

**Engineering Study of Particulate  
Generation of the LIGHTNIN  
MAG Mixer MBI**



Prepared By

***Oak Grove Technologies, Inc.***

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**OAK GROVE TECHNOLOGIES, INC.**

**RESEARCH REPORT**

**OGT #96831**

**TLG #2620.01**

**Engineering Study of Particulate Generation of the LIGHTNIN MAG  
Mixer MBI**

April 3, 2000

**Prepared for:**

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## **Objective**

The purpose of this engineering study was to evaluate the particulate generation of the Lightning Hyperflow Bearing, part # 22585D601, used in the Lightning Mag Mixer MBI. The intent was to provide documented evidence that the Lightning Hyperflow bearing does not generate particulate in excess of the allowable limit set by USP standards.

## **Conclusion**

Based on a five-day continuous study, during which the Lightning Mag Mixer was run at 100% speed, the Lightning Hyperflow Bearing met the criteria set by the USP for particulate generation in large volume injectables. Results indicated that at the end of day five, the particulate generation within the mixer system fell below the limits of 25 particles per mL equal to or greater than 10 $\mu$ m and 3 particles per mL equal to or greater than 25 $\mu$ m.

## **Background**

LIGHTNIN is a leading manufacture of sealed magnetic mixers that utilize magnetic mixing motors and shafts. A study was performed at Martin Petersen Company to test the Hyperflow Bearing of the LIGHTNIN Mag Mixer MBI for particulate generation. Because the bearing remains within the vessel while mixing and it is a wearing part, it is of interest to determine the amount of particulate it will generate over time.

The results of the study showed that over a five-day period the bearing shed an amount of particulate within the acceptable limits set by the USP. The study was accomplished by installing a new bearing, cleaning the mixer, filling it with 100 Liters WFI, and mixing at maximum speed for five days, sampling every twelve hours, and analyzing for particulate. After a five-day period of mixing, the amount of particulate generation was within acceptable USP limits.

## **Experimental Overview**

The LIGHTNIN Mag Mixer MBI was studied to determine the amount of particulate its bearings would generate over the time span of five days. A 200-L stainless steel testing vessel was filled with 96 Liters of ambient Water for Injection. The Mixer was run for five (5) days, sampling every twelve (12) hours. Samples consisting of 120 mL WFI were submitted to Northview Laboratories for particulate analysis. After the completion of five (5) days, the tank was drained of remaining WFI. This study was intended to provide information and documentation regarding particulate generation of the LIGHTNIN Mag Mixer MBI that falls within the USP set standards. For large volume injectables the particulate limit at 10  $\mu$ m is 25 particles per mL, and at 25 $\mu$ m the limit is 3 particles per mL. All samples must stay within these limits in order to be considered acceptable.

## **Materials & Methods**

### ***Test Environment***

1. The testing was performed in an environment that was clean and did not contribute any amount of foreign particulate matter.
2. Test specimens (i.e. vessel, impeller, and bearings) were cleaned utilizing the CIP procedure to the extent that any extraneous particles had a negligible effect on the outcome of the test.
3. All equipment used in preparation of the vessel (i.e. funnels, HDPE water containers) was rinsed thoroughly with DI.
4. Non-shedding garments and powder free gloves were worn during the final preparation of vessel (adding WFI after CIP had been completed) and throughout all sampling.
5. Particulate-free sampling commodities; bottles, and water containers were obtained from laboratory supplies vendors and were maintained in a clean condition until use.
6. All other equipment used was thoroughly rinsed with DI, and sterilized with alcohol.

### ***Equipment***

1. One hundred (100) Liters Water for Injection (WFI) stored in two (2) LPE containers of 56 Liters each.
2. NALGENE® Low Particulate HDPE Sampling Bottles, capacity: 125 mL.
3. Isopropyl Alcohol for wipe-down purposes.
4. Sterile tubing and coupling.
5. Nonshedding garments and powder free gloves.
6. Stainless Steel Measuring Stick.
7. Stainless Steel Thermometer.

