



ACTS TESTING LABS, INC.  
 25 Anderson Road  
 Buffalo, NY 14225-4928  
 Tel (716)897-3300  
 Fax (716)897-0876  
 Broadway 684-3380

Technical Report 4B-2306E  
 P. O. 4034

Page 1 of 1

Mr. Joe Russ

**SUBJECT:**

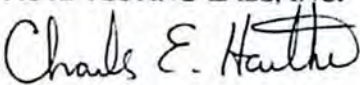
Analyses of two (2) solid samples for Luminous Transmittance Test.

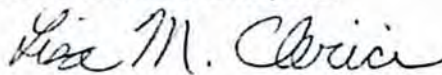
**RESULTS:**

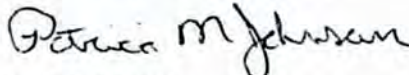
	ACTS # 4B-2306E <u>SAMPLE A</u>	ACTS #4B-2307E <u>SAMPLE B</u>
% Transmittance	9.8	17.5

**EXPERIMENTAL:**

The analyses were conducted according to ASTM Method E 306-66.

ACTS TESTING LABS, INC.  
  
 Charles E. Hartke  
 Manager, Chemistry Laboratory

ACTS TESTING LABS, INC.  
  
 Lisa M. Clerici, Supervisor  
 Wet Chemistry Laboratory

ACTS TESTING LABS, INC.  
  
 Patricia M. Johnson  
 Quality Assurance Officer

rar

Our reports and letters are for the exclusive use of the client to whom/which they are addressed. Communication of ACTS Testing Labs, Inc. reports and letters to any others and/or use of the name of ACTS Testing Labs, Inc. requires our prior written approval. Our letters and reports are limited solely (i) to standards and procedures identified in them and (ii) to the sample(s) tested. Test results are not necessarily indicative nor representative (i) of the quality of the lot from which the sample was taken or (ii) of apparently similar or identical products. Unless otherwise stated, it is the responsibility of the client to insure the representativeness of the samples submitted to ACTS Testing Labs, Inc. for testing.



ACTS TESTING LABS, INC.

25 Anderson Road  
Buffalo, NY 14225-4928

Tel (716)897-3300

Fax (716)897-0876

*INC-ADU 294 - 694-330*

*AMBER VIALS*

Technical Report 3B-1747M  
P.O. #1242

Page 1 of 1

Ms. Jennifer Platt

SUBJECT:

Analyses of three (3) solid samples for Luminous Transmittance Test.

RESULTS:

	ACTS # 3B-1747M <u>SAMPLE A</u>	ACTS #3B-1748M <u>SAMPLE B</u>	ACTS #3B-1749M <u>SAMPLE C</u>
% Transmittance	7.9 <i>pass</i>	1.3 <i>pass</i>	1.4 <i>pass</i>

EXPERIMENTAL:

The analysis was conducted according to ASTM Method E 306-66.

ACTS TESTING LABS, INC.

*Charles E. Hartke*

Charles E. Hartke  
Manager, Chemistry Laboratory

ACTS TESTING LABS, INC.

*Lisa M. Clerici*

Lisa M. Clerici, Senior Analyst  
Chemistry Laboratory

ACTS TESTING LABS, INC.

*Pamela M. Polniak*

Pamela M. Polniak  
Manager, Quality Assurance

smd

*3916  
BOARDWALK  
CREEK, N.Y. 14227*

*MUST BE < 10% TO PASS*

Our reports and letters are for the exclusive use of the client to whom/which they are addressed. Communication of ACTS Testing Labs, Inc. reports and letters to any others and/or use of the name of ACTS Testing Labs, Inc. requires our prior written approval. Our letters and reports are limited solely (i) to standards and procedures identified in them and (ii) to the sample(s) tested. Test results are not necessarily indicative nor representative (i) of the quality of the lot from which the sample was taken or (ii) of apparently similar or identical products. Unless otherwise stated, it is the responsibility of the client to insure the representativeness of the samples submitted to ACTS Testing Labs, Inc. for testing.

## LIGHT TRANSMISSION

**Apparatus<sup>1</sup>**—Use a spectrophotometer of suitable sensitivity and accuracy, adapted for measuring the amount of light transmitted by either transparent or translucent glass or plastic materials used for pharmaceutical containers. For glass containers of nominal capacity up to 5 mL, use a suitable spectrophotometer having an aperture not larger than 2 mm × 1 cm. For containers made of translucent materials other than glass, use a suitable spectrophotometer equipped with an attachment that is capable of measuring and recording light transmitted in diffused as well as parallel rays.

