TECHNICAL MEMORANDUM

DATE 14 November 2018 **Project No.** 188514056 Task01

TO Erlab (Kunshan) D.F.S Co., Ltd.

FROM Golder Associates Consulting Limited **EMAIL** QZhu@golder.com

CONTAINMENT ASSESSMENT

Golder Associates Consulting Limited conducted containment assessment for Erlab (Kunshan) D.F.S Co., Ltd. for "High Precision Safety Weighing Cabinets (Captair 321W Smart)" on Oct. 11, 2018 at the Erlab facility in Kunshan, Jiangsu, China.

The assessment was based on the International Society for Pharmaceutical Engineering (ISPE) guideline "Assessing the Particulate Containment Performance of Pharmaceutical Equipment". Lactose was used as surrogate to simulate powder weighing process. The containment performance target (CPT) was set at 1μg/m^3.

Air sample analysis was performed by Maxxam lab in Lake Zurich, IL, US with high performance liquid chromatography (HPLC).

Table 1: Measuring results of lactose weighing process in the weighing cabinet

Operator / Location	Measured concentration (μg/m^3)		
	Test Run 1	Test Run 2	Test Run 3
Background prior to operation	<0.0804	<0.0779	<0.0791
Background during operation	<0.0524	<0.0576	<0.0591
Left side	<0.0517	<0.0577	<0.0591
Right side	<0.0513	<0.0576	<0.0590
Front opening	<0.0516	<0.0577	<0.0592
Waste transfer port	<0.0518	<0.0578	<0.0592
HEPA exhaust on the top	<0.0513	<0.0575	<0.0590
Operator	<0.0515	<0.0578	<0.0599

When using Lactose for dispensing and weighing in the weighing cabinet (Captair 321W Smart), personal exposures and area concentrations were below the CPT 1μg/m^3.

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