### ***Experimental Procedure***

1. Before beginning the study, the existing bearings were removed from the mixer, and replaced with new ones. These bearings are manufactured by YEMERI, part # 22585D601 and are of lot # MC 62151, code 22.
2. The LIGHTNIN Mag Mixer MBI assembly was installed, including the new Hyperflow bearing, the motor, and an 8" impeller installed on port #10.
3. The mixer was run through the CIP process consisting of a pre-rinse, a detergent cycle followed by a rinse, and a final rinse. The 2% detergent solution was made up of 100 Liters DI water combined with 2 Liters of STERIS PRO-KLENZ AST 1000.
4. The WFI was sampled prior to adding it to the vessel. Two (2) samples of 125 mL were taken from each of the 56 Liter carrying containers to establish a baseline for the study.
5. The WFI was added to the vessel, assuring the impeller was completely covered, and allowing enough excess to allow for sampling.
6. The water level was measured from the upper rim of the tank to the water/air interface. The final volume of the WFI was calculated to be 96 Liters.
7. After adding the first container of WFI a particle was noticed floating on the surface of the water. This particle was removed by touching one gloved finger to the surface of the water near the particle.
8. A 3 ½" rubber tube was wiped down with isopropyl alcohol and attached to the output valve of the vessel for sampling.

9. Four (4) samples of 125 mL were taken from the vessel to establish a baseline for the testing vessel.
10. The laboratory sample request form was completed and the samples were sent to Northview Laboratories, Inc. for particulate analysis.
11. The temperature of the WFI was taken once each sampling period by taking an additional amount of WFI and measuring temperature to designate ambient temperature for reference purposes.
12. The mixer was started in the clockwise direction, and worked up to the maximum speed of 175 RPM. The motor and the mixer had a gear ratio of 1 to 10. The motor had a maximum speed of 1750 RPM, so increasing it to maximum velocity resulted in the mixer running at the speed of 175 RPM.
13. The mixer was run continuously for twelve (12) hours.
14. The mixer was stopped and four (4) samples of 125 mL were taken from the vessel.
15. The samples were sealed, labeled and documented.
16. The mixer was started and run continuously at 175 RPM for twelve hours (12).
17. The mixer was stopped and four (4) samples of 125 mL were taken from the vessel.
18. The samples were sealed, labeled, and documented.
19. The sampling was continued at twelve (12) hour intervals for a five (5) day period for a total of eight (8) initial samples, and forty (40) mixed samples.
20. Once per day, all samples taken from the previous twenty-four (24) hour period were sent to the lab for particulate analysis, along with the laboratory sample request form. This assured that the time between sampling and delivery of specimen to the lab for analysis was less than thirty-six (36) hours.
21. The vessel was drained of remaining WFI, and no visible particulate was observed.

### ***Analysis of Samples***

All WFI samples collected were analyzed for particulate generation by using the method listed below. For analysis by the light obscuration particle count test each sample was mixed by inverting twenty-five times within ten seconds and then allowed a two-minute stabilizing period. Three separate 5-mL aliquots were run through an electronic liquid particle counting system. The resulting data is based on the average of the second and third runs.

- Light Obscuration Method  
Method outlined in USP 24 <788>.

### **Results & Discussion**

Results of the test of particulate generation by the light obscuration method are presented in Appendix A. The data sheets that correspond to the sampling are included in Appendix B.

Initial samples were taken to establish a pre-sample baseline that showed that there was no preexisting particulate present in either the WFI or the tank. During each sampling, four (4) samples were taken in order to get an accurate representation of the particulate content of the WFI. As can be seen in the results, in a group of four samples one sample reading may stray from the average count of the others. Including four readings allowed for a better indication of the true result.

For this study Water for Injection was chosen because of its aggressive nature and low lubricity. Because of this, the bearings will generate particulate faster than in a substance that would provide more lubricity. The test was performed at the maximum mixer speed of 175 RPM

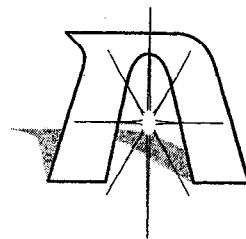
to simulate the most mechanically stressing condition. Although subjected to a five-day study involving factors which represent a worst case scenario, the bearings passed the light obscuration particle count test with an amount of particulate generation that falls within the set USP limits for large volume injectables.

