

October 13th 2008

To: XX

From: I. Vande Velde

Reference: 2008-024

Cc: XX

Re: IH monitoring Methylphenidate HCl (item 0009988 - 42 mg) during back-to-back cleaning activities press Korsch 3 (room 1313) and dump station press Korsch 3 (room 2307A) and charging press Korsch 3 (room 2307A), on September 17th, 19th, 23th and 26th 2008

Summary

Based on the sample results, the requirements for respiratory protection for back-to-back cleaning press Korsch 3 (including filters) needs to be changed in PAPR or air supplied hood (current PPE chart asks for a full facepiece).

Based on the sample results, the requirements for respiratory protection for back-to-back cleaning dump station press Korsch 3 can be reduced to half mask (current PPE chart asks for a full facepiece).

For charging to press Korsch 3 via dump station (rooms 2307A), more data points are needed before we can make a final decision.

Actions:

- *Adapt PPE charts for rooms 1313 and 2307A based on results of this report (Ingrid)*
- *Perform additional sampling for charging press Korsch 3 (Ingrid);*
- *Communicate results to operators (Ingrid works with Jardee).*

1. Aim of the monitoring

IH monitoring Methylphenidate HCl (item 0009988 - 42 mg) during back-to-back cleaning activities press Korsch 3 (room 1313) and dump station press Korsch 3 (room 2307A) and charging press Korsch 3 (room 2307A), on September 17th, 19th, 23th and 26th 2008 following our IH sampling plan for 2008.

Item 0009988: Core, OROS Methylphenidate HCl 42 mg - DL1: 11.5 % - DL2: 19.8 %.

2. Equipment

See attachment 1. for the detailed calibration information of the pumps.

Sampling filter: 25 mm 5 micron Teflon filter (IOM5).

3. Process description, sampling approach and analysis

3.1. *Process description, sampling approach and analysis*

Personal monitoring was performed of the operators during different activities.

3.1.1. Back-to-back cleaning press Korsch 3 (including filters) (room 1313)

On 09.17.08, 2 operators performed the back-to-back cleaning of press Korsch 3 (including filters: removing prefilters and cleaning HEPA-filters).

Operator 1:

- Removed filters from filter housing
- Vacuumed filter housing
- Cleaned out HEPA-filters.

Operator 2:

- Assisted operator 1 (weighing filters in bags, ...)
- Disconnected hose with tablets
- Vacuumed press and floor.

During this activity, the operators wore:

- standard GMP gowning
- PAPR
- white Tyvek and booties
- gloves.

3.1.2. Back-to-back cleaning dump station press Korsch 3 (room 2307A)

On 09.17.08, 09.19.08 and 09.23.08, monitoring was performed during cleaning of the dump station of press Korsch 3 (room 2307A). The top of the totes is vacuumed, totes are removed from the dump stations, the totes are cleaned at the outside with isopropanol wipes and the dump stations and surroundings are vacuumed.

During this activity, the operators wore:

- standard GMP gowning
- half mask (or no respiratory protection - depending on the operator)
- white Tyvek and booties (not done in all cases - depending on the operator)
- gloves.

3.1.3. Charging to press Korsch 3 via dump station (room 2307A)

On 09.26.08, a personal monitoring was performed of an operator while charging the tote to press Korsch 3 (= opening the valve).

During charging, the operator wore:

- standard GMP gowning
- gloves.

3.2. *Analysis*

The samples were analyzed by Bureau Veritas.

A high pressure liquid chromatography method was used:

Methylphenidate HCl: NAT-2002-03012

4. Results

<i>Nr.</i>	<i>Activity</i>	<i>Pump</i>	<i>Dur. (min)</i>	<i>Conc. Methylphenidate HCl ($\mu\text{g}/\text{m}^3$)</i>
09.17.08 - item: 0009988 - ID: 0823603				
28047244	Rooms 1313 - back-to-back cleaning press Korsch 3 (including filters) - operator 1 (worked most closely to the filters) (PAPR)	AVV3	44	920
28060711	Rooms 1313 - back-to-back cleaning press Korsch 3 (including filters) - operator 2 (assisted operator 1 with removing and cleaning filters) (PAPR)	AVV5	48	211*
28054677	Room 2307A - back-to-back cleaning dump station press Korsch 3 - operator 3, right side body (no extra respiratory protection)	AVV1	23	5.3
28054682	Room 2307A - back-to-back cleaning dump station press Korsch 3 - operator 3, left side body (no extra respiratory protection)	AVV2	28	7.2
28060696	Blank	-	-	< 0.1 μg on filter
09.19.08 - item: 0009988 - ID: 0823604				
28049551	Room 2307A - back-to-back cleaning dump station press Korsch 3 - operator 4 (no extra respiratory protection)	AVV5	22	19
28060723	Room 2307A - back-to-back cleaning dump station press Korsch 3 - operator 5 (no extra respiratory protection)	AVV1	23	34
09.23.08 - item: 0009988 - ID: 0823605				
28060692	Room 2307A - back-to-back cleaning dump station press Korsch 3 - operator 6 (half mask + white Tyvek + booties)	AVV1	22	78
28060732	Room 2307A - back-to-back cleaning dump station press Korsch 3 - operator 7 (half mask + white Tyvek + booties)	AVV3	22	3.3
09.26.08 - item: 0009988 - ID: not documented				
28047246	Room 2307A - charging Korsch 3 via dump station press Korsch 3 - operator 8 (no extra respiratory protection)	AVV4	11	7.5
28060693	Blank			< 0.1 μg on filter

* The volume was 95.2 liters (instead of 35.2 liters reported in the lab report) - the concentration was corrected taking into account the volume of 95.2 liters (= 211 $\mu\text{g}/\text{m}^3$ instead of 570 $\mu\text{g}/\text{m}^3$).

5. Discussion

Methylphenidate HCl:

The J&J occupational exposure limit based on an 8-hour TWA is 40 µg/m³.

The J&J occupational exposure limit based on a 12-hour extended work shift TWA is 20 µg/m³.

The J&J short term exposure limit based on a 15-minute time-weighted average is not defined.

In compression, operators work 8-hours shifts since September 2008.

5.1. Back-to-back cleaning press Korsch 3 (including filters) (room 1313)

Based on the statistical analysis on the 2 personal samples of this campaigns - combined with 3 results available from former sampling (see report 2000-015) - respiratory protection with an assigned protection factor (APF) of 1000 (= PAPR or air supplied hood) is needed to have enough confidence the operators are sufficient protected (see details in attachment 4a).

The PPE chart needs to be adapted to reflect this requirement (current PPE chart asks for a full facepiece).

