January 07, 2016

Adam Myers
SSCI
3065 Kent Avenue
West Lafayette, IN 47909

Dear Mr Myers:

Testing for Study #151142-203, entitled **"A NON-GLP ANTIMICROBIAL PRESERVATIVES EFFECTIVENESS EVALUATION OF SIX PRODUCTS WHEN CHALLENGED WITH FOUR MICROORGANISM SPECIES BASED ON EUROPEAN PHARMACOPOEIA METHOD 5.1.3."** is complete. A Preservative Effectiveness Evaluation of six test products was conducted with samples taken at 24 hours, 7 days, 14 days, and 28 days following inoculation, for the two bacterial species (*Pseudomonas aeruginosa* [ATCC #9027] and *Staphylococcus aureus* [ATCC #6538]). Samples were taken at 14 days, 21 days, and 28 days following inoculation with the fungal species, (*Aspergillus brasiliensis* [ATCC #16404] and *Candida albicans* [ATCC #10231]). Testing was based upon the methods outlined in European Pharmacopoeia 7.0, 5.1.3., *Efficacy Of Antimicrobial Preservation,* 01/2011:50103 and details are enclosed as Study Protocol #151142-203 (Addendum 1). Three deviations from Study Protocol #151142-203 occurred and one deviation from BioScience Standard Operating Procedures occurred during the course of this evaluation and are documented as Deviation 01, 02, 03, 04 and included in Addendum 1.

All six test products met the acceptance criteria outlined in the European Pharmacopoeia 7.0. 5.1.3. *Efficacy Of Antimicrobial Preservation,* 01/2011:50103. Acceptance Criteria, Table 5.1.3.1, *Parenteral preparations, eye preparations, intrauterine preparations and intramammary preparations*: Criteria A for bacteria is a 3 $\log_{10}$ reduction following 24 hours of exposure to the test product with no Colony Forming Units (CFU) recovered after 28 days of exposure to the test product and the Criteria A for fungi is a 2 $\log_{10}$ reduction following 7 days of exposure to the test product with no increase in the number of viable microorganisms compared to the previous reading after 28 days of exposure to the test product. All results are included in Addendum 2.

This final report is amended to reflect the changes to the Initial Population (CFU/1.0 mL of product), the Log_{10} Reduction, and the Percent Reduction for the fungal species due to the varying volumes of product employed for the fungal evaluation. Tables 1, 2, 7, 8, 13, and 14 were updated to reflect the changes to the Initial Population (CFU/1.0 mL of product), the Log_{10} Reduction, and the Percent Reduction of *Aspergillus brasiliensis* (ATCC #16404) and *Candida albicans* (ATCC #10231). The data reported for Test Product #2 and Test Product #6 for *Candida albicans* (ATCC #10231) remained as originally reported in Addendum 2. All raw data is included in Addendum 3

We appreciate the opportunity to assist you and look forward to serving you in the near future with any of your testing needs. Please contact our Sales and Marketing Department at (877) 858-2754, toll free.

Sincerely,

Dan Dragotoiu
Study Director: In-Vitro Laboratory

ADDENDUM 1

Protocol #151142-203
Protocol Deviation Recording Forms (Form No. 99-QA-004)

November 23, 2015

PROTOCOL #151142-203

A NON-GLP ANTIMICROBIAL PRESERVATIVES EFFECTIVENESS EVALUATION OF SIX PRODUCTS WHEN CHALLENGED WITH FOUR MICROORGANISM SPECIES BASED ON EUROPEAN PHARMACOPOEIA METHOD 5.1.3.

Prepared for:

SSCI (SPONSOR)
3065 Kent Avenue
West Lafayette, IN 47909

Prepared by:

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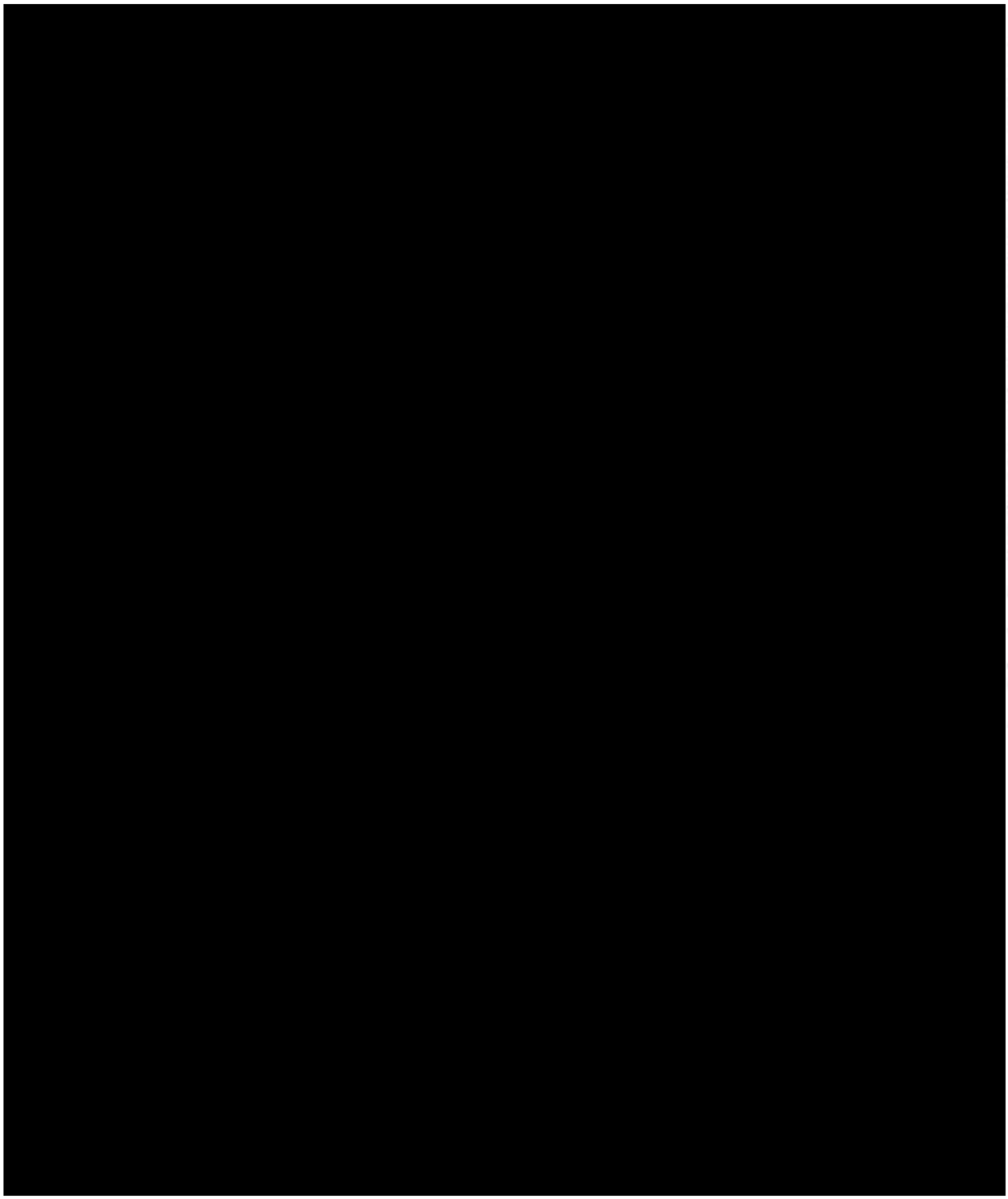
TABLE OF CONTENTS



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