbiologist

3200 N. San Fernando Blvd., Burbank, California 91504
(818) 845-0070 • Fax: (818) 845-0030
E-Mail: MicroQualityLabs@sbcglobal.net

- **THE EUROPEAN MARKET ACCEPTANCE CRITERIA**

Topical Preparations A2

Log 10 Reduction		2d	7d	14d	28d
Bacteria	A	2	3	-	NI
	B	-	-	3	NI
Yeast/Mold	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	
Bacteria	-	2	-	NI	
Yeast/Mold	-	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
Bacteria	A	N/A	N/A	N/A	.1% of inoculum or less	Same or less than level after 14 days
Yeast/Mold	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%

3200 N. San Fernando Blvd., Burbank, California 91504
(818) 845-0070 • Fax: (818) 845-0030
E-Mail: MicroQualityLabs@sbcglobal.net

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.

SEP 2 6 2016

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

MLO1
SEP 2 6 2016

Michelle Luu 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