5.2. Back-to-back cleaning dump station press Korsch 3 (room 2307A)

Based on the statistical analysis on the 6 personal samples, respiratory protection with an assigned protection factor (APF) of 10 (= half mask) is needed to have enough confidence the operators are sufficient protected (see details in attachment 4b).

The PPE requirements can be reduced for this activity (current PPE chart asks for a full facepiece).

5.3. Charging to press Korsch 3 via dump station (room 2307A)

For this activity, only 1 sample result is available at this time.

Based on the statistical analysis on the personal sample, we are only 71 % sure no respiratory protection is needed during the charging to the press.

More sampling is required before we can make a final decision.

6. Conclusion

Based on the sample results, the requirements for respiratory protection for back-to-back cleaning press Korsch 3 (including filters) needs to be changed in PAPR or air supplied hood (current PPE chart asks for a full facepiece).

Based on the sample results, the requirements for respiratory protection for back-to-back cleaning dump station press Korsch 3 can be reduced to half mask (current PPE chart asks for a full facepiece).

For charging to press Korsch 3 via dump station (room 2307A), more data points are needed before we can make a final decision.

Actions:

- Adapt PPE charts for rooms 1313 and 2307A based on results of this report (Ingrid);
-

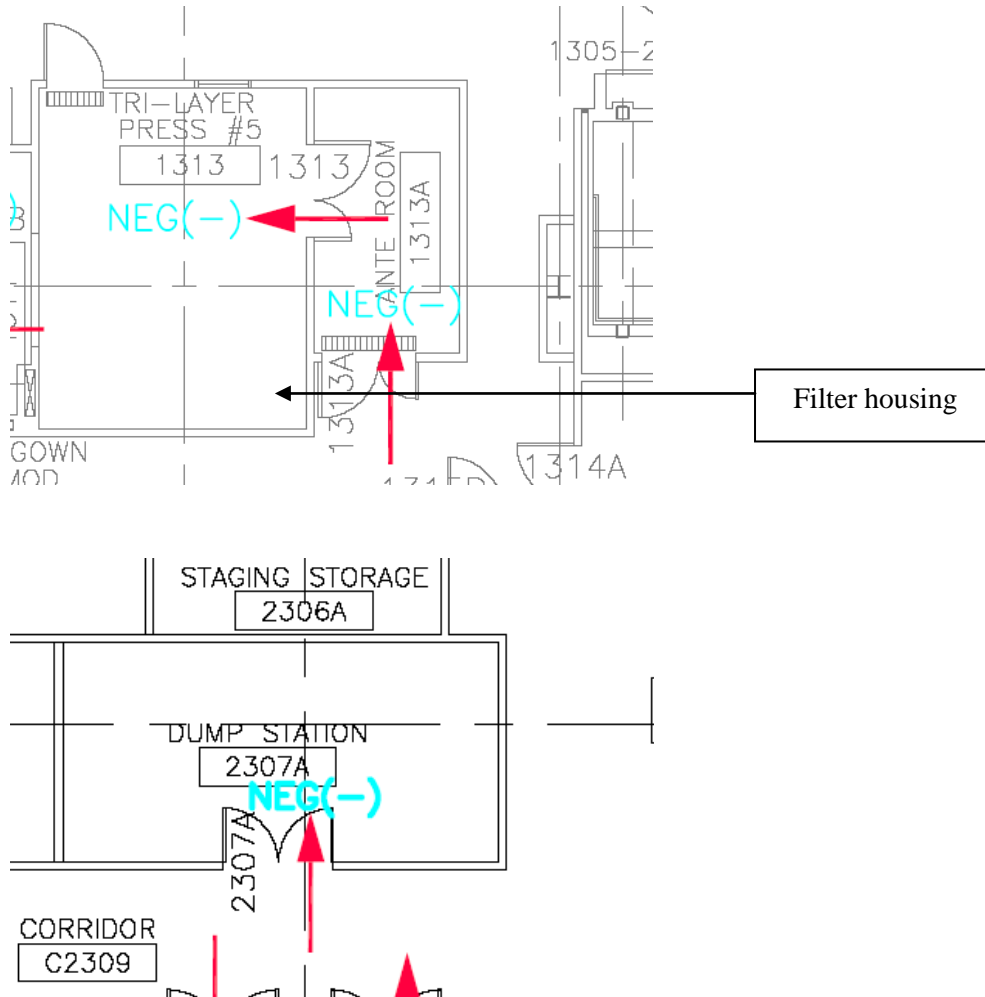
-
- Perform additional sampling for charging press Korsch 3 (Ingrid);
 - Communicate results to operators (Ingrid works with Jardee).

Kind regards,

Ingrid Vande Velde

- + attachment 1: Layout rooms 1313 and 2307A
 - + attachment 2: Calibration data of the pumps
 - + attachment 3: Pictures
 - + attachment 4: Statistical analysis data
 - + attachment 5: Analytical laboratory report Bureau Veritas 526300 and 526301
 - + attachment 6: Industrial hygiene field data sheets (in original report only)
-

Attachment 1: Layout rooms 1313 (press Korsch 3) and 2307A
 (dump station press Korsch 3)



Attachment 2: Calibration data of the pumps

Type	Number	Flow before (l/min)	Date	Flow after (l/min)	Date	Average flow (l/min)
Aircheck 2000	AVV3 (SN 787)	2.023	09.17.08	1.963	09.18.08	1.993
Aircheck 2000	AVV5 (SN 714)	2.002	09.17.08	1.965	09.18.08	1.983
Aircheck 2000	AVV1 (SN 791)	2.006	09.17.08	1.968	09.18.08	1.987
Aircheck 2000	AVV2 (SN 782)	2.028	09.17.08	1.969	09.18.08	1.999
Aircheck 2000	AVV5 (SN 714)	2.013	09.19.08	1.998	09.19.08	2.006
Aircheck 2000	AVV1 (SN 791)	1.997	09.19.08	2.030	09.19.08	2.014
Aircheck 2000	AVV1 (SN 791)	2.056	09.23.08	2.012	09.24.08	2.034
Aircheck 2000	AVV3 (SN 787)	2.032	09.23.08	1.991	09.24.08	2.012
Aircheck 2000	AVV4 (SN 787)	2.064	09.26.08	2.048	09.26.08	2.056

Attachment 3: Pictures



Back-to-back cleaning - press Korsch 3 - removing pre-filters



Back-to-back cleaning - press Korsch 3 - vacuuming filter housing



Back-to-back cleaning - press Korsch 3 - cleaning out HEPA-filters



Back-to-back cleaning - press Korsch 3 - disconnecting hoses with tablets



Back-to-back cleaning - dump station press Korsch 3 - vacuuming top tote



Back-to-back cleaning - dump station press Korsch 3 - vacuuming inflatable seal

Attachment 4a. Back-to-back cleaning press Korsch 3 (including filters)
(room 1313)

Version: IHDataAnalyst V1.0
Date: 10/14/2008 3:31:09 PM
File: G:\Vacaville\Reports IH\Reports IH 2007-2008\Statistics\2008-024a.xls

FACILITY INFORMATION

Facility: Vacaville (Alza - GPSG)
Department: OROS
Building: V2, room 1313
Process: Press Korsch 3
Task: Back-to-back cleaning press Korsch 3 (including filters) (room 1313)

SUBSTANCE INFORMATION

Substance: Methylphenidate HCl
OEL: 40 ug/m³

COMMENTS

Compression works 8 hour shifts since September 2008.