## **Appendix A**

### **Results of Light Obscuration Particulate Count Test**

# Northview Laboratories, Inc.

1880 Holste Road ✧ Northbrook, IL 60062 ✧ 847/564-8181 ✧ Fax 847/564-8269



## REPORT OF ANALYSIS

CLIENT 4473-0

REPORT DATE: 3/9/00

Ms. Kathryn Wolf  
Oak Grove Technologies  
975 Campus Drive  
Mundelein IL 60060

NV REPORT NUMBER: T0C001

YOUR P.O. NUMBER: 5393

### SAMPLE IDENTIFICATION

120 mL of WFI  
4 x 120 mL colorless liquid in translucent bottles with screw caps  
Sample Code: 0302001  
Bottle Number: 1-1, 1-2, 1-3, 1-4  
Date Received: 3/3/00

### TEST PARTICULATE MATTER – LIGHT OBSCURATION METHOD

### RESULTS

Date Tested: 3/7/00

The sample was mixed by inverting twenty-five times within ten seconds and then allowed a two minute stabilizing period. Three separate 5 mL aliquots were run through an electronic liquid particle counting system. The data provided is based on the average of the second and third runs.

<u>Bottle Number</u>	<u>Time</u>	<u>Average Particle Count per mL</u>	
		<u>≥ 10 μm</u>	<u>≥ 25 μm</u>
1-1	9:45 AM	9.5	1.1
1-2	9:45 AM	7.6	0.6
1-3	10:10 AM	6.4	0.1
1-4	10:10 AM	3.0	0.4

**PROCEDURE REFERENCE**  
USP 24 <788> Light Obscuration Method

**NORTHVIEW LABORATORIES, INC.**

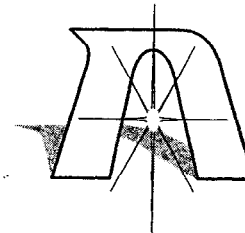
*Rene K. Wilmot*  
Rene K. Wilmot 3/9/00

:pl



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## REPORT OF ANALYSIS

CLIENT 4473-0

REPORT DATE: 3/9/00

Ms. Kathryn Wolf  
Oak Grove Technologies  
975 Campus Drive  
Mundelein IL 60060

NV REPORT NUMBER: T0C002

YOUR P.O. NUMBER: 5393

### SAMPLE IDENTIFICATION

120 mL of WFI  
4 x 120 mL of colorless liquid in translucent bottles with screw caps  
Sample Code: 0302002  
Bottle Number: 2-1, 2-2, 2-3, 2-4  
Date Received: 3/3/00

### TEST

### PARTICULATE MATTER – LIGHT OBSCURATION METHOD

### RESULTS

Date Tested: 3/7/00

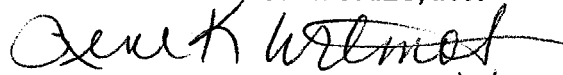
The sample was mixed by inverting twenty-five times within ten seconds and then allowed a two minute stabilizing period. Three separate 5 mL aliquots were run through an electronic liquid particle counting system. The data provided is based on the average of the second and third runs.

<u>Bottle Number</u>	<u>Time</u>	<u>Average Particle Count per mL</u>	
		<u>≥ 10 μm</u>	<u>≥ 25 μm</u>
2-1	10:25 AM	22.7	2.4
2-2	10:26 AM	6.5	0.6
2-3	10:28 AM	7.0	0.5
2-4	10:29 AM	4.0	0.2

### PROCEDURE REFERENCE

USP 24 <788> Light Obscuration Method

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Rene K. Wilmot 3/9/00

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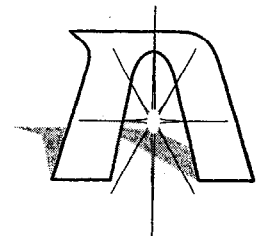
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## REPORT OF ANALYSIS

CLIENT 4473-0

REPORT DATE: 3/14/00

Ms. Kathryn Wolf  
Oak Grove Technologies  
975 Campus Drive  
Mundelein IL 60060

NV REPORT NUMBER: T0C003

YOUR P.O. NUMBER: 5393

### SAMPLE IDENTIFICATION

120 mL of WFI  
4 x 120 mL of colorless liquid in translucent bottles with screw caps  
Sample Code: 0302003  
Bottle Number: 3-1, 3-2, 3-3, 3-4  
Date Received: 3/6/00

TEST PARTICULATE MATTER – LIGHT OBSCURATION METHOD

### RESULTS

Date Tested: 3/8/00

The sample was mixed by inverting twenty-five times within ten seconds and then allowed a two minute stabilizing period. Three separate 5 mL aliquots were run through an electronic liquid particle counting system. The data provided is based on the average of the second and third runs.