### Preparation of Specimen—

**GLASS**—Break the container or cut it with a circular saw fitted with a wet abrasive wheel, such as a carborundum or a bonded diamond wheel. Select sections to represent the average wall thickness in the case of blown glass containers, and trim them as necessary to give segments of a size convenient for mounting in the spectrophotometer. After cutting, wash and dry each specimen, taking care to avoid scratching the surfaces. If the specimen is too small to cover the opening in the specimen holder, mask the uncovered portion of the opening with opaque paper or masking tape, provided that the length of the specimen is greater than that of the slit in the spectrophotometer. Immediately before mounting in the specimen holder, wipe the specimen with lens tissue. Mount the specimen with the aid of a tacky wax, or by other convenient means, taking care to avoid leaving fingerprints or other marks on the surfaces through which light must pass.

**PLASTIC**—Cut circular sections from two or more areas of the container, and wash and dry them, taking care to avoid scratching the surfaces. Mount in the apparatus as described for *Glass*.

**Procedure**—Place the section in the spectrophotometer with its cylindrical axis parallel to the plane of the slit and approximately centered with respect to the slit. When properly placed, the light beam is normal to the surface of the section and reflection losses are at a minimum.

Measure the transmittance of the section with reference to air in the spectral region of interest, continuously with a recording instrument or at intervals of about 20 nm with a manual instrument, in the region of 290 nm to 450 nm.

**Limits**—The observed light transmission does not exceed the limits given in Table I for containers intended for parenteral use.

The observed light transmission for containers of Type NP glass and for plastic containers for products intended for oral or topical administration does not exceed 10% at any wavelength in the range from 290 nm to 450 nm.

Table I. Limits for Glass Types I, II, and III and Plastic Classes I–VI.

Nominal Size (in mL.)	Maximum Percentage of Light Transmission at Any Wavelength Between 290 nm and 450 nm	
	Flame-sealed Containers	Closure-sealed Containers
1	50	25
2	45	20
5	40	15
10	35	13
20	30	12
50	15	10

NOTE—Any container of a size intermediate to those listed above exhibits a transmission not greater than that of the next larger size container listed in the table. For containers larger than 50 mL, the limits for 50 mL apply.

<sup>1</sup> For further detail regarding apparatus and procedures, reference may be made to the following publications of the American Society for Testing and Materials, 1916 Race St., Philadelphia, PA 19103: "Standard Method of Test for Haze and Luminous Transmittance of Transparent Plastics," ASTM Designation D-1003-61; "Tentative Method of Test for Luminous Reflectance Transmittance, and Color of Materials," ASTM E 308-66.



August 30, 2013

CERTIFICATE OF COMPLIANCE

ITEM :

6, 8, 13, 16, 20, 30, 40, 60 DRAM CHILD RESISTANT PRESCRIPTION VIALS  
Push & Turn, Reversibles, Green Neck, and Push Tab.

RESIN GRADE:

HOMOPOLYMER POLYPROPYLENE NEXIO HIVAL 2412 MATERIAL CODE: 1000601  
FDA APPROVED MATERIAL –

FDA Regulation 21 CFR177.1520(c), item 1.1.a, for the safe use of olefin polymers  
in articles or components of articles intended for food contact with all Food Types per  
Table 1 of FDA Regulation 21 CFR176.170(c) and Conditions of use per Table 2 of  
FDA Regulation 21 CFR176.170(c).

MEETS OR EXCEEDS USP STANDARDS

MANUFACTURER DATES: 4/1/2013-8/1/2013

The Consumer Product Safety Commission regulation to which these products are being certified is 16  
CFR 1700.

The date this product was tested for compliance with this regulation cited above by:

Perritt Laboratories  
145 South Main Street  
Highstown, NJ 08520  
4/15/2009

Light Transmission testing using method of USP 661, the above listed bottles meet the  
requirement of NMT 10% at any wavelength. (4%-6%)

SGS U.S. Testing Company Inc.  
75 Passaic Ave.  
Fairfield, NJ 07004  
June 2007

COMPLIANCE STATEMENT

THIS WILL CERTIFY THAT THE PRODUCT SUPPLIED  
WAS PRODUCED ACCORDING TO THE GOOD  
MANUFACTURING PRACTICES AND SPECIFICATIONS

DATE OF ISSUANCE

August 30, 2013