



# Validated Performance

the key to any Flexible Containment System



...make the data driven choice with ILC Dover.

ILC Dover has been creating innovative Flexible Containment Systems for pharmaceutical customers since 1998. During that time ILC, third parties, and our customers have generated a considerable array of containment data that verifies performance levels ranging from 1  $\mu\text{g}/\text{m}^3$  down to 4 nanogram/ $\text{m}^3$ .

## DOVERPAC<sup>®</sup>

- Our flagship product that offers the capability of offloading and charging potent compounds.

Date of Monitoring: January 16, 2008

Location: ILC Dover, Frederica, Delaware

Analyte: Lactose

Sample Medium: 25-mm Polytetrafluoroethylene Filter (1.0- $\mu\text{m}$  Pore Size) in Two-Piece Conductive Cassette

### Personal Sample Breathing Zone (PSBZ)

Sample Set	N	Mean	Range Lowest	Highest	Standard Deviation	Stan- dard Error	95% Confidence Interval for Population Mean
Personal Sample Breathing Zone (PSBZ) – ILC DoverPac <sup>®</sup> System and cutting and crimping of liner							
Transfer of lactose - includes both filling DoverPac <sup>®</sup> from vessel and discharge of DoverPac <sup>®</sup> to vessel	12	0.078 $\mu\text{g}/\text{m}^3$	0.012 $\mu\text{g}/\text{m}^3$	0.23 $\mu\text{g}/\text{m}^3$	0.076 $\mu\text{g}/\text{m}^3$	0.022	0.0295 to 0.127 $\mu\text{g}/\text{m}^3$
Filling DoverPac <sup>®</sup> from vessel only	6	0.027 $\mu\text{g}/\text{m}^3$	0.012 $\mu\text{g}/\text{m}^3$	0.047 $\mu\text{g}/\text{m}^3$	0.013 $\mu\text{g}/\text{m}^3$	0.0053	0.0131 to 0.0402 $\mu\text{g}/\text{m}^3$
Discharge DoverPac <sup>®</sup> from vessel only	6	0.13 $\mu\text{g}/\text{m}^3$	0.030 $\mu\text{g}/\text{m}^3$	0.23 $\mu\text{g}/\text{m}^3$	0.080 $\mu\text{g}/\text{m}^3$	0.033	0.0460 to 0.213 $\mu\text{g}/\text{m}^3$



Notes: All airborne contaminant concentrations are expressed in micrograms of the surrogate test compound per cubic meter of air ( $\mu\text{g}/\text{m}^3$ ).

"N" refers to the number of data points included in the sample population.

## COMIL ENCLOSURE

- Robust clear enclosure safely provides containment during milling operations.

Trial #	Sample Details	Sampling Time (minutes)	Mean Flow Rate (l.min <sup>-1</sup> )	Total Volume (m <sup>3</sup> )	Mass of API Detected (µg)	Airborne Concentration of API (µg.m <sup>-3</sup> )	8-hour TWA Exposure (µg.m <sup>-3</sup> )
1	Personal sample 9943	78	2	0.156	<0.015	<0.096	<0.016
2	Personal sample 9948	57	2	0.114	<0.015	<0.13	<0.015

The containment data for the Comil Flexible Enclosure was generated by Vega Consulting.



Vega is an independent occupational hygiene consultancy located in the North East of England which was established in 1989 by Ed Brown, our technical director. We provide our customers with a comprehensive range of Occupational Hygiene Services to ensure that their working environments meet the appropriate standards and thereby ensure that their staff are safe from exposure to workplace physical, biological and chemical agents.

## DRUM TRANSFER SYSTEM

For offloading drummed materials in a safe and efficient manner at fixed and varying heights.

Date of Monitoring: March 5, 2008

Location: ILC Dover, Frederica, Delaware

Analyte: Lactose

Sample Medium: 25-mm Polytetrafluoroethylene Filter (1.0-µm Pore Size) in Two-Piece Conductive Cassette

Personal Sample Breathing Zone (PSBZ)



Sample Set	N	Mean	Range		Standard Deviation	Standard Error	95% Confidence Interval for Population Mean
			Lowest	Highest			
Personal Sample Breathing Zone (PSBZ) – Discharge of Drums Through Drum Transfer Station Using Neck Dam Connection With Standard Crimp Separation (With And Without Enclosure Change)							
With and without enclosure change	12	0.072 µg/m <sup>3</sup>	0.020 µg/m <sup>3</sup>	0.17 µg/m <sup>3</sup>	0.052 µg/m <sup>3</sup>	0.015	0.0382 to 0.105 µg/m <sup>3</sup>
Without enclosure change	6	0.066 µg/m <sup>3</sup>	0.020 µg/m <sup>3</sup>	0.15 µg/m <sup>3</sup>	0.052 µg/m <sup>3</sup>	0.021	0.0113 to 0.120 µg/m <sup>3</sup>
With enclosure change	6	0.078 µg/m <sup>3</sup>	0.035 µg/m <sup>3</sup>	0.17 µg/m <sup>3</sup>	0.058 µg/m <sup>3</sup>	0.024	0.0172 to 0.138 µg/m <sup>3</sup>
Personal Sample Breathing Zone (PSBZ) – Discharging Drums Through Drum Transfer Station Using Bag Sleeve Transfer							
Using bag sleeve transfer	6	0.015 µg/m <sup>3</sup>	0.0074 µg/m <sup>3</sup>	0.043 µg/m <sup>3</sup>	0.014 µg/m <sup>3</sup>	0.0057	0.000483 to 0.0298 µg/m <sup>3</sup>

Notes: All airborne contaminant concentrations are expressed in micrograms of the surrogate test compound per cubic meter of air (µg/m<sup>3</sup>).

"N" refers to the number of data points included in the sample population.

# Validated Performance

The containment data for both the DoverPac system and the Drum Transfer System was generated by IES Engineers.



IES is a fully integrated engineering and environmental, health, and safety consulting firm providing an extensive range of technical services to the bio/pharmaceutical, healthcare, specialty chemical, food, printing, and industrial sectors.

## ILC Dover's Proven Process



Since 1947, ILC Dover has built a global reputation for out-of-the-box thinking that makes the seemingly impossible possible. Our engineered solutions solve our customers' most complex challenges through the creative and efficient application of flexible materials often integrated with advanced equipment and hardware.

We look beyond the boundaries of convention to help customers see what could be. Every day, everything we do brings new solutions to light. Are you ready to take your vision beyond boundaries? *Let's talk.*



One Moonwalker Road  
Frederica, DE 19946 USA  
+1.302.335.3911  
+1.800.631.9567  
customer\_service@ilcdover.com

[www.ilcdover.com](http://www.ilcdover.com)