EXPOSURE ASSESSMENT SUMMARY

Final Rating:
Certainty Level:
Start Date:

Final APF:
Certainty Level:
Start Date:

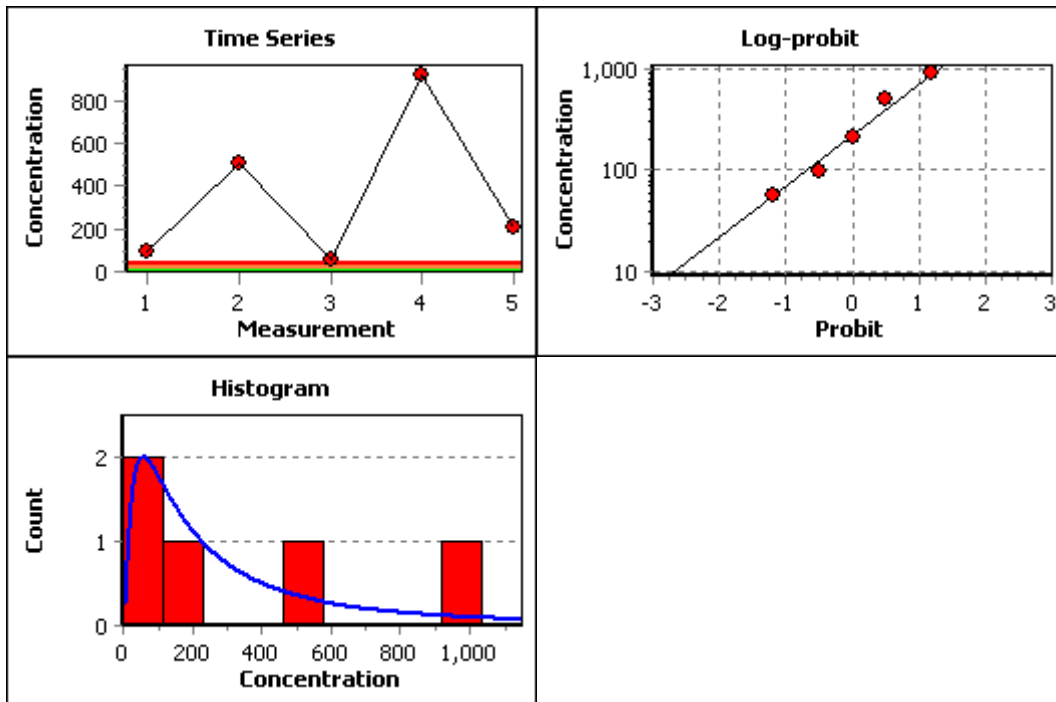
Final Rating w/ PPE:
Certainty Level:

GOODNESS-OF-FIT TEST

Subjective Analysis:
Do the data appear to be (reasonably) lognormal?
Comments:

Objective Analysis:
Fillibens Test: R = 0.991 critical R = 0.880
Interpretation: the lognormal distribution hypothesis is not rejected.
Comments:

Goodness-of-fit Charts:



ORDER STATISTICS

n = 5
min = 55.0000
max = 920.0000
median = 211.0000

DESCRIPTIVE STATISTICS

mean = 359.0000
sd = 361.0000
gm = 221.0000
gsd = 3.1800

COMPLIANCE STATISTICS

X0.95 = 1.48E0003 95%LCL = 569.0000 95%UCL = 2.85E0004
ExcFrac = 0.9300 95%LCL = 0.624 95%UCL = 0.994

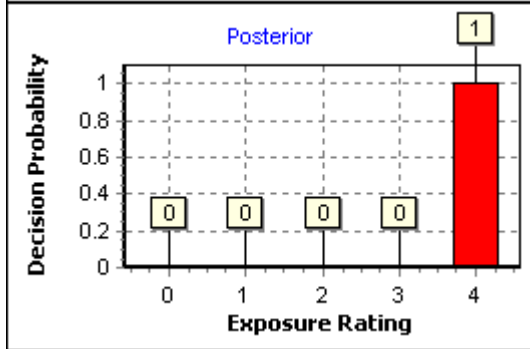
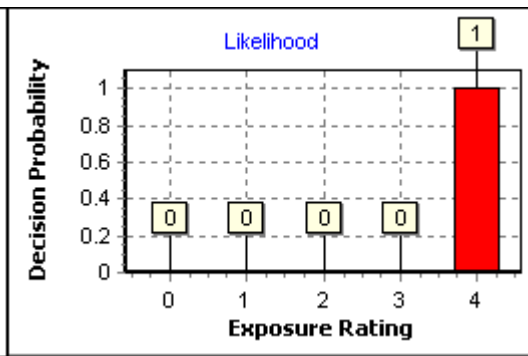
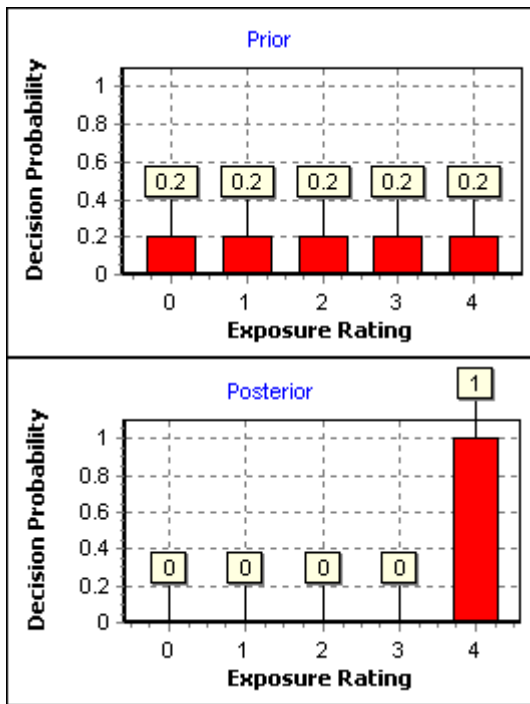
NON-PARAMETRIC COMPLIANCE STATISTICS

BAYESIAN DECISION ANALYSIS

WARNING: The true exposure profile GSD may exceed the maximum GSD set for the BDA "Parameter Space."

