

**TEST ARTICLE NAME**

Gylon style 3504

**TEST ARTICLE IDENTIFICATION**

See Test Article

**TEST ARTICLE RECEIVED**

April 24, 2009

**SPONSOR**

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**STUDY TITLE**

USP Physicochemical Testing – Plastics – Complete

**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	< 1.0 mL	≤10.0 mL

\*Based on non-volatile residue results.

Date Prepared: April 26, 2009

Date Study Completed: April 29, 2009

Condition of Test Article Extract: clear and yellow

Condition of Control: clear and colorless

**CONCLUSION**

Under the conditions of this test, the test results met the USP limits.

**METHOD**

A 632.0 cm<sup>2</sup> portion of the test material was extracted at 70°C for 24 hours in 105 mL of USP Purified Water. Non-volatile residue, residue on ignition, heavy metals as lead and buffering capacity were determined in the eluate as outlined in the current USP.

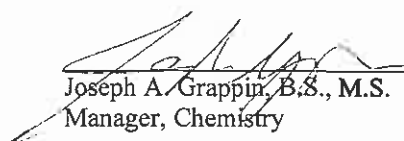
**REFERENCES**

United States Pharmacopeia 31, National Formulary 26 (USP), General Chapter <661>, Physicochemical Tests-Plastics (2008).

United States Pharmacopeia 31, National Formulary 26 (USP), General Chapter <281>, Residue on Ignition (2008).

Results and conclusions apply only to the test article tested. Any extrapolation of these data to other samples is the sponsor's responsibility. All procedures were conducted in conformance with good manufacturing practices and certified to ISO 13485:2003.

**APPROVAL**

  
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4-29-09  
Date