Bottle Number	Time	Average Particle Count per mL	
		$\geq 10 \mu\text{m}$	$\geq 25 \mu\text{m}$
3-1	5:57 PM	7.7	0.9
3-2	5:58 PM	5.6	0.5
3-3	5:58 PM	7.0	0.2
3-4	5:59 PM	7.7	0.2

Note: Samples were refrigerated prior to testing.

PROCEDURE REFERENCE  
USP 24 <788> Light Obscuration Method

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*Rene K. Wilmot*  
3/14/00

Rene K. Wilmot, Team Leader

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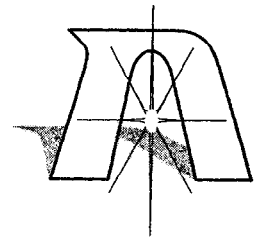
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## REPORT OF ANALYSIS

CLIENT 4473-0

REPORT DATE: 3/14/00

Ms. Kathryn Wolf  
Oak Grove Technologies  
975 Campus Drive  
Mundelein IL 60060

NV REPORT NUMBER: T0C004

YOUR P.O. NUMBER: 5393

### SAMPLE IDENTIFICATION

120 mL of WFI  
4 x 120 mL of colorless liquid in translucent bottles with screw caps  
Sample Code: 0303004  
Bottle Number: 4-1, 4-2, 4-3, 4-4  
Date Received: 3/6/00

### TEST

### PARTICULATE MATTER - LIGHT OBSCURATION METHOD

### RESULTS

Date Tested: 3/8/00

The sample was mixed by inverting twenty-five times within ten seconds and then allowed a two minute stabilizing period. Three separate 5 mL aliquots were run through an electronic liquid particle counting system. The data provided is based on the average of the second and third runs.


<u>Bottle Number</u>	<u>Time</u>	<u>Average Particle Count per mL</u>	
		<u>≥ 10 μm</u>	<u>≥ 25 μm</u>
4-1	6:15 AM	7.8	1.1
4-2	6:15 AM	7.3	1.5
4-3	6:15 AM	11.2	1.6
4-4	6:15 AM	11.8	2.0

Note: Samples were refrigerated prior to testing.

### PROCEDURE REFERENCE

USP 24 <788> Light Obscuration Method

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Rene K. Wilmot, Team Leader 3/14/00

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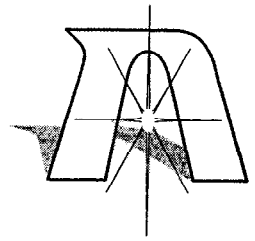
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## REPORT OF ANALYSIS

CLIENT 4473-0

REPORT DATE: 3/14/00

Ms. Kathryn Wolf  
Oak Grove Technologies  
975 Campus Drive  
Mundelein IL 60060

NV REPORT NUMBER: T0C010

YOUR P.O. NUMBER: 5393

### SAMPLE IDENTIFICATION

120 mL of WFI  
4 x 120 mL of colorless liquid in translucent bottles with screw caps  
Sample Code: 0303005  
Bottle Number: 5-1, 5-2, 5-3, 5-4  
Date Received: 3/7/00

### TEST PARTICULATE MATTER – LIGHT OBSCURATION METHOD

### RESULTS

Date Tested: 3/9/00


The sample was mixed by inverting twenty-five times within ten seconds and then allowed a two minute stabilizing period. Three separate 5 mL aliquots were run through an electronic liquid particle counting system. The data provided is based on the average of the second and third runs.