Exposure Rating:	0-T	1-HC	2-WC	3-C	4-PC
Cutoff	0.4	4	20	40	>40

(ug/m ³)					
Cutoff (%OEL)	1	10	50	100	>100
Prior	0.2	0.2	0.2	0.2	0.2
Likelihood	0.000	0.000	0.000	0.000	1.000
Posterior	0.000	0.000	0.000	0.000	1.000
Cum Likelihood	0.000	0.000	0.000	0.000	
Cum Posterior	0.000	0.000	0.000	0.000	

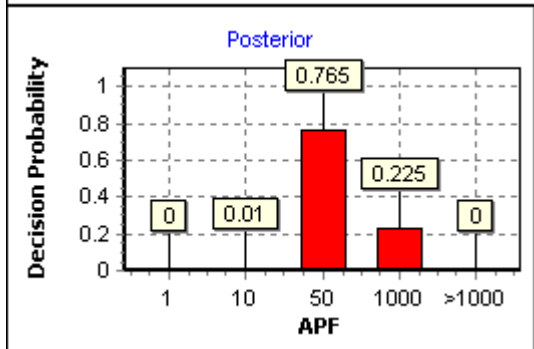
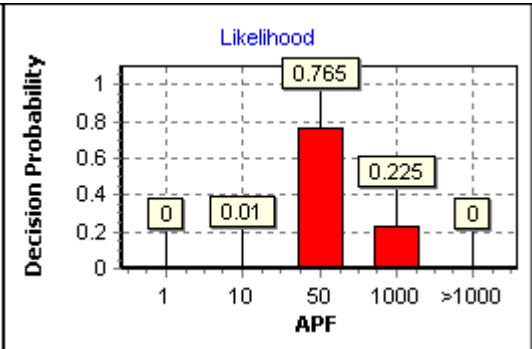
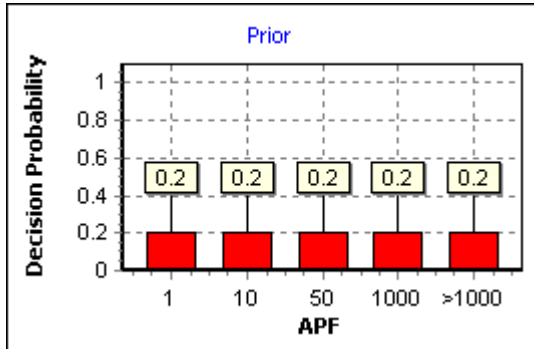


Parameter space: Gmin = 0.00818 Gmax = 200
 Dmin = 1.05 Dmax = 4

PPE SELECTION

WARNING: The true exposure profile GSD may exceed the maximum GSD set for the PPE "Parameter Space."

Respirator APF:	1	10	50	1000	>1000
Prior	0.2	0.2	0.2	0.2	0.2
Likelihood	0.000	0.010	0.765	0.225	0.000
Posterior	0.000	0.010	0.765	0.225	0.000



Parameter space:

Dmin = 1.05

Gmin = 2

Dmax = 4

Gmax = 2E5

Attachment 4b: Back-to-back cleaning dump station press Korsch 3
(room 2307A)

Version: IHDataAnalyst V1.0
Date: 10/14/2008 3:33:26 PM
File: G:\Vacaville\Reports IH\Reports IH 2007-2008\Statistics\2008-024b.xls

FACILITY INFORMATION

Facility: Vacaville (Alza - GPSG)
Department: OROS
Building: V2, room 2307A
Process: Press Korsch 3
Task: Back-to-back cleaning dump station press Korsch 3 (room 2307A)

SUBSTANCE INFORMATION

Substance: Methylphenidate HCl
OEL: 40 ug/m³

COMMENTS

Compression works 8 hour shifts since September 2008.

EXPOSURE ASSESSMENT SUMMARY

Final Rating:
Certainty Level:
Start Date:

Final APF:
Certainty Level:
Start Date:

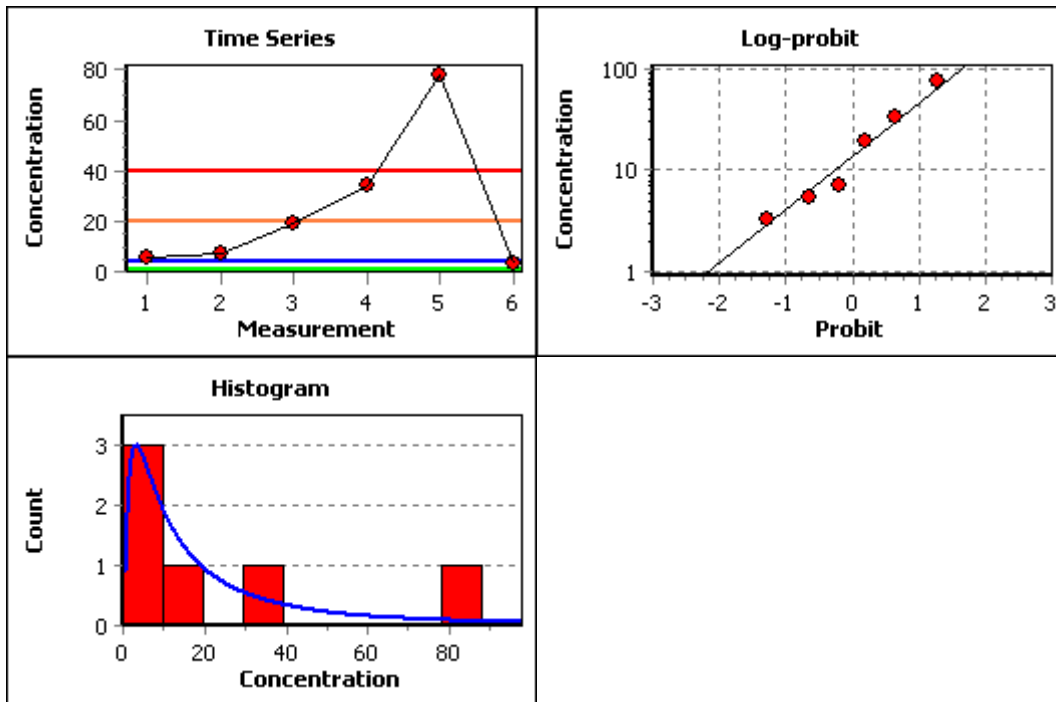
Final Rating w/ PPE:
Certainty Level:

GOODNESS-OF-FIT TEST

Subjective Analysis:
Do the data appear to be (reasonably) lognormal?
Comments:

Objective Analysis:
Fillibens Test: R = 0.984 critical R = 0.889
Interpretation: the lognormal distribution hypothesis is not rejected.
Comments:

Goodness-of-fit Charts:



ORDER STATISTICS

n = 6
 min = 3.3000
 max = 78.0000
 median = 13.1000

DESCRIPTIVE STATISTICS

mean = 24.5000
 sd = 28.6000
 gm = 13.6000
 gsd = 3.3500

COMPLIANCE STATISTICS

X0.95 = 99.3000 95%LCL = 39.2000 95%UCL = 1.2E0003
 ExcFrac = 0.1860 95%LCL = 0.048 95%UCL = 0.480

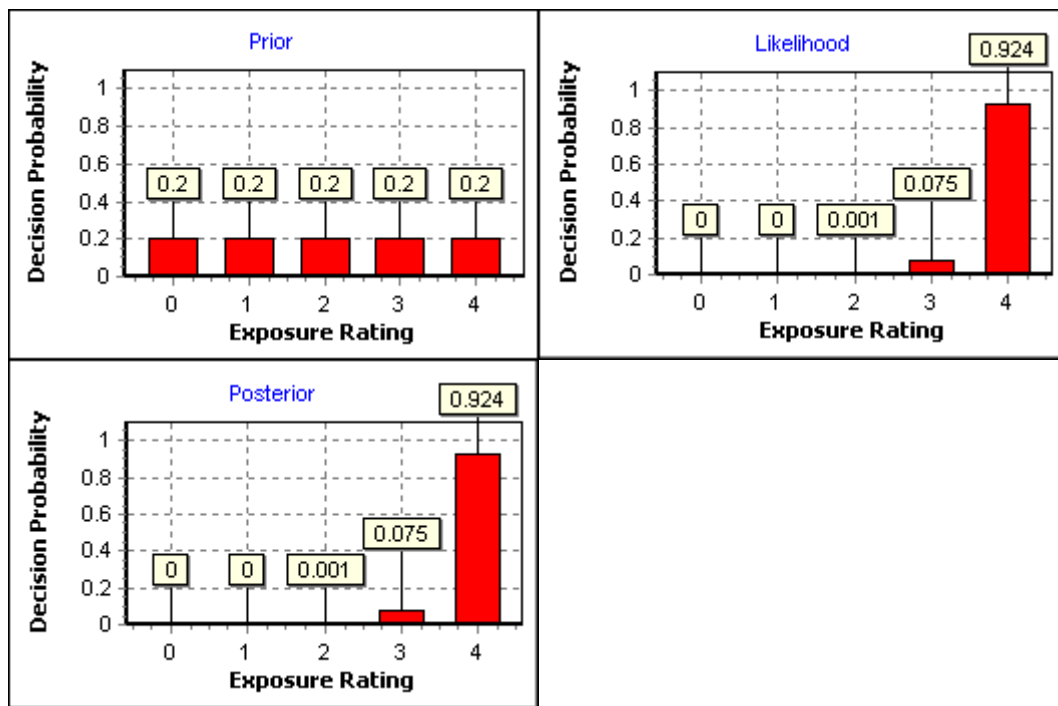
NON-PARAMETRIC COMPLIANCE STATISTICS

BAYESIAN DECISION ANALYSIS

WARNING: The true exposure profile GSD may exceed the maximum GSD set for the BDA "Parameter Space."

Exposure Rating:	0-T	1-HC	2-WC	3-C	4-PC
Cutoff	0.4	4	20	40	>40

(ug/m ³)					
Cutoff (%OEL)	1	10	50	100	>100
Prior	0.2	0.2	0.2	0.2	0.2
Likelihood	0.000	0.000	0.001	0.075	0.924
Posterior	0.000	0.000	0.001	0.075	0.924
Cum Likelihood	0.000	0.000	0.001	0.076	
Cum Posterior	0.000	0.000	0.001	0.076	

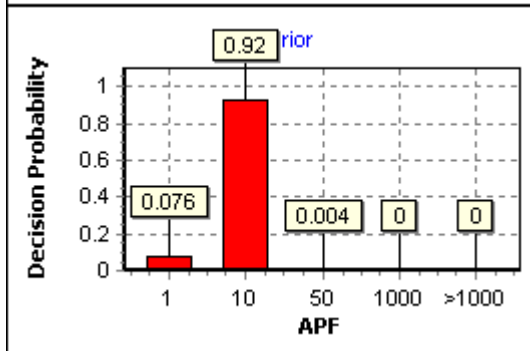
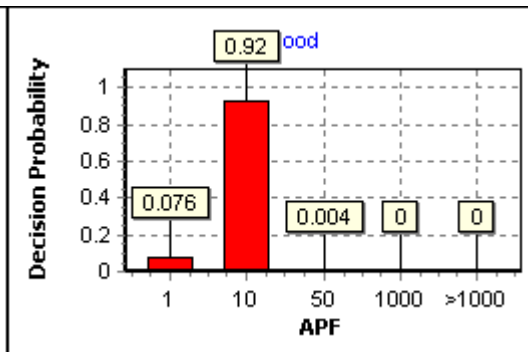
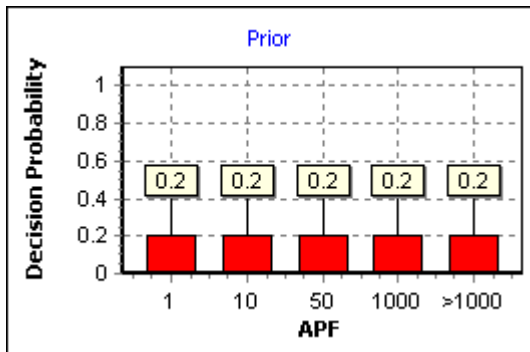


Parameter space: Gmin = 0.00818 Gmax = 200
Dmin = 1.05 Dmax = 4

PPE SELECTION

WARNING: The true exposure profile GSD may exceed the maximum GSD set for the PPE "Parameter Space."

