

## Containment measurement of a MODUL<sup>TM</sup> S with WOL-ECM installation

### 1. Introduction

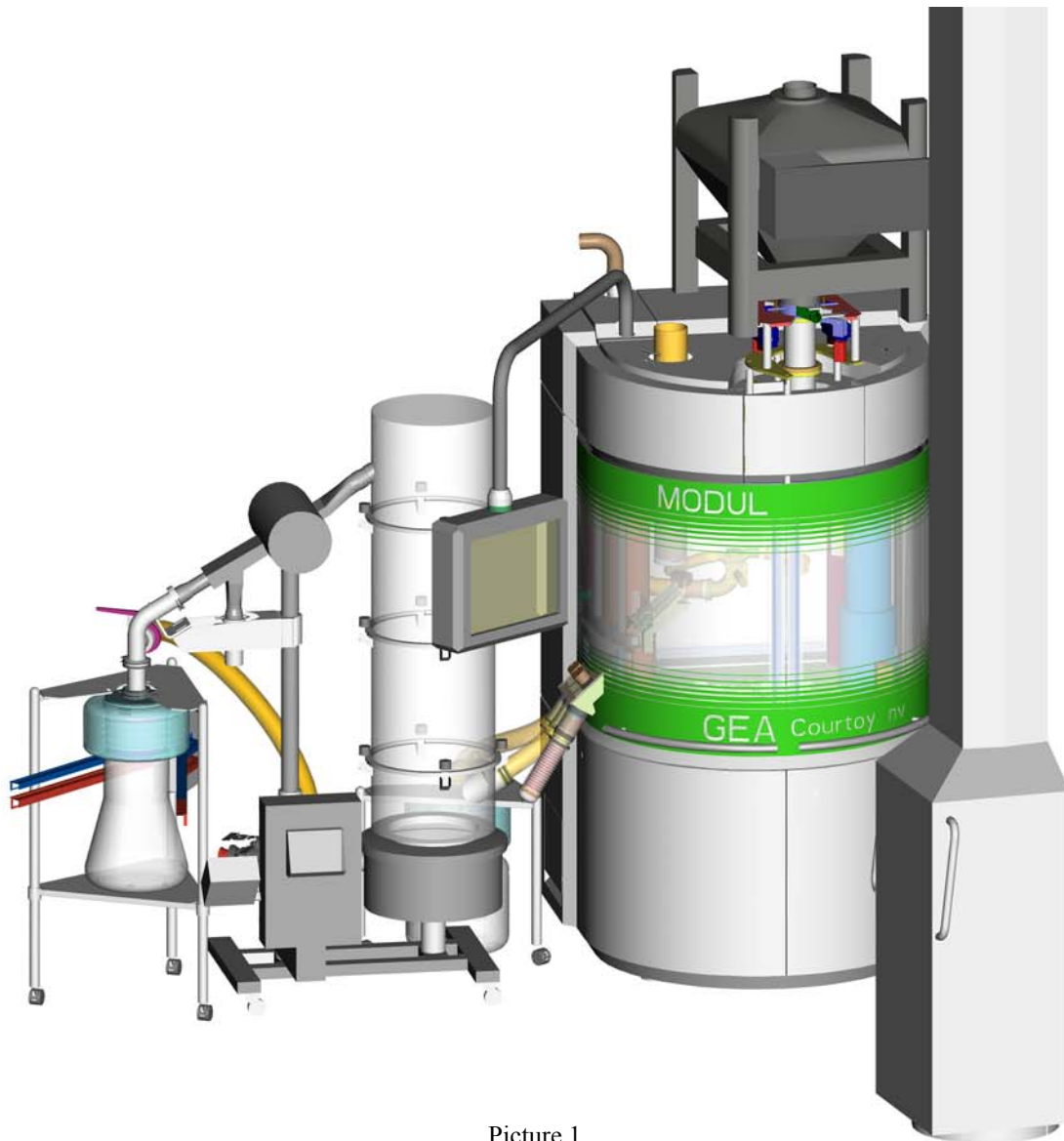
This document describes the results of an extensive containment measurement carried out on a complete tableting installation, including a Courtoy MODUL<sup>TM</sup> S machine with Wash-off-line Exchangeable Compression Module.

The reported results are for a particular equipment installation and a particular formulation with active compound. The results should be used as a reference only, in comparison with which the containment level for other formulations can be estimated. These results do not constitute a containment level guarantee and should not be relied upon exclusively to prevent all possible illnesses, injuries or losses.

### 2. The installation

Please refer to picture 1

- Courtoy MODUL<sup>TM</sup> S tablet press with WOL-ECM (Wash-off-line Exchangeable Compression module)
- Powder feed: Buck Systems post hoist and IBC with Buck High-Containment Quick-Release Split Butterfly Valve DN 100 mm, installed on top of the tablet press
- Krämer AG combined and washable tablet deduster and metal-detector, type E3100C/1000 + LOCK MET 30+
- Courtoy contained tablet recipient based on an ILC Dover LDPE continuous liner with a heat seal & cut disconnection principle.



