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STUDY REPORT TE120555 / 12-B1706

GYLON BLUE 3504

LOT 3504-6608 BLEND #7383

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TESTS ON PLASTIC MATERIALS AND COMPONENTS USED TO PACKAGE MEDICAL ARTICLES ACCORDING TO UNITED STATES PHARMACOPOEIA 35 NF 30

GENERAL CHAPTERS: 661, SECTION "PHYSICOCHEMICAL TESTS".

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TABLE OF CONTENTS

1.0 OBJECTIVE OF THE STUDY

The aim of this study is to investigate if the test material meets the requirements of the United States Pharmacopoeia regarding the General Chapter 661 for plastic materials used to package medical articles as directed under *Physicochemical Tests* in the section *Test Methods*.
Additionally a FTIR spectrum identifying the material type will be taken on request of the sponsor.

2.0 REFERENCES

The study is conducted based upon the United States Pharmacopoeia 35 NF 30 (edition 2012), General Chapter <661> "Containers - Plastics".
FTIR analyses according EP 7.4 (2012), Chapter 2.2.24, Absorption Spectrophotometry, Infrared.

3.0 TEST MATERIAL IDENTIFICATION

The following information is supplied by the Sponsor on a test registration form or other correspondence wherever applicable; it does not apply to confidential information.

Test Material Name: Gylon Bue 3504
Lot: 3504-6608 BLEND #7383
CAS/Code: Not Applicable
Physical State: Solid
Color: Blue
Stability: Not Supplied

Sterilized: Not supplied
Solubility: Not Applicable
Storage Conditions: Room temperature
Safety Precautions: Not Applicable

4.0 EXPERIMENTAL DESIGN.

4.1 Testing Parameters

Extraction Medium: Ultra Purified Water (UPW) was used as the *Extraction Medium*, maintained at a temperature at 70°C during 24 hours extraction of the *Sample Preparation*.

Blank: UPW without test articles was used in the tests where a blank is specified.

Sample Preparation and Sample Preparation Extract:
A piece of the test article (dimensions 20 cm x 15 cm x 0,31 cm) with a total surface area of 621.7 cm^2 was cut into little pieces of approximately 0.5 cm^2 and transferred into a glass-stoppered 250 mL extraction flask.

The pieces were washed twice with 150 mL UPW prior to the extraction. 103.6 mL *of Extraction Medium* was added to the drained pieces and placed in an incubator at the temperature specified for *the Extraction Medium* for 24 hours. After the extraction the extract was cooled till room temperature. The extract was shaken vigorously and finally decantated.

4.2 Non-Volatile Residue

50.0 mL of the *Sample Preparation Extract* and the *Blank* were transferred to suitable, tarred crucibles and evaporated till almost dry on a moderately heated hot plate. The residual extracts were finally dried till dryness in a drying oven during 1 hour at 103°C. The residue obtained from the *Sample Preparation Extract* weighed 1.2 mg.
(Limit is 15 mg)

4.3 Residue on Ignition

The Residue on Ignition test was not applicable since the obtained Non-Volatile Residue value was already lower than the 5 mg Residue on Ignition Limit.
(Limit is 5 mg)

4.4 Heavy Metals

20.0 mL of the *Sample Preparation Extract* was transferred into one of two matched 50-mL color comparison tubes. The pH was adjusted between 3.0 and 4.0 with 1 N Acetic acid. The extract was diluted to 35 mL with UPW and mixed.

Into a second color comparison tube 0.2 mL of *Lead Stock Solution (100 ppm)* and 20.0 mL of the *Blank* were mixed. The pH was adjusted between 3.0 and 4.0 with 1 N Acetic acid. The mixture was diluted to 35 mL with UPW and mixed.

To both tubes 1.2 mL of Thioacetamide-Glycerin base TS solution and 2 mL of Acetate Buffer pH 3.5 were added, mixed and diluted to 50 mL marker with UPW.

After 10 minutes no color produced in the tube containing the *Sample Preparation Extract.* When viewed downward against a white surface the color was less intense than the color produced in the tube containing the reference *Standard Lead Solution.* The concentration of heavy metals in the *Sample Preparation Extract* was therefore less than 1 ppm.

4.5 Buffering Capacity

20 mL of the *Sample Preparation Extract* was titrated to a pH 7 using 0.050 mL 0.01N Hydrochloric acid Solution. The *Blank* was titrated to a pH 7 using 0.100 mL 0.01N Sodium Hydroxide Solution. The difference in volumes added between the *Sample Preparation Extract* and the *Blank* was therefore 0.150 mL.
(Limit is 10.0 mL)

5.0 SUMMARY OF RESULTS

The results and the evaluation criteria for the different tests performed are listed below.

TEST	TEST RESULT	EVALUATION CRITERIA According USP 661 (20 mL UPW for 120 cm^2)	PASS / FAIL
Non-Volatile Residue	1.2 mg	≤ 15 mg	PASS
Residue on Ignition [1]	Not Performed [1]	≤ 5 mg	Not Applicable
Heavy Metals	No color, less intense than reference	Color is less intense than color of the *Standard Lead Solution (1mg/L)*	PASS
Buffering Capacity	0.150 mL	≤ 10 mL	PASS

[1] *Residue on Ignition is only performed when the Non-Volatile Residue is ≥ 5 mg.*

Table 01: Summary of Test Results

6.0 FTIR SPECTRUM

A FTIR spectrum is made with a Varian FTIR Spectrometer, Model 800FTS Scimitar (Toxikon ID LSE1699) according SOP 3.2.10 Rev. 01 and SOP 2.2.3.36 Rev. 01.