Respirator APF:	1	10	50	1000	>1000
Prior	0.2	0.2	0.2	0.2	0.2
Likelihood	0.076	0.920	0.004	0.000	0.000
Posterior	0.076	0.920	0.004	0.000	0.000



Parameter space: Gmin = 2
 Dmin = 1.05 Dmax = 4

Gmax = 2E5

Attachment 4c: Charging to press Korsch 3 via dump station (rooms 2307A)

Version: IHDataAnalyst V1.0
Date: 10/14/2008 3:38:49 PM
File: G:\Vacaville\Reports IH\Reports IH 2007-2008\Statistics\2008-024c.xls

FACILITY INFORMATION

Facility: Vacaville (Alza - GPSG)
Department: OROS
Building: V2, room 2307A
Process: Press Korsch 3
Task: Charging press Korsch 3 via dump station (room 2307A)

SUBSTANCE INFORMATION

Substance: Methylphenidate HCl
OEL: 40 ug/m³

COMMENTS

Compression works 8 hour shifts since September 2008.

EXPOSURE ASSESSMENT SUMMARY

Final Rating:
Certainty Level:
Start Date:

Final APF:
Certainty Level:
Start Date:

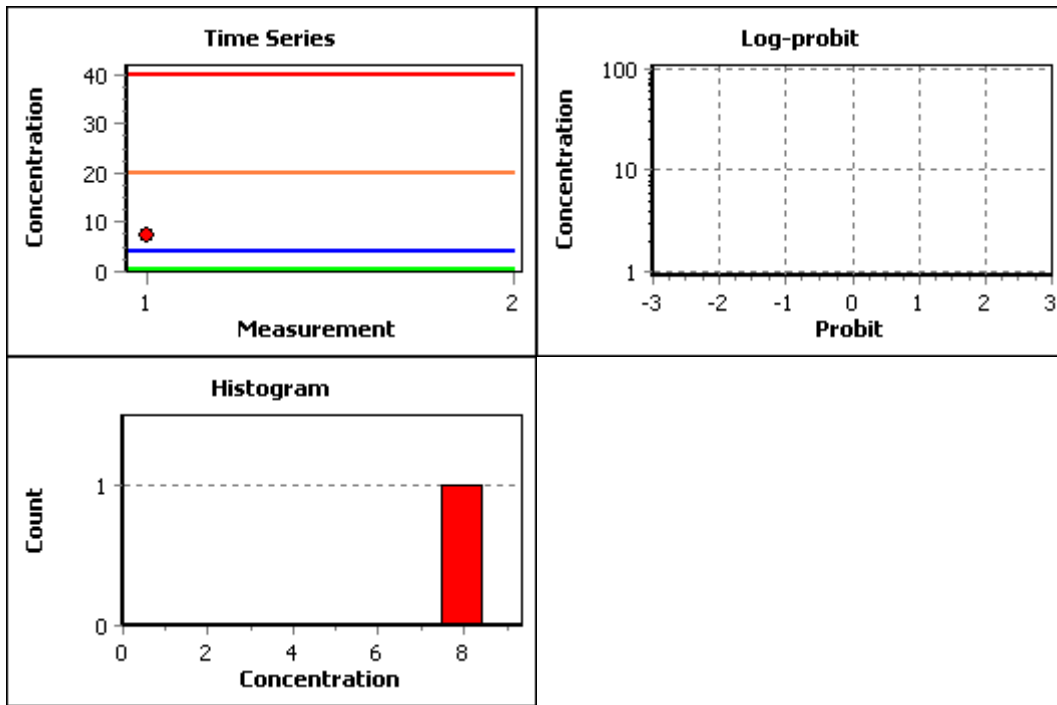
Final Rating w/ PPE:
Certainty Level:

GOODNESS-OF-FIT TEST

Subjective Analysis:
Do the data appear to be (reasonably) lognormal?
Comments:

Objective Analysis:
Note: n<3, cannot do GOF test
Comments:

Goodness-of-fit Charts:



ORDER STATISTICS

n = 1
 min = 7.5000
 max = 7.5000
 median = 7.5000

DESCRIPTIVE STATISTICS

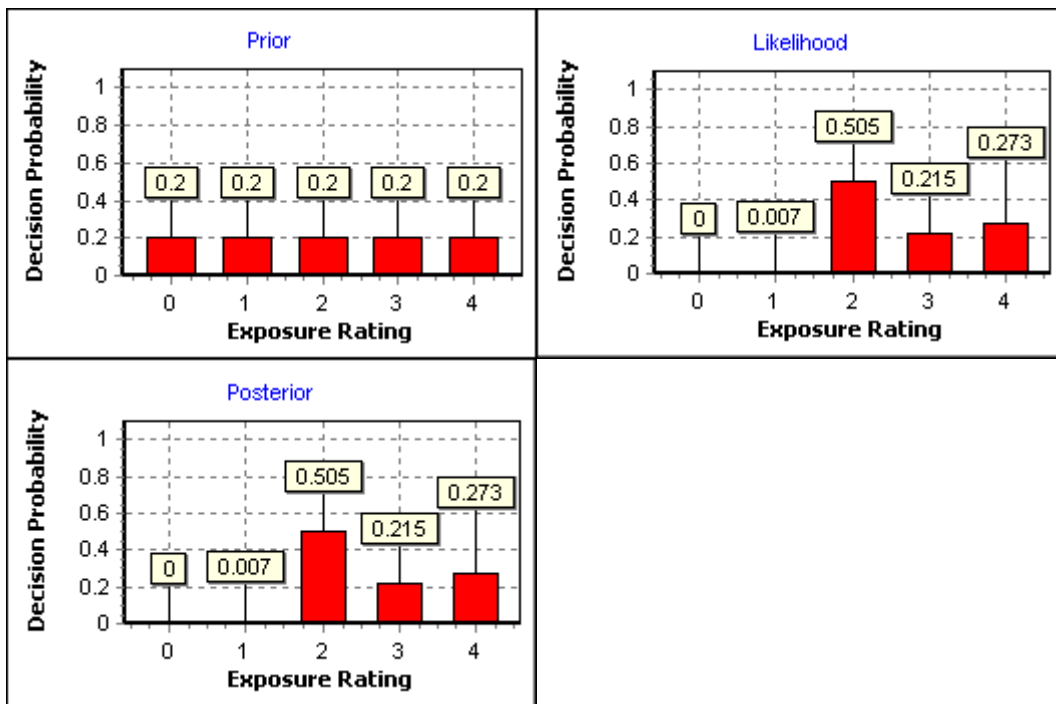
COMPLIANCE STATISTICS

NON-PARAMETRIC COMPLIANCE STATISTICS

BAYESIAN DECISION ANALYSIS

Exposure Rating:	0-T	1-HC	2-WC	3-C	4-PC
Cutoff (ug/m ³)	0.4	4	20	40	>40
Cutoff (%OEL)	1	10	50	100	>100
Prior	0.2	0.2	0.2	0.2	0.2
Likelihood	0.000	0.007	0.505	0.215	0.273
Posterior	0.000	0.007	0.505	0.215	0.273