Picture 1

### **3. The test formulation**

The composition of the test formulation is:

- 10% Micronized Paracetamol
- 87,5% Prosolv (98% silicified microcrystalline cellulose + 2% colloidal silicon dioxide)
- 0,5 % Aerosil (silicic acid)
- 2% Magnesium Stearate

#### **4. Test method**

- 1) Air samples taken at various locations on and around the installation, during the different stages of the complete tableting operation:
  - tablet production
  - switch of powder feeding IBC
  - disconnection of the various contained elements and transfer to the washing room
  - automatic washing of the various elements, opening & disassembly
  - manual final cleaning of individual components.
- 2) Swab samples taken at various locations on and around the installation, in between the various phases of operation.  
All swabs except for those on the Buck Valve are taken on a 100 cm<sup>2</sup> swab area. The swabs of the HC valve are taken on both the passive and the active half and over the full area of the metal disc and the seat (total area: 154 cm<sup>2</sup>).

#### **5. Measurement results and comments**

A detailed test report, indicating the exact number of air and swab samples, their location and the measured values (ng/m<sup>3</sup> for air samples, µg/swab for swabs) is available and can be presented on demand.

The following is a summary of the results:

##### *5.1. Docking IBC1 and production Run #1*

###### Air samples:

- Highest recorded value: 300 ng/m<sup>3</sup> at the IBC cover lid.
- Second highest value: 10 ng/m<sup>3</sup> at the sensor on the operator.
- All other samples are below the detectable limit of 7 ng/m<sup>3</sup>.

###### Swab samples:

- Highest values on the IBC and on top of the press, but all below 20 µg/swab.

##### *5.2. Undocking IBC1 and docking IBC2*

###### Air samples:

- All values below the detectable limit of 35 ng/m<sup>3</sup>

Swab samples:

- Highest values on the Buck HC valve and on top of the IBC
- Passive half of Buck HC valve: 1.000 µg/swab
- Active half of Buck HC valve: 5.000 µg/swab
- On top of the IBC: 70 µg/swab

*5.3. Production Run # 2*

Air samples:

- Highest recorded value is 144 ng/m<sup>3</sup>, on the right side of the metal detector
- Second highest value is 72 ng/m<sup>3</sup>, outside the ECM underneath the tablet chute
- All other values are below the detection limit of 9 ng/m<sup>3</sup>

No swab samples taken.

*5.4. Undocking IBC2.*

All air samples below detectable limit of 33 ng/m<sup>3</sup>

Swab samples:

- Passive half of Buck HC valve: 600 µg/swab
- Active half of Buck HC valve: 2700 µg/swab

*5.5. Disconnection of all contained elements and transfer to washing room*

Four elements are removed from the installation after performing a contained disconnection of its interfaces (inlets & outlets) using the heat seal & cut disconnection of LDPE lay-flat tubing:

- the powder in-feed section of the tablet press, including the active half of the Buck HC valve
- the WOL ECM
- the combined deduster / metal checker
- the tablet recipients for good and rejected tablets

Air samples:

- Highest recorded value: 450 ng/m<sup>3</sup> at the split ball valve used for contained disconnection & reconnection, of the deduster to the dust extraction unit.
- Second highest value: 225 ng/m<sup>3</sup> at the sensor on the operator.

Swab samples:

- Highest value: 5100 µg/swab under the split ball valve of the ECM (visible powder residue)

### *5.6. Automated washing, opening & disassembling*

This was only performed for the powder in-feed section and the WOL-ECM. The contained & washable deduster / metal detector will be subject to an additional measurement.

The detergent used for the automated washing of the WOL ECM is 0,5 % COSA PUR 80.

#### Air samples:

- highest recorded value on the operator: 96 ng/m<sup>3</sup>

#### Swab samples:

- highest value: 2,6 µg/swab

### *5.7. Manual cleaning of the individual components*

The components disassembled from the powder in-feed and the WOL-ECM are cleaned manually with water and the same detergent as used for the automated washing cycle.

#### Air samples:

- all values below the detection level of 20 ng/m<sup>3</sup>.

No swab samples taken.

### *5.8. Inspection of the inside of the MODUL<sup>TM</sup> S, after removal of the in-feed section and the WOL-ECM*

#### Air samples:

- Highest recorded value is 111 ng/m<sup>3</sup> on the operator (due to a small powder leak at the split ball valve for the dust extraction).
- 54 ng/m<sup>3</sup> on the room outside the machine.

No swab samples taken.

## **6. Conclusion**

The above described installation allows to limit the concentration of airborne Paracetamol particles below  $0,5 \mu\text{g}/\text{m}^3$  ( $500 \text{ ng}/\text{m}^3$ ) during the entire operation of the tableting system (machine set-up, production runs, disassembly & transfer, automatic washing & manual cleaning) for a 10% micronized Paracetamol formulation.

This indicates that the MODUL<sup>TM</sup> S with WOL ECM can process potent compounds with

- a normal particle size distribution,
- an API OEL of  $1 \mu\text{g}/\text{m}^3$  or higher, for an API concentration of 10% or lower,
- or, alternatively, an API OEL of  $0,1 \mu\text{g}/\text{m}^3$  or higher, for an API concentration of 1% or lower,
- provided that the prescribed SOPs are followed for set-up, operation, disassembling, washing and cleaning of the installation.

Courtoy recommends performing containment level testing for any specific combination of formulation and installation (equipment selection & type of set-up) to establish the effective containment level achieved.

## **APPENDIX: Photographs of installation**



PHOTO 1: MODUL™ S tablet press with Multi-Control 4 interface panel



PHOTO 2: MODUL™ S with open front doors. WOL ECM visible



PHOTO 3: Buck DN100 High-Containment Quick-Release valve & Buck powder IