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Specializing in Laboratory Services, Sterilization & Packaging

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Dr. Roberts,

Recently STS tested two of Natural-Immunogenic's products, Argentyn 23 and Sovereign Silver, against a modified USP<51> GLP protocol, the antimicrobial effectiveness test. A 6 minute time point was added. The STS study and test numbers were GLP-2005-0011 and M05-0297, respectively.

The USP <51> has 4 categories of products and related performance criteria, and I have outlined them below:

Category 1

Injections, other parenterals including emulsions, otic products, sterile nasal products, and ophthalmic products made with aqueous bases or vehicles

Bacteria

For each bacterium tested the number of organisms recovered per ml was reduced by a mean value of not less than 1.0 logs at 7 days, not less than 3.0 log at 14 days and no increase from the 14 days' count at 28 days.

Yeast and Mold

For the yeast and mold tested the number of organisms recovered per ml remained at or below the initial concentration at 7, 14 and 28 days.

Category 2

Topically used products made with aqueous bases or vehicles, nonsterile nasal products, and emulsions, including those applied to mucous membranes.

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.

Category 3

Oral products other than antacids, made with aqueous bases or vehicles.

Bacteria

Not less than 1.0 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.

Category 4


Antacids made with an aqueous base.

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

The performance criteria become less stringent from category 1 to category 4. Based on the results generated from the study, the performance of both Sovereign Silver and Argentyn 23 both exceeded the minimum performance criteria outlined in all of the categories in USP <51>. Further, those criteria were met within 6 minutes. The first time point in USP <51> is at 7days.

Should you have any questions, do not hesitate to contact me.

Best Regards,



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