Cum Likelihood	0.000	0.007	0.511	0.727	
Cum Posterior	0.000	0.007	0.511	0.727	



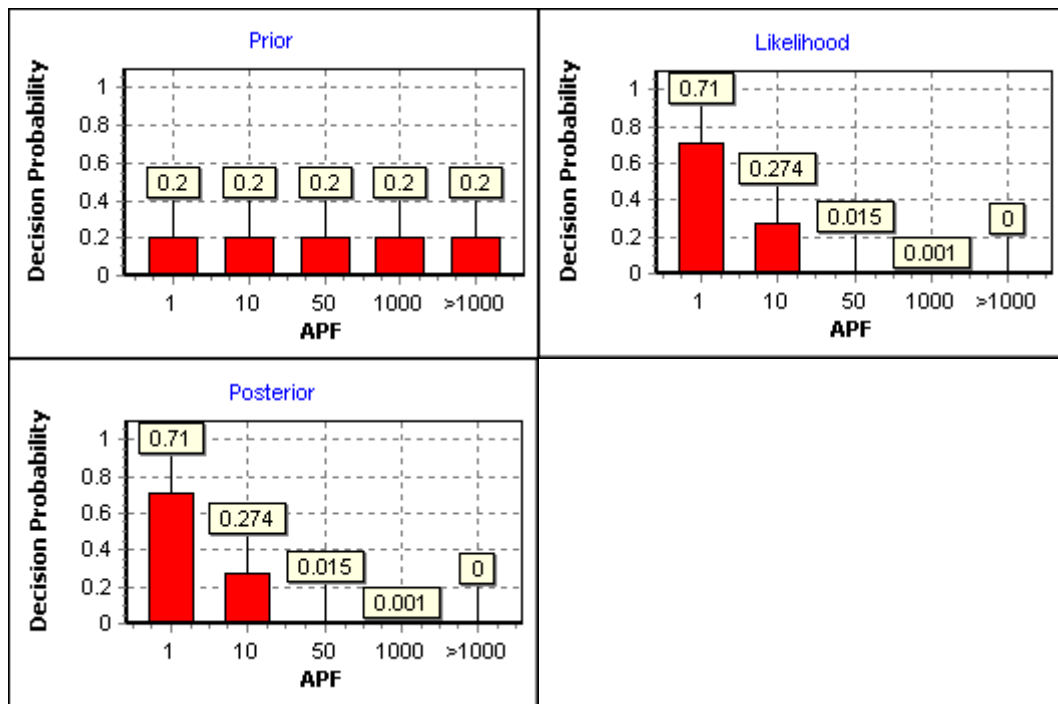
Parameter space:

Gmin = 0.00818
Dmin = 1.05

Gmax = 200

PPE SELECTION

Respirator APF:	1	10	50	1000	>1000
Prior	0.2	0.2	0.2	0.2	0.2
Likelihood	0.710	0.274	0.015	0.001	0.000
Posterior	0.710	0.274	0.015	0.001	0.000



Parameter space:
Dmin = 1.05

Gmin = 2
Dmax = 4

Gmax = 2E5



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Health, Safety & Environmental Services

Laboratory Analysis Report

Industrial Hygiene Laboratory
95 Oakwood Road
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Fax (847) 726-3323
Toll Free (888) 576-7522

TO:

INGRID VANDE VELDE
ALZA
700 EUBANKS DR.
VACAVILLE, CA 95688
USA

REPORT DATE OCT 03, 2008
SAMPLES REC'D SEP 24, 2008
REQUEST NUMBER 526300
PAGE NUMBER 1 OF 5

SAMPLE	AIR VOLUME / ANALYSIS REQUESTED	MEDIA TYPE / RESULTS	ANALYZED DATE
28055377	186.63 Liters ACETAMINOPHEN HYDROCODONE BITARTRATE	25mm Glass Fiber Filter Micrograms 86 1.4	OCT 03, 2008 Micrograms/Cubic Meter 460 7.6
28055384	20.26 Liters ACETAMINOPHEN HYDROCODONE BITARTRATE	25mm Glass Fiber Filter Micrograms < 0.1 < 1.0	OCT 03, 2008 Micrograms/Cubic Meter < 4.9 < 49
28020098	ACETAMINOPHEN (BLANK) HYDROCODONE BITARTRATE (BLANK)	25mm Glass Fiber Filter Micrograms < 0.1 NONE DETECTED < 1.0 NONE DETECTED	OCT 03, 2008

COMMENTS:

IF PRESENT, DE MEANS DESORPTION EFFICIENCY

Respectfully submitted,

William M. Walsh, CIH, ROH
Vice President, Laboratory Services

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**BUREAU
VERITAS**

Bureau Veritas

Health, Safety & Environmental Services

Laboratory Analysis Report

Industrial Hygiene Laboratory
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Lake Zurich, IL 60047
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Fax (847) 726-3323
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TO:

INGRID VANDE VELDE
ALZA
700 EUBANKS DR.
VACAVILLE, CA 95688
USA

REPORT DATE OCT 03, 2008
SAMPLES REC'D SEP 24, 2008
REQUEST NUMBER 526300
PAGE NUMBER 2 OF 5

SAMPLE	AIR VOLUME / ANALYSIS REQUESTED	MEDIA TYPE / RESULTS	ANALYZED DATE
28047244	87.69 Liters METHYLPHENIDATE HCl	25mm 5 Micron Teflon Filter Micrograms 80	OCT 02, 2008 Micrograms/Cubic Meter 920
28060711	35.2 Liters METHYLPHENIDATE HCl	25mm 5 Micron Teflon Filter Micrograms 20	OCT 02, 2008 Micrograms/Cubic Meter 570
28054677	45.7 Liters METHYLPHENIDATE HCl	25mm 5 Micron Teflon Filter Micrograms 0.24	OCT 02, 2008 Micrograms/Cubic Meter 5.3
28054682	55.96 Liters METHYLPHENIDATE HCl	25mm 5 Micron Teflon Filter Micrograms 0.4	OCT 02, 2008 Micrograms/Cubic Meter 7.2
28049551	44.12 Liters METHYLPHENIDATE HCl	25mm 5 Micron Teflon Filter Micrograms 0.83	OCT 02, 2008 Micrograms/Cubic Meter 19

COMMENTS:

IF PRESENT, DE MEANS DESORPTION EFFICIENCY

Respectfully submitted,

William M. Walsh, CIH, ROH
Vice President, Laboratory Services

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Health, Safety & Environmental Services

Laboratory Analysis Report

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Toll Free (888) 576-7522

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700 EUBANKS DR.
VACAVILLE, CA 95688
USA

REPORT DATE OCT 03, 2008
SAMPLES REC'D SEP 24, 2008
REQUEST NUMBER 526300
PAGE NUMBER 3 OF 5

SAMPLE	AIR VOLUME / ANALYSIS REQUESTED	MEDIA TYPE / RESULTS	ANALYZED DATE
28060723	46.31 Liters METHYLPHENIDATE HCl	25mm 5 Micron Teflon Filter Micrograms 1.6	OCT 02, 2008 Micrograms/Cubic Meter 34
28060696	METHYLPHENIDATE HCl (BLANK)	25mm 5 Micron Teflon Filter Micrograms < 0.1 NONE DETECTED	OCT 02, 2008

COMMENTS:

IF PRESENT, DE MEANS DESORPTION EFFICIENCY

Respectfully submitted,

William M. Walsh, CIH, ROH
Vice President, Laboratory Services

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Health, Safety & Environmental Services

Industrial Hygiene Laboratory

95 Oakwood Road
Lake Zurich, IL 60047
Phone (847) 726-3320
Fax (847) 726-3323
Toll Free (888) 576-7522

TO:

INGRID VANDE VELDE
ALZA
700 EUBANKS DR.
VACAVILLE, CA 95688
USA

REPORT DATE OCT 03, 2008
SAMPLES REC'D SEP 24, 2008
REQUEST NUMBER 526300
PAGE NUMBER 4 OF 5

REPORTING LIMIT	ANALYSIS REQUESTED	METHODOLOGY	CAS #
.1 Micrograms	ACETAMINOPHEN IOM2	NAT-2001-00827 HIGH PRESSURE LIQUID CHROMATOGRAPHY	103-90-2
1 Micrograms	HYDROCODONE BITARTRATE IOM2	NAT-2001-00995 HIGH PRESSURE LIQUID CHROMATOGRAPHY	143-71-5
.1 Micrograms	METHYLPHENIDATE HCl IOM5	NAT-2002-03012 HIGH PRESSURE LIQUID CHROMATOGRAPHY	298-59-9

COMMENTS:

- * CONCENTRATION CALCULATED USING AIR VOLUMES SUPPLIED BY CLIENT
- * UNLESS OTHERWISE NOTED, SAMPLES RECEIVED IN GOOD CONDITION
- * MODIFICATIONS MAY BE MADE TO ABOVE METHODS TO OPTIMIZE RESULTS (AVAILABLE UPON REQUEST)
- * RESULTS ARE STRICTLY LIMITED TO SAMPLES ANALYZED

Respectfully submitted,

William M. Walsh, CIH, ROH
Vice President, Laboratory Services

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BUREAU
VERITAS

Bureau Veritas

Health, Safety & Environmental Services

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REQUEST CLIENT COMMENTS:

REQUEST LAB COMMENTS:

REF: PO #992024112.

UNLESS OTHERWISE NOTED, ALL QC CRITERIA WERE MET.

Respectfully submitted,

William M. Walsh, CIH, ROH
Vice President, Laboratory Services

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Health, Safety & Environmental Services

Laboratory Analysis Report

Industrial Hygiene Laboratory
95 Oakwood Road
Lake Zurich, IL 60047
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REPORT DATE OCT 08, 2008
SAMPLES REC'D SEP 30, 2008
REQUEST NUMBER 526301
PAGE NUMBER 1 OF 5

SAMPLE	AIR VOLUME / ANALYSIS REQUESTED	MEDIA TYPE / RESULTS	ANALYZED DATE
28055387	19.8 Liters ACETAMINOPHEN HYDROCODONE BITARTRATE	25mm Glass Fiber Filter Micrograms 0.25 < 1.0	OCT 03, 2008 Micrograms/Cubic Meter 13 < 51
28020111	20.36 Liters ACETAMINOPHEN HYDROCODONE BITARTRATE	25mm Glass Fiber Filter Micrograms 0.12 < 1.0	OCT 03, 2008 Micrograms/Cubic Meter 6.1 < 49
28055393	20.5 Liters ACETAMINOPHEN HYDROCODONE BITARTRATE	25mm Glass Fiber Filter Micrograms 0.31 < 1.0	OCT 03, 2008 Micrograms/Cubic Meter 15 < 49

COMMENTS:

IF PRESENT, DE MEANS DESORPTION EFFICIENCY

Respectfully submitted,

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PAGE NUMBER 2 OF 5

SAMPLE	AIR VOLUME / ANALYSIS REQUESTED	MEDIA TYPE / RESULTS	ANALYZED DATE
28055447	ACETAMINOPHEN (BLANK) HYDROCODONE BITARTRATE (BLANK)	25mm Glass Fiber Filter Micrograms < 0.1 NONE DETECTED < 1.0 NONE DETECTED	OCT 03, 2008
28060692	44.75 Liters METHYLPHENIDATE HCl	25mm 5 Micron Teflon Filter Micrograms 3.5	OCT 02, 2008 Micrograms/Cubic Meter 78
28060732	44.25 Liters METHYLPHENIDATE HCl	25mm 5 Micron Teflon Filter Micrograms 0.15	OCT 02, 2008 Micrograms/Cubic Meter 3.3
28047246	22.62 Liters METHYLPHENIDATE HCl	25mm 5 Micron Teflon Filter Micrograms 0.17	OCT 02, 2008 Micrograms/Cubic Meter 7.5

COMMENTS:

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SAMPLE	AIR VOLUME / ANALYSIS REQUESTED	MEDIA TYPE / RESULTS	ANALYZED DATE
28060735	20.39 Liters METHYLPHENIDATE HCl	25mm 5 Micron Teflon Filter Micrograms 2.8	OCT 02, 2008 Micrograms/Cubic Meter 140
28060693	METHYLPHENIDATE HCl (BLANK)	25mm 5 Micron Teflon Filter Micrograms < 0.1 NONE DETECTED	OCT 02, 2008

COMMENTS:

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REQUEST LAB COMMENTS:

REF: P.O. #992024112.

UNLESS OTHERWISE NOTED, ALL QC CRITERIA WERE MET.
PARTIAL REPORT, HYDROMORPHONE RESULTS WILL BE SENT AS
SOON AS THEY ARE COMPLETED.

Respectfully submitted,

William M. Walsh, CIH, ROH
Vice President, Laboratory Services

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