

**STUDY TITLE**

Determination of the Physicochemical Attributes of a Polymeric Material per USP <661> Plastic Packaging Systems and Their Materials of Construction

**SPONSOR**

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**TEST ARTICLE NAME**

PVC Rigid Sheet

**TEST ARTICLE IDENTIFICATION**

PVC Rigid Sheet

**TEST ARTICLE PHYSICAL DESCRIPTION**

PVC Rigid Sheet

**TEST ARTICLE RECEIVED**

October 16, 2019

**PURPOSE**

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

**RESULTS**

Test	Assay Results	USP Limits	Met / Did Not Meet Limit
Non-Volatile Residue	<1 mg	≤15 mg	Met
Residue on Ignition	<1 mg*	≤5 mg	Met
Heavy Metals	<1 ppm	≤1 ppm	Met
Buffering Capacity	<1.0 mL	≤10.0 mL	Met

\*Based on non-volatile residue results.

Condition of Extracts	
Test Article	Clear and colorless with a few, fine, white particulates
Control Blank	Clear and colorless with no particulates

Date Extract Prepared: October 21, 2019


Date Test Concluded: October 23, 2019

**METHOD**

The entire sheet was included for testing. A 1172.16 cm<sup>2</sup> 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 195 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.

**REFERENCES**

United States Pharmacopeia 42, National Formulary 37 (USP), General Chapter <661>, Plastic Packaging Systems and Their Materials of Construction (2019).

APPROVAL		24 OCT 2019
	Margaret K. LaPlante, BS Technical Support Specialist, Analytical Services	Date

*Results 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 all applicable GMP regulations and in compliance with the ISO 13485 standard, with the test method accredited to the ISO 17025 standard.*