A little piece of the test article was clamped on the PIKE Miracle ATR-module that enables a direct scan on the neat material without any sample preparation according EP 7.4 (2012), Chapter 2.2.24.

The FTIR spectrum shown in the figure on the next page presented distinct and sharp peaks at wave numbers 1199cm^{-1} and 1146cm^{-1}. Additional less intense peaks were found at wave numbers 780cm^{-1}, 717cm^{-1} and 638cm^{-1}.

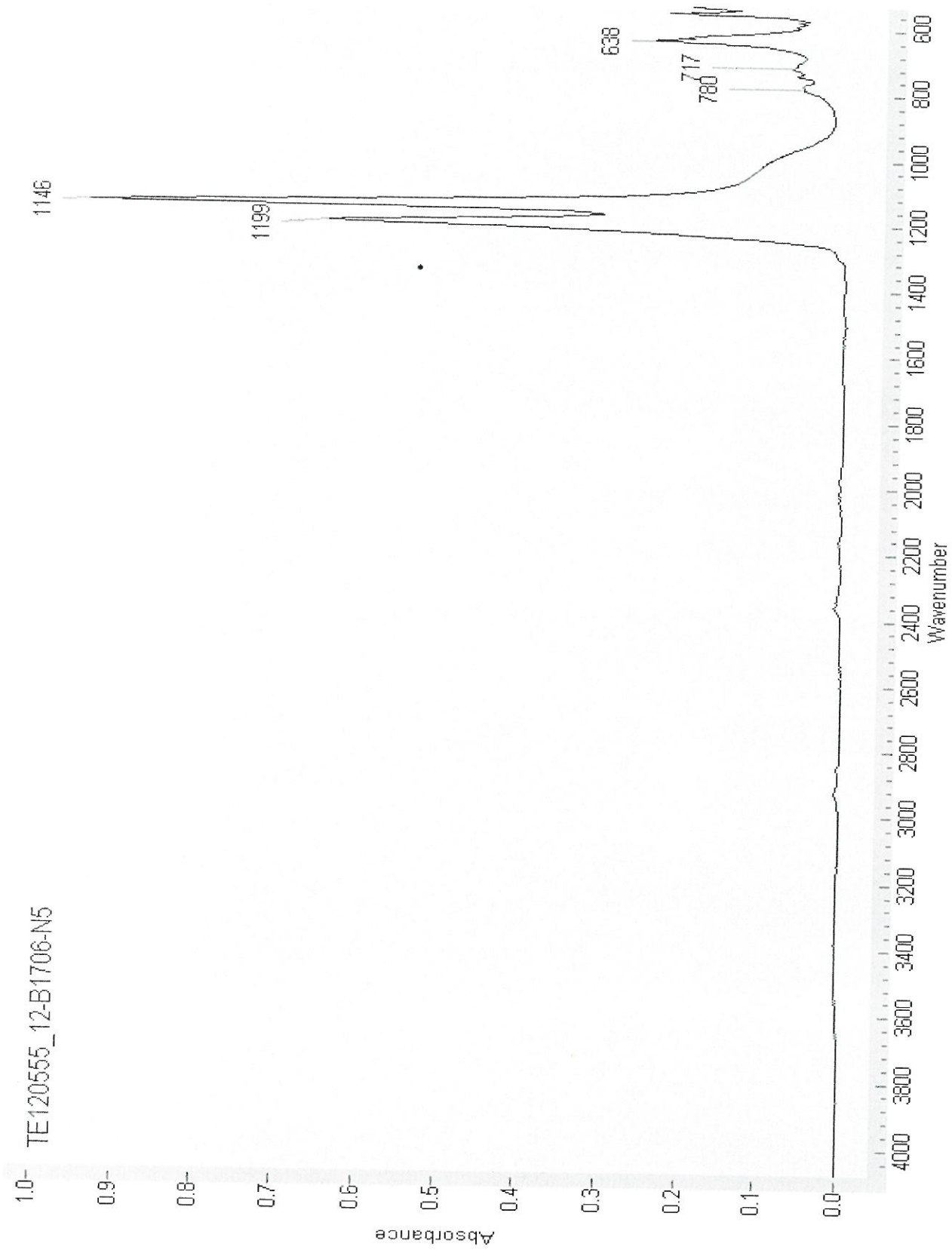

Figure 1: FTIR spectrum

7.0 CONCLUSION

Based on the evaluation criteria mentioned above, the test material, "Gylon Blue 3504 / Lot 3504-6608 Blend #7383" does meet the requirements of the United States Pharmacopoeia regarding the General Chapter 661 for plastic materials used to package medical, section "Physicochemical Tests".

8.0 RECORDS

The original final report and possible amended reports are forwarded to the Sponsor.

A copy of the final report and possible amended reports, original raw data and records, lab-notebooks, the sponsor signed contract, communications and documentation of deviations are archived at Toxikon Europe for a minimum of 10 years according to SOP 4.2.8 Revision 08 and SOP 4.2.7 Revision 02, or will be sent to the sponsor on written request.

All unused test articles will be discarded by Toxikon Europe earliest 6 months after sample receipt, or will be sent back to the sponsor on written request.