

## WEST MONARCH ANALYTICAL LABORATORIES

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Revision 0

David Star L.J. Star Incorporated 2396 Edison Boulevard Twinsburg, OH 44087 Request:

COM06-I-1572

Project:

9250.001

PO#:

00001308

Received:

07/14/06

Completed:

08/11/06

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Sample No.

Sample Description

Sample Identification

061572-01

Glass/Metal Ports

Sample #1: Metaglas Borosilicate Glass

(Schott Suprax 8488, DIN 7080)

061572-02

Glass/Metal Ports

Sample #2: Metaglas Soda Lime Glass

(Schott B270 Superwite, DIN 8902)

061572-03

Glass/Metal Ports

Sample #3: FuseView BoroPlus

The samples were cut by the customer and photographed as received. As glass was broken from the steel rings for testing an effort was made not to include glass from the glass/steel interface which had a green material. Due to the size of the pieces in sample 061572-01 some of the green material may have been included with the glass tested.

|                        | Revision 0  |            |              |
|------------------------|-------------|------------|--------------|
| David Star             |             | Request:   | COM06-I-1572 |
| L.J. Star Incorporated |             | Project:   | 9250.001     |
| 2396 Edison Boulevard  |             | PO#:       | 00001308     |
| Twinsburg, OH 44087    |             | Received:  | 07/14/06     |
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|                        | Page 2 of 4 |            |              |

## Chemical Resistance of Glass Containers per US Pharmacopoeia

|                                                                                                            | mL 0.020 N H <sub>2</sub> SO <sub>4</sub> | Glass Type |
|------------------------------------------------------------------------------------------------------------|-------------------------------------------|------------|
| Glass/Metal Ports Sample #1: Metaglas Borosilicate Glass (Schott Suprax 8488, DIN 7080) 061572-01          | 0.33                                      | I          |
| Glass/Metal Ports<br>Sample #2: Metaglas Soda Lime Glass<br>(Schott B270 Superwite, DIN 8902)<br>061572-02 | 4.98                                      | III        |
| Glass/Metal Ports Sample #3: Fuse-View BoroPlus 061572-03                                                  | 8.98                                      | NP         |
| NIST 623 $(0.34 \pm 0.05)$                                                                                 | 0.39                                      |            |
| NIST 622 $(7.67 \pm 0.38)$                                                                                 | 7.69                                      |            |

The above samples were tested for chemical resistance according to USP 29 <661>, "Powdered Glass Test." NIST 622 SRM and NIST 623 SRM were analyzed along with the samples listed above as a quality assurance standard. The results obtained are within the specification for the glass type listed above.

NP indicates for non parenteral use.

## **Analysis of Glass Metal Ports**

|                                                                                       | % B <sub>2</sub> O <sub>3</sub> |
|---------------------------------------------------------------------------------------|---------------------------------|
| Sample #1: Metaglas Borosilicate<br>Glass (Schott Suprax 8488, DIN 7080)<br>061572-01 | 11.6                            |
| Sample #3: Fuse-View BoroPlus 061572-03                                               | <0.1                            |

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Photographs are attached.

Reference(s):

IN170/28, 32

Method Summary:

B<sub>2</sub>O<sub>3</sub>: Volumetric as Manitol complex (AM-I-0020 Rev.1)

IN171/44

Prepared By:

Date:

Reviewed/Approved By:

Date:

08/11/06

Neal T. Nichols (1) 08/11/06

Brown a mitable Brian D. Mitchell

Thank you for using WEST MONARCH Analytical Laboratories.

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**Photographs** 



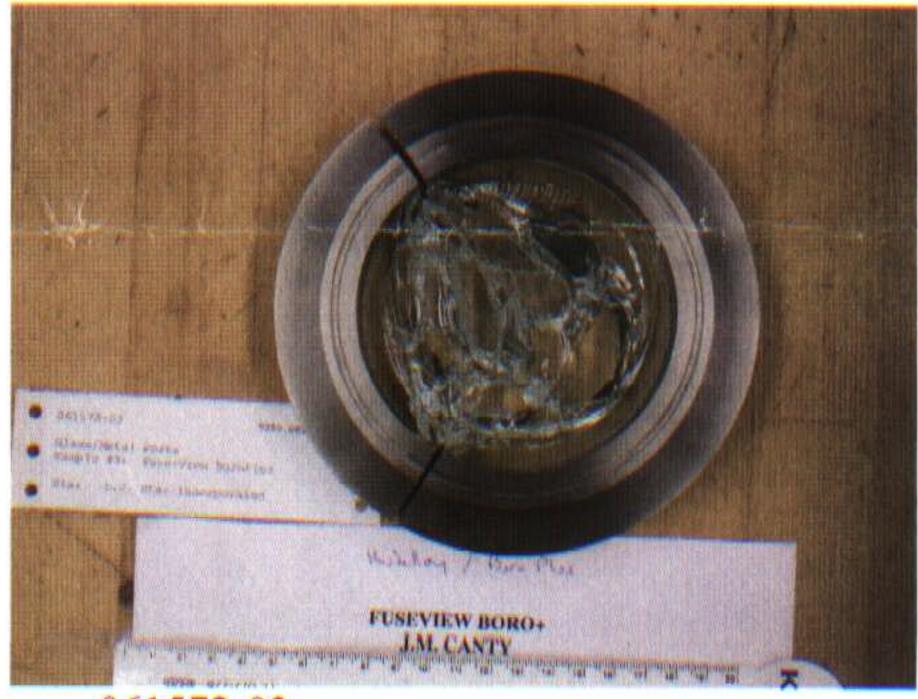
061572-01



061572-02



061572-03



061572-03