

28th, June 2021

The Manager

Otis Herbal Centre

P.O Box 62

Anamabo

Dear Sir/Madam,

REPORT OF ANALYSIS ON OTIS HERBAL BITTERS

Please find attached results of acute toxicity (LD₅₀) studies, phytochemical and microbiological analyses on “**Otis Herbal Bitters**”, an herbal medicinal product submitted for testing on 20th April, 2021.

Product Type: Decoction De/087/21

Claims on label: constipation and piles

Summary of attached results

1. The highest dose (5000 mg/kg) of **Otis Herbal Bitters** orally administered to the experimental animals did not cause death or any physical signs of toxicity such as impaired locomotion, labored breathing or erection of the hair at the end of the 14 days observational period. Thus, the oral LD₅₀ of Otis Herbal Bitters is estimated to be greater than 5000 mg/kg indicating that it may not be toxic and the recommended dose of 2 tablespoonful 2 times daily is within the accepted margin of safety.
2. The levels of the Total Aerobic Microbial Counts (TAMC) and the Total Yeast and Mold Counts (TYMC) represent the estimates of overall microbial contaminants (germs) found in the product. The level of microbial contaminant in the product where above the accepted limit.
3. **Otis Herbal Bitters** contains Phenolic compounds, reducing sugars and Saponins indicating that Otis Herbal Bitters may be plant based. The pH of the product falls outside the acceptable range.

Recommendation

Putting all the results together **Otis Herbal Bitters could not be recommended for registration by the FDA because the pH of the product falls outside the acceptable range and the microbial contamination was above the acceptable limit.** Thus, the manufacturer is advised to submit reformulated

samples to the Centre for evaluation.

Thank you

Dr. Alfred Appiah

(Deputy Executive Director)