NELSON
LABORATORIES

FINAL REPORT

MEM ELUTION

PROCEDURE NO. STP0032 REV 03
PROTOCOL DETAIL SHEET NO. 200900805 REV 01

LABORATORY NO. 465456

PREPARED FOR:

JODIE ALEXANDER
OERLIKON BALZERS COATING USA, INC.
1181 JANSEN FARM COURT
ELGIN IL 60123

SUBMITTED BY:

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QAU AUDIT STATEMENT

[X] USFDA (21 CFR PART 58) [ ] USEPA (40 CFR PART 160)

MEM ELUTION

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1. The test was conducted in accordance with the USFDA or USEPA Regulations as noted above.

2. In accordance with the Good Laboratory Practice Regulations, the Cell Exposure phase(s) of this study was inspected by the Quality Assurance Unit on: 12 Mar 2009. The findings of the inspection(s) were reported to the Study Director on: 18 Mar 2009 and to Management on: 17 Mar 2009.

3. The Quality Assurance Unit has reviewed this report and has determined that the methods and standard testing procedures are accurately described, and that the reported results accurately reflect the raw data.

4. The name of the study director, the names of other scientists or professionals, and the names of all supervisory personnel, involved in the study:

Michelle Lee
Bobbi Rushton-Castro
Dr. Jerry Nelson
Jeff Hills

QUALITY ASSURANCE: Danielle Short DATE: 20 Mar 2009

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MEM ELUTION

LABORATORY NUMBER:	465456
PROCEDURE NUMBER:	STP0032 REV 03
PROTOCOL DETAIL SHEET NUMBER:	200900805 REV 01
SAMPLE SOURCE:	Oerlikon Balzers Coating USA, Inc.
TYPE OF TEST:	Solid
SAMPLE IDENTIFICATION:	Refer to Table 1 P.O. #PO09--00718
DEVIATIONS:	None
CELL LINE:	Mouse Heteroploid Connective Tissue (L-929)
INCUBATION PERIOD:	72 ± 3 hours at 37 ± 1°C
METHOD OF SCORING:	Cytopathic Effect (0-4)
AMOUNT TESTED/SAMPLE EXTRACT:	226.9 cm^2 / 75.6 mL
PROTOCOL APPROVAL DATE:	10 Mar 2009
SAMPLE RECEIVED DATE:	05 Mar 2009
LAB PHASE START DATE:	10 Mar 2009
LAB PHASE COMPLETION DATE:	18 Mar 2009
REPORT ISSUE DATE:	18 Mar 2009

INTRODUCTION:

The MEM Elution test was designed to determine the cytotoxicity of extractable substances. An extract of the sample was added to cell monolayers and incubated. The cell monolayers were examined and scored based on the degree of cellular destruction.

ACCEPTANCE CRITERIA:

The United States Pharmacopeia & National Formulary states that the sample meets the requirements if the reactivity grade is not greater than grade 2 or a mild reactivity. The AAMI/ISO 10993-5 standard states that the overall assessment of the results shall be made by capable persons based upon the data and results. Nelson Laboratories acceptance criteria was based upon the negative and media controls receiving "0" reactivity grades and positive results receiving a 3-4 reactivity grades (moderate to severe).

PROCEDURE:

The amount of test material extracted was based on ANSI/AAMI/ISO and USP surface area recommendations or weight (0.20 g/mL extract fluid for polymers and plastic). The sample was extracted for 24-25 hours at 37 ± 1°C in 1X Minimal Essential Media with 5% calf serum. Positive (Latex Natural Rubber) and negative (Polypropylene Pellets) controls were extracted and included in the assay. A blank of extraction media (media control) was also included in the assay.

Multiple well cell culture plates were seeded with a verified quantity of L-929 cells and incubated until 80-90% confluent. The cell culture media was removed from the plates. The test extracts were filtered and the appropriate amount of extract was added to each well on the cell culture plates. Each extract was tested on three wells of cells. The cells were incubated at 37 ± 1°C with 5 ± 1% CO_2 for 72 ± 3 hours.

The cell monolayers were examined microscopically. The wells were scored as to the degree of discernable morphological cytotoxicity on a relative scale of 0 to 4:

CONDITIONS OF ALL CULTURES	REACTIVITY	GRADE
No cell lysis, intracytoplasmic granules.	NONE	0
Not more than 20% rounding, occasional lysed cells.	SLIGHT	1
Not more than 50% rounding, no extensive cell lysis.	MILD	2
Not more than 70% rounding and lysed cells.	MODERATE	3
Nearly complete cell destruction.	SEVERE	4

The results from the three wells were averaged to give a final cytotoxicity score.

RESULTS:

The results are summarized in Table 1. The test is acceptable if all three of the negative control and medium control test wells have a score of 0 and all three of the positive control test wells have a score of 3 or higher.

The sample meets USP requirements if none of the cell culture exposed to the sample shows greater than a mild reactivity (grade 2).

CONCLUSION:

Interpretation of the data is the responsibility of the sponsor and no conclusion can be made by Nelson Laboratories, Inc. (NLI).

DATA DISPOSITION:

The raw data and final report from this study are archived at NLI or an approved off-site location.

Oerlikon Balzers Coating USA, Inc.
Lab Number 465456

MEM Elution

STATEMENT OF UNCERTAINTY:

If applicable, the statement of uncertainty is available to sponsors upon request.

Bobbi Rushton Castro
Bobbi Rushton-Castro
Study Director

19 Mar 2009
Study Completion Date

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TABLE 1. Results

IDENTIFICATION	SCORE #1	SCORE #2	SCORE #3	AVERAGE
Negative Control	0	0	0	0
Media Control	0	0	0	0
Positive Control	4	4	4	4
#4 Balinit - A - Medical Ti N	0	0	0	0

NELSON LABORATORIES	FORM TITLE: PDS Approval Form	PDS NUMBER: 200900805
		PDS REVISION: 1

PREPARED FOR SPONSOR		LABORATORY / CONTRACTOR
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FAX:	847-695-4051	

PROTOCOL SPECIFICATIONS			
PARENTAL DOCUMENT:	MEM Elution, STP0032, 3		
SECTION:	Biocompatibility		
PDS INITIATION DATE:	06-Mar-2009	EXPIRATION DATE:	06-Mar-2011

JUSTIFICATION:

No changes to the Standard Testing Protocol.

PROTOCOL SPECIFICATIONS:

Test according to Standard Test Protocol.

○ Additional pages attached for protocol specifications ◉ No additional pages needed

The sponsor is responsible for test/control article characterization.
This includes, but is not limited to, identity, strength, purity, and stability.

****PLEASE SIGN, DATE, & RETURN TO NELSON LABORATORIES****

SPONSOR APPROVAL:

*SIGNATURE: Jodie Alexander

DATE: 3/6/2009

PRINT NAME Jodie Alexander

NELSON LABS STUDY DIRECTOR APPROVAL:

SIGNATURE: Bobbi Rushton Castro

DATE: 10 Mar 2009

PRINT NAME: Bobbi Rushton Castro

*SIGNING THIS DOCUMENT SIGNIFIES AN ACCEPTANCE OF THE NELSON LABORATORIES TESTING TERMS AND CONDITIONS AS ATTACHED OR AS LISTED AT WWW.NELSONLABS.COM/PROTOCOLCONDITIONS.JSP

FOR OFFICE USE ONLY		
LAB NUMBER: 465456	☑ FDA GLP	☐ NON-GLP
SAMPLE ID.	See sample submission form	

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