<u>Bottle Number</u>	<u>Time</u>	<u>Average Particle Count per mL</u>	
		<u>≥ 10 μm</u>	<u>≥ 25 μm</u>
(5-1)	5:56 PM	6.2	0.7
(5-2)	5:56 PM	9.8	1.1
(5-3)	5:56 PM	8.1	1.0
(5-4)	5:56 PM	9.3	0.3

Note: Samples were refrigerated prior to testing.

**PROCEDURE REFERENCE**  
USP 24 <788> Light Obscuration Method

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Rene K. Wilmot, Team Leader 3/14/00

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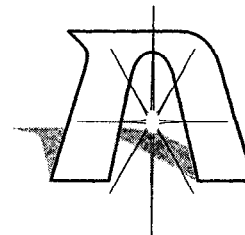
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## REPORT OF ANALYSIS

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REPORT DATE: 3/14/00

Ms. Kathryn Wolf  
Oak Grove Technologies  
975 Campus Drive  
Mundelein IL 60060

NV REPORT NUMBER: T0C009

YOUR P.O. NUMBER: 5393

### SAMPLE IDENTIFICATION

120 mL of WFI  
4 x 120 mL of colorless liquid in translucent bottles with screw caps  
Sample Code: 0304006  
Bottle Number: 6-1, 6-2, 6-3, 6-4  
Date Received: 3/7/00

### TEST

### PARTICULATE MATTER – LIGHT OBSCURATION METHOD

### RESULTS

Date Tested: 3/9/00

The sample was mixed by inverting twenty-five times within ten seconds and then allowed a two minute stabilizing period. Three separate 5 mL aliquots were run through an electronic liquid particle counting system. The data provided is based on the average of the second and third runs.

Bottle Number	Time	Average Particle Count per mL	
		$\geq 10 \mu\text{m}$	$\geq 25 \mu\text{m}$
6-1	5:30 PM	24.6	2.1
6-2	5:30 PM	9.8	0.6
6-3	5:30 PM	19.9	1.4
6-4	5:30 PM	16.2	2.6

Note: Samples were refrigerated prior to testing.

### PROCEDURE REFERENCE

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3/14/00

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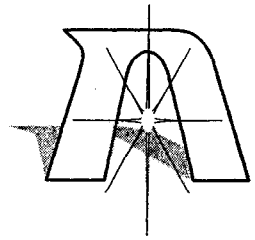
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## REPORT OF ANALYSIS

CLIENT 4473-0

REPORT DATE: 3/14/00

Ms. Kathryn Wolf  
Oak Grove Technologies  
975 Campus Drive  
Mundelein IL 60060

NV REPORT NUMBER: T0C008

YOUR P.O. NUMBER: 5393

### SAMPLE IDENTIFICATION

120 mL of WFI  
4 x 120 mL of colorless liquid in translucent bottles with screw caps  
Sample Code: 0304007  
Bottle Number: 7-1, 7-2, 7-3, 7-4  
Date Received: 3/7/00

### TEST PARTICULATE MATTER - LIGHT OBSCURATION METHOD

### RESULTS

Date Tested: 3/8/00

The sample was mixed by inverting twenty-five times within ten seconds and then allowed a two minute stabilizing period. Three separate 5 mL aliquots were run through an electronic liquid particle counting system. The data provided is based on the average of the second and third runs.

<u>Bottles</u> <u>Number</u>	<u>Time</u>	<u>Average Particle Count per mL</u>	
		<u>≥ 10 μm</u>	<u>≥ 25 μm</u>
7-1	6:05 PM	9.5	1.5
7-2	6:05 PM	11.0	0.8
7-3	6:05 PM	7.3	0.4
7-4	6:05 PM	13.4	1.5

Note: Samples were refrigerated prior to testing.

