



## JK BioScience, Inc.

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Food, Drug, Cosmetic, Medical Devices  
Water, Soil, Wastewater, Environmental  
Consulting and Research  
Analytical Laboratories

February 14, 2019

Attn: Lee, Kyungmin

Clean cu

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Republic of Korea

**Summary of Test Results for Sample: Cleancu antimicrobial copper PE**  
**Study Title: 21 CFR 177.1520**

The above-referenced subject was performed by JK BioScience Analytical Laboratories. N-hexane and xylene extraction study was done in accordance with the 21CFR177.1520, conducted from January 31 to February 14, 2019.

Maximum extractable fraction studies were performed on the submitted samples in accordance with 21 CFR 177.1520. The pre-weighed sample is extracted at 50°C temperature in N-Hexane for 2 hours and filtered. The filtrate is evaporated and the total residue weighed as a measure of the solvent extractable fraction. The sample is extracted in xylene by heating and stirring in a bottle with little free space. The solution is allowed to cool without stirring and is filtered off; the total solids content of the filtrate is then determined as a measure of the solvent extractable fraction.

The result for the analysis of maximum extractable fraction in N-hexane is 1.85%, which doesn't exceed the 5.5% limit and the maximum extractable fraction result in xylene is 2.98%, which doesn't exceed the 11.3% limit of the FDA as specified in 21 CFR 177.1520 (c) 2.1. based on lab report No. 19-1189. Please refer to the attached Certificate of Analysis for more detailed information.

**Testing Results:**

Sample	N-hexane Result (%)	N-hexane Limit (%)	xylene Result (%)	xylene Limit (%)	Method of Analysis
Cleancu antimicrobial copper PE	1.85	5.50	2.98	11.3	21CFR177.1520