

STUDY TITLE

Determination of the Physicochemical Attributes of a Polymeric Material per USP <661> Containers - Plastics, Physicochemical Tests

SPONSOR

Baik Jong Doo
K. P. Tech Co., Ltd.
37, Simigok-ro
Idong-myeon, Cheoin-gu, Yongin-si, Gyeonggi-do, 17130
Korea

TEST ARTICLE NAME

PET rigid sheet

TEST ARTICLE IDENTIFICATION

PET rigid sheet

TEST ARTICLE PHYSICAL DESCRIPTION

PET rigid sheet

TEST ARTICLE RECEIVED

March 3, 2016

PURPOSE

The purpose of this study was to describe the physicochemical attributes as part of the overall characterization of the test article.

RESULTS

	Assay Results	Limits Based on Area
Non-Volatile Residue	< 1 mg	≤15 mg
Residue on Ignition	< 1 mg*	≤5 mg
Heavy Metals	< 1 ppm	≤1 ppm
Buffering Capacity	< 1 mL	≤10.0 mL

*Based on non-volatile residue results

Condition of Extracts	
Test Article	Clear and colorless
Control Blank	Clear and colorless

Date Extract Prepared: March 10, 2016

Date Test Concluded: March 14, 2016

CONCLUSION

The test article met the USP limits for USP <661> Containers - Plastics, Physicochemical Tests.

No significant extractables originated from the test article.

METHOD

A 600 cm² portion of the test article was rinsed twice with a sufficient volume of purified water to cover the test article, and then extracted at 70°C for 24 hours in 100 mL of purified water. A control blank of purified water was similarly prepared without the test article. Non-volatile residue, residue on ignition, heavy metals, and buffering capacity were determined on the test article extract as outlined in the current USP. The non-volatile residue testing utilized a 50.0 mL portion of the test article extract.

COMMENT

This report has been revised to correct the sponsor name, company name and address. The conclusions were not affected. This report was originally signed by Angela V. Booth on March 17, 2016.

REFERENCES

- United States Pharmacopeia 38, National Formulary 33 (USP), General Chapter <231>, Heavy Metals (2015).
- United States Pharmacopeia 38, National Formulary 33 (USP), General Chapter <281>, Residue on Ignition (2015).
- United States Pharmacopeia 38, National Formulary 33 (USP), General Chapter <661>, Containers - Plastics (2015).

APPROVAL	<i>Angela V Booth</i>	<i>4-15-16</i>
Angela V. Booth, BS, MBA		Date
Laboratory Operations Manager, Analytical Services		

Results and conclusions apply only to the test article tested. Any extrapolation of these data to other articles is the sponsor's responsibility. This test was performed under an ISO 13485:2003 certified Quality System, with the test method accredited to the ISO 17025:2005 Standard.