PROCEDURE REFERENCE  
USP 24 <788> Light Obscuration Method

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Rene K. Wilmot, Team Leader 3/14/00

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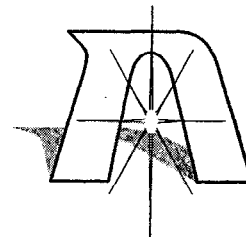
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## REPORT OF ANALYSIS

CLIENT 4473-0

REPORT DATE: 3/14/00

Ms. Kathryn Wolf  
Oak Grove Technologies  
975 Campus Drive  
Mundelein IL 60060

NV REPORT NUMBER: T0C007

YOUR P.O. NUMBER: 5393

### SAMPLE IDENTIFICATION

120 mL of WFI  
4 x 120 mL of colorless liquid in translucent bottles with screw caps  
Sample Code: 0305008  
Bottle Number: 8-1, 8-2, 8-3, 8-4  
Date Received: 3/7/00

### TEST PARTICULATE MATTER – LIGHT OBSCURATION METHOD

### RESULTS

Date Tested: 3/8/00

The sample was mixed by inverting twenty-five times within ten seconds and then allowed a two minute stabilizing period. Three separate 5 mL aliquots were run through an electronic liquid particle counting system. The data provided is based on the average of the second and third runs.

Bottle Number	Time	Average Particle Count per mL	
		$\geq 10 \mu\text{m}$	$\geq 25 \mu\text{m}$
8-1	6:10 AM	9.0	1.6
8-2	6:10 AM	8.0	1.1
8-3	6:10 AM	7.2	1.0
8-4	6:10 AM	11.1	0.8

Note: Samples were refrigerated prior to testing.

PROCEDURE REFERENCE  
USP 24 <788> Light Obscuration Method

NORTHVIEW LABORATORIES, INC.

Rene K. Wilmot, Team Leader

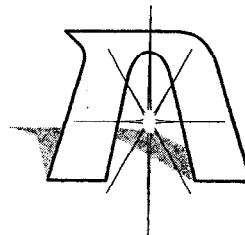
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## REPORT OF ANALYSIS

CLIENT 4473-0

REPORT DATE: 3/14/00

Ms. Kathryn Wolf  
Oak Grove Technologies  
975 Campus Drive  
Mundelein IL 60060

NV REPORT NUMBER: T0C006

YOUR P.O. NUMBER: 5393

### SAMPLE IDENTIFICATION

120 mL of WFI  
4 x 120 mL of colorless liquid in translucent bottles with screw caps  
Sample Code: 0305009  
Bottle Number: 9-1, 9-2, 9-3, 9-4  
Date Received: 3/7/00

### TEST

### PARTICULATE MATTER – LIGHT OBSCURATION METHOD

### RESULTS

Date Tested: 3/8/00

The sample was mixed by inverting twenty-five times within ten seconds and then allowed a two minute stabilizing period. Three separate 5 mL aliquots were run through an electronic liquid particle counting system. The data provided is based on the average of the second and third runs.


Bottle Number	Time	Average Particle Count per mL	
		$\geq 10 \mu\text{m}$	$\geq 25 \mu\text{m}$
9-1	6:05 PM	16.5	1.3
9-2	6:05 PM	24.7	2.6
9-3	6:05 PM	12.4	1.4
9-4	6:05 PM	13.4	0.9

Note: Samples were refrigerated prior to testing.

### PROCEDURE REFERENCE

USP 24 <788> Light Obscuration Method

NORTHVIEW LABORATORIES, INC.

  
Rene K. Wilmot, Team Leader 3/14/00

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Atlantic, Midwest, and Pacific

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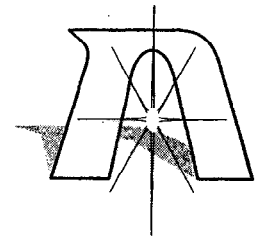
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# Northview Laboratories, Inc.

1880 Holste Road ✧ Northbrook, IL 60062 ✧ 847/564-8181 ✧ Fax 847/564-8269



## REPORT OF ANALYSIS

CLIENT 4473-0

REPORT DATE: 3/14/00

Ms. Kathryn Wolf  
Oak Grove Technologies  
975 Campus Drive  
Mundelein IL 60060

NV REPORT NUMBER: T0C005

YOUR P.O. NUMBER: 5393

### SAMPLE IDENTIFICATION

120 mL of WFI  
4 x 120 mL of colorless liquid in translucent bottles with screw caps  
Sample Code: 03060010  
Bottle Number: 10-1, 10-2, 10-3, 10-4  
Date Received: 3/7/00

### TEST PARTICULATE MATTER – LIGHT OBSCURATION METHOD

### RESULTS

Date Tested: 3/8/00

The sample was mixed by inverting twenty-five times within ten seconds and then allowed a two minute stabilizing period. Three separate 5 mL aliquots were run through an electronic liquid particle counting system. The data provided is based on the average of the second and third runs.

