

## JK BioScience, Inc.

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

January 06, 2017

Attn: Young-Sun You **BIO POLYMER CO., LTD.** 

#305 Business Incubator, The Catholic University of Korea, Gibongro 43, Wonmigu, Bucheon City, Gyeonggido, South Korea

> Summary of Test Results for Sample: <u>BIO FILM</u> 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 December 12, 2016 to January 5, 2017.

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 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 dissolved completely in xylene by heating and stirring in a bottle with little free space. The solution is allowed to cool without stirring, whereupon the insoluble portion precipitates and is filtered off; the total solids content of the filtrate is then determined as a measure of the soluble fraction.

The result for the analysis of maximum extractable fraction in N-hexane is 0.80%, which doesn't exceed the 5.5% limit and the maximum soluble fraction result in xylene is 3.30%, which doesn't exceed the 30% limit of the FDA as specified in 21 CFR 177.1520 (c) 3.1a. BIO FILM based on lab report No. 16-1717. 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
BIOFILM	0.80	5.50	3.30	30	21CFR177.1520

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The results in the above table shows that the base resin meets the requirements of the U.S. Food and Drug Administration as specified in 21 CFR 177.1520 Olefin polymers. The product meets the respective FDA regulation 21 CFR 177.1520 (c) specifications 3.1a.: Olefin copolymers for use in articles that contact food except for articles used for packing or holding food during cooking.

If you have any questions regarding these results or if you require additional information, please feel free to contact me.

Respectfully Submitted,

Roy Lung

Laboratory Manager

Project Control Consultant

JK BioScience, Inc.

U.S. FDA & EPA Consulting, Research and Analytical Laboratories