
Final Project Summary

WO# 2009-12-0636

Final Report Date: 2/5/09

Customer information: Company: iBody Science

Project Title: USP Challenge Study and Preparatory Testing of 1 Skin Solution Oil Product

Objective: Challenge product using Antimicrobial Effectiveness Method (04-4-MC056) based on US Pharmacopeia 31-NF 26 <51>. Also, perform USP Preparatory Testing to determine if the product is inhibitory when testing by the USP Total Aerobic Microbial Count method based on USP Pharmacopeia 21-NF 26 <2021>..

Study Outline: Unopened containers of the following product were provided by the client:
1) Skin Solution Oil Product Lot# 086290 Exp Date 092612

Part 1) USP Challenge Study:

The product was divided into six sterile containers. Each of the sample containers were inoculated separately with one of the following organisms; *Escherichia coli* (ATCC# 8739), *Pseudomonas aeruginosa* (ATCC# 9027), *Staphylococcus aureus* (ATCC# 6538), *Candida albicans* (ATCC# 10231) and *Aspergillus niger* (ATCC# 16404). One of the six sub samples was not inoculated with an organism and served as the negative control. Following inoculation, the control and inoculated samples were incubated at 23± 1°C for 28 days. Samples were assessed for outgrowth of the indicator organisms on days 0, 14, and 28 as per USP 31 – NF 26 <51>.

The criteria for preservative effectiveness (based on US Pharmacopeia 31 - NF 26 <51>) of topically used products made with aqueous bases or vehicles, non-sterile nasal products and emulsions, including those applied to mucous membranes (category 2) is as follows:

Bacteria: Not less than 2.0 log reduction from the initial count at 14 days, and no increase from the 14 days' count at 28 days.

Yeast and Molds: No increase from the initial calculated count at 14 and 28 days.

Part 2) USP Preparatory Testing:

The product was inoculated with *Escherichia coli* (ATCC# 8739), *Staphylococcus aureus* (ATCC# 6538) and *Bacillus subtilis* (ATCC# 6633). It was assessed for inhibition of organism growth using the Total Aerobic Microbial Count testing method and then compared to each positive control. The criteria for preparatory testing states that the product must demonstrate a greater than 70% bioburden recovery of the inoculated bacteria in comparison to a control.

Results:

Part 1) USP Challenge Study:

**iBody Science Skin Solution Oil Product
CFU/g (average of duplicate platings)**

Day	<i>E. coli</i>	<i>S. aureus</i>	<i>P. aeruginosa</i>	<i>C. albicans</i>	<i>A. niger</i>	Uninoculated Bacterial control	Uninoculated Yeast/mold control
Inoculation level	550,000	820,000	1,000,000	1,400,000	6,200,000		
Day 0	680,000	890,000	530,000	1,400,000	3,000,000	<10 est.	<10 est.
Day 14	<10 est.	<10 est.	<10 est.	<10 est.	820,000	<10 est.	<10 est.
Day 28	<10 est.	<10 est.	<10 est.	<10 est.	3,900,000	<10 est.	<10 est.

Part 2) USP Preparatory Testing:

iBody Science Skin Solution Oil Product CFU/g (average of duplicate platings)

Dilution	<i>E. coli</i> % Bioburden Recovery	<i>S. aureus</i> % Bioburden Recovery	<i>B. subtilis</i> % Bioburden Recovery
1/10	82	91	91
1/100	90	104	88
1/1000	87	99	99
1/10000	87	95	94

Conclusions:

Part 1) USP Challenge Study:

The criteria for preservative effectiveness (based on US Pharmacopeia 31 - NF 26 <51>) of topically used products made with aqueous bases or vehicles, non-sterile nasal products and emulsions, including those applied to mucous membranes (category 2) is as follows:

Bacteria: Not less than 2.0 log reduction from the initial count at 14 days, and no increase from the 14 days' count at 28 days.

Yeast and Mold: No increase from the initial calculated count at 14 and 28 days.

Based on these criteria, the product tested, **iBody Science Skin Solution Oil Product**, meets the requirements for antimicrobial effectiveness for bacteria, yeast and mold. There was an increase in *A. niger* counts between Day 14 and Day 28 but according to the testing criteria it did not reach high enough levels to be considered a failure when compared to the initial inoculation level and the Day 0 testing results.

Part 2) USP Preparatory Testing:

The criteria for preparatory testing (based on U.S. Pharmacopeia USP 31-NF 26 <2021>) states that the product must demonstrate a greater than 70% bioburden recovery of the inoculated bacteria in comparison to a control medium. Based on these criteria, the product tested, **iBody Science Skin Solution Oil Product** meets the requirements for USP preparatory testing at all dilutions tested.