<u>Bottle Number</u>	<u>Time</u>	<u>Average Particle Count per mL</u>	
		<u>≥ 10 μm</u>	<u>≥ 25 μm</u>
10-1	6:10 AM	15.5	1.6
10-2	6:10 AM	4.9	0.9
10-3	6:10 AM	12.5	1.8
10-4	6:10 AM	14.2	1.3

Note: Samples were refrigerated prior to testing.

### PROCEDURE REFERENCE

USP 24 <788> Light Obscuration Method

NORTHVIEW LABORATORIES, INC.

Rene K. Wilmot, Team Leader

3/14/00

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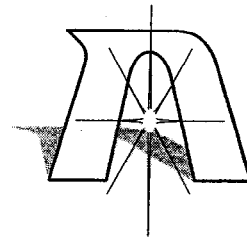
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## REPORT OF ANALYSIS

CLIENT 4473-0

REPORT DATE: 3/15/00

Ms. Kathryn Wolf  
Oak Grove Technologies  
975 Campus Drive  
Mundelein IL 60060

NV REPORT NUMBER: T0C012

YOUR P.O. NUMBER: 5393

### SAMPLE IDENTIFICATION

120 mL of WFI  
4 x 120 mL of colorless liquid in translucent bottles with screw caps  
Sample Code: 03060011  
Bottle Number: 11-1, 11-2, 11-3, 11-4  
Date Received: 3/8/00

### TEST PARTICULATE MATTER - LIGHT OBSCURATION METHOD

### RESULTS

Date Tested: 3/10/00

Each sample bottle was mixed by inverting twenty-five times within ten seconds and then allowed a two minute stabilizing period. Three separate 5 mL aliquots were run through an electronic liquid particle counting system. The data provided is based on the average of the second and third runs.

Bottle Number	Time	Average Particle Count per mL	
		$\geq 10 \mu\text{m}$	$\geq 25 \mu\text{m}$
11-1	5:56 PM	15.6	1.4
11-2	5:56 PM	11.8	1.7
11-3	5:56 PM	16.2	1.9
11-4	5:56 PM	12.4	0.8

Note: Samples were refrigerated prior to testing.

### PROCEDURE REFERENCE

USP 24 <788> Light Obscuration Method

NORTHVIEW LABORATORIES, INC.

Rene K. Wilmot, Team Leader

3/16/00

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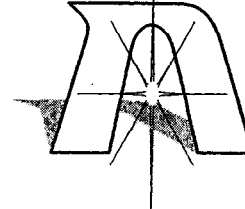
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## REPORT OF ANALYSIS

CLIENT 4473-0

REPORT DATE: 3/15/00

Ms. Kathryn Wolf  
Oak Grove Technologies  
975 Campus Drive  
Mundelein IL 60060

NV REPORT NUMBER: T0C011

YOUR P.O. NUMBER: 5393

### SAMPLE IDENTIFICATION

120 mL of WFI  
4 x 120 mL of colorless liquid in translucent bottles with screw caps  
Sample Code: 03070012  
Bottle Number: 12-1, 12-2, 12-3, 12-4  
Date Received: 3/8/00

### TEST

### PARTICULATE MATTER – LIGHT OBSCURATION METHOD

### RESULTS

Date Tested: 3/10/00

Each sample bottle was mixed by inverting twenty-five times within ten seconds and then allowed a two minute stabilizing period. Three separate 5 mL aliquots were run through an electronic liquid particle counting system. The data provided is based on the average of the second and third runs.

<u>Bottle Number</u>	<u>Time</u>	<u>Average Particle Count per mL</u>	
		<u>≥ 10 μm</u>	<u>≥ 25 μm</u>
12-1	6:15 AM	15.6	2.2
12-2	6:15 AM	20.7	0.8
12-3	6:15 AM	16.5	1.4
12-4	6:15 AM	20.5	0.8

Note: Samples were refrigerated prior to testing.

### PROCEDURE REFERENCE

USP 24 <788> Light Obscuration Method

NORTHVIEW LABORATORIES, INC.

*Rene K. Wilmot*  
Rene K. Wilmot, Team Leader 3/16/00

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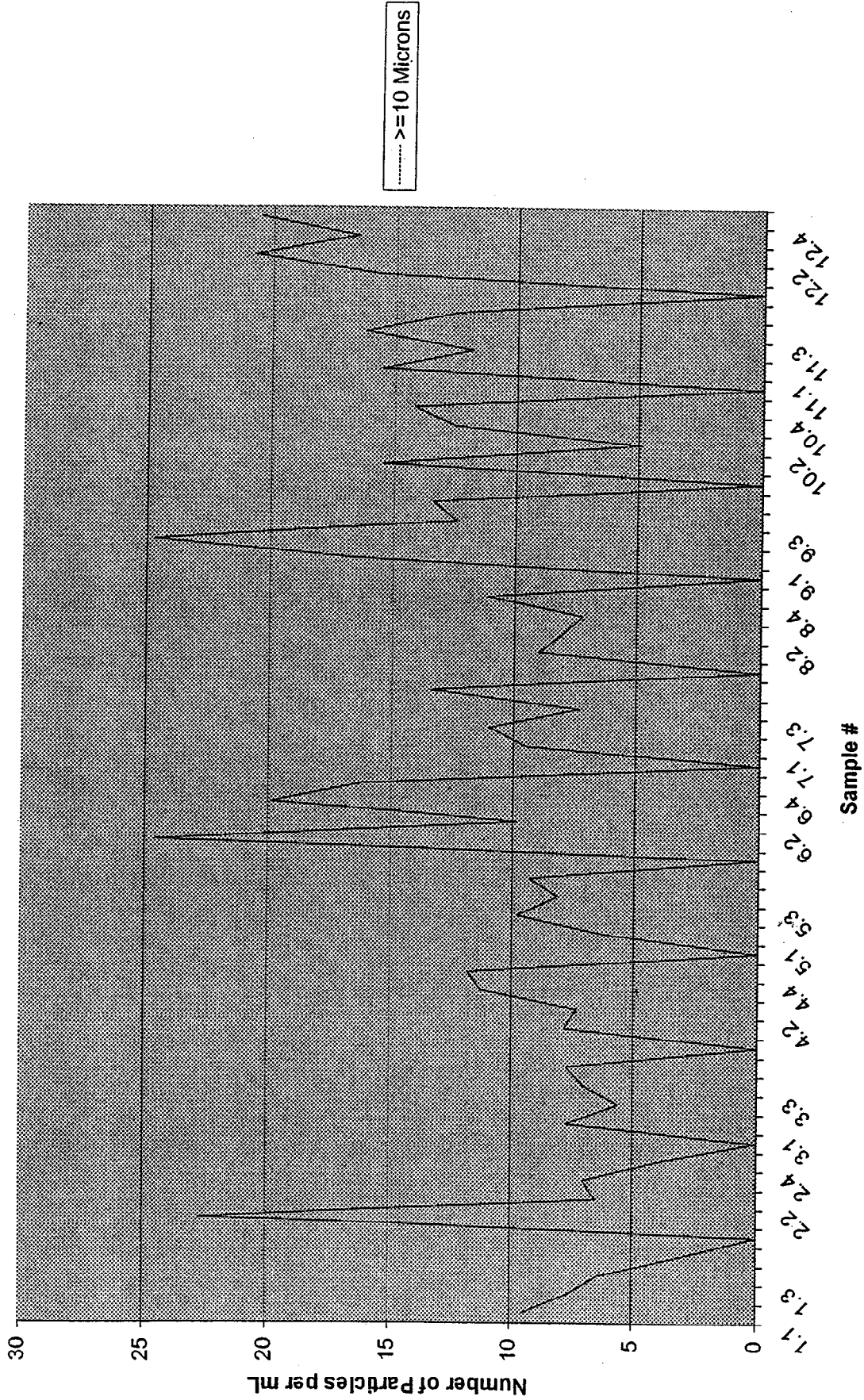
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# Average Particulate Greater than or Equal to 10 Microns



# Average Particulate Greater than or Equal to 25 Microns

