

STUDY REPORT

Study Title:

Antimycobacterial Activity of KHG fiteBac Test Substances K18 & K21 Using MTB Cultures
(MTB: mycobacterium Tuberculosis)

Study Identification Number

JKS MTB 2014-1

Study Sponsor

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Test Facility

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Test Substance Information

K18 lot # AJ32-88-1
K21 lot# AJ32-88-2

Test Microorganism Information

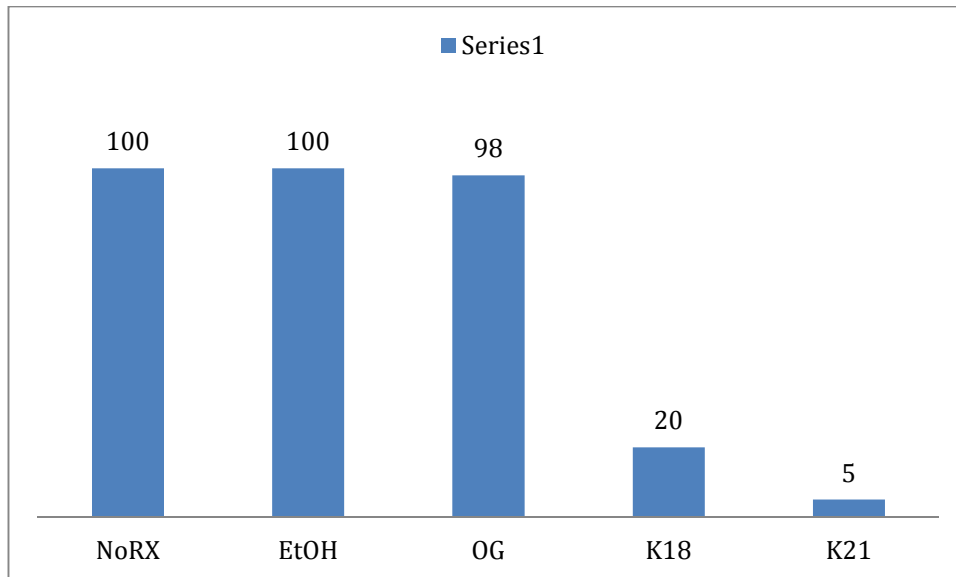
Mycobacterium tuberculosis (Erdman strain)

Summary of Procedure

- + Test MTB grown in liquid culture (Middlebrook 7H9 broth with 0.2% glycerol and 5% BSA and 2% dextrose) under standardized conditions;
 - + Test and control substances (ethanol only) used in identical volumes;
- + The concentrations of K18 & K21 are nominal because of insolubility in H₂O. The bacteria were treated with the reagents for 24 hrs before plating;
 - + At conclusion of the drug contact time (24 hours), MTB was plated and plaques (colonies) were counted 48 hours later. Reductions of microorganisms (i.e. plaques) were calculated in comparison to plaques in untreated MTB cultures (in several parallel test plates).

Preliminary Test Results (i.e. First Series of Testing)

- + The ethanol and no treatment controls have about the same colony count set as “100” in the graph below.
 - + 1% OG showed marginal reduction ~ less than 2Xfold.
 - + K18 at 1% ~ 20X reduction in colonies.
 - + K21 at 1% 50-200 fold reduction in colonies.



Comments

The graphic figure above shows the over-all impression of growth patterns of MTB plaques w & w/o treatment. Data to be confirmed by repeated testing (see below).

Despite of the diminished solubility of K21 in aqueous media, there is evidently a more important component of their effectiveness that does not require solubility. The compounds when added to the bacteria media may form micro precipitate (crystals) that are able to exert their toxic effect. This needs further investigation though.

We are repeating the experiment for confirmation and because the colony growth in the controls and OG was too extensive to count in order to obtain a meaningful number for these samples and require further dilution of the bacteria before adding to the plates. We were able to count the colonies of bacteria treated with the Ks and K21 was about 2-3X more effective than K18.

I have added K18 & 21 in ethanol to 1% OG solution to yield 1% Ks and both immediately precipitated. In any event, given these findings we need to no longer consider the solubility issue. There is nothing like experimental science to teach and lead the way.

Sincerely,

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