

TEST RESULT CERTIFICATE

Sponsor	Malema Sensors	Technical Initiation	5/16/2017
Address	1060 S Rogers Circle Boca Raton, Florida 33487	Technical Completion	5/18/2017
Contact	Kalash Jhamb	Report Date	5/22/2017
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Test Article	PEEK (polyetheretherketone (PEEK))- Solvay KT-880NT
Lot/Batch #	5.5 mm Lot - gamma irradiated
Study	USP <661.2> Physicochemical Tests for Plastic Packaging Systems without PET & PETG
Comments	Extraction was performed via submersion of test articles at 6 cm ² /mL. Surface area was approximated at 171 cm ² per unit.

REFERENCES: The study was conducted based upon the following references: United States Pharmacopeia 40, National Formulary 35, 2017. Chapter <661.2> Plastic Packaging Systems for Pharmaceutical Use, Physicochemical Tests.

ISO/IEC 17025, 2005, General Requirements for the Competence of Testing and Calibration Laboratories.

GENERAL PROCEDURE: The purpose of the study was to determine the physical and chemical properties of the plastic test article by aqueous extraction for Appearance, Absorbance, Acidity or Alkalinity and Total Organic Carbon (TOC).

Preparation of Solution C1: The test article (3.5 units) was submerged and extracted with purified water (100 mL) at 6 cm²/mL. The test article was extracted at 70 ± 2°C for 24 ± 2 hours at maintained temperature. The test article with extract was cooled to room temperature, the contents of the test article were emptied into another container, and the extract was labelled as Solution C1. A blank was prepared similarly by heating purified water in a glass container closed with inert closure.

Appearance: Appearance of the Solution C1 was compared to purified water.

Absorbance: The absorbance of Solution C1 was measured from 230 to 360 nm by UV/Vis spectrometer, using the blank as the reference solution.

Instrumentation:

Instrument	Perkin Elmer Spectrum Lambda 40 UV/Vis Spectrometer
Software	Winlab 6.0.4 © 2011

Acidity or Alkalinity: To 20 mL of Solution C1, 0.1 mL of Phenolphthalein TS was added and the color of the solution was noted, then 0.4 mL of 0.01 N Sodium Hydroxide was added to the same solution and the color of the solution was noted. To this solution, 0.8 mL of 0.01 N Hydrochloric Acid and 0.1 mL of Methyl Red TS 2 were added and the color of the solution was noted.

Total Organic Carbon (TOC): Solution C1 was analyzed for Total Organic Carbon (TOC) by converting TOC to Carbon Dioxide (CO₂) by acidification and chemical wet oxidation with Sodium Persulfate. The CO₂ liberated from the test article extract will be measured using an infrared detector.

Instrumentation:

Instrument	Tekmar Dohrmann, Phoenix 8000 TOC Analyzer
Software	TOC Talk version 3.6.429

RESULTS: The results are presented in Table 1.

Table 1
Results of Physicochemical Tests

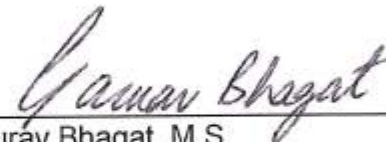
Test	Test Result	Evaluation Criteria	Meets Criteria
Appearance of Solution	Clear and colorless as purified water	Clear and Colorless as purified water	Yes
Absorbance	-0.0465 < 0.20 AU	Absorbance Between 230 to 360 NMT 0.20 AU	Yes
Acidity or Alkalinity	Color of the Solution: Colorless	Solution is clear after addition of 0.1 mL of Phenolphthalein TS	Yes
	Color of the Solution: Pink	Solution is pink after addition of 0.4 mL of 0.01 N sodium hydroxide	Yes
	Color of the Solution: Red	Solution is orange-red or red after addition of 0.8 mL of 0.01 N hydrochloric Acid and 0.1 mL of Methyl Red TS 2	Yes
Total Organic Carbon (TOC)	2.79 mg/L	NMT 8 mg/L between Solution C1 and Blank	Yes

CONCLUSION: The test article meets criteria for Appearance of Solution, Absorbance, Acidity or Alkalinity and Total Organic Carbon of the United States Pharmacopeia 40, National Formulary 35, 2017. Chapter <661.2> Plastic Packaging Systems for Pharmaceutical Use; Physicochemical Tests, based upon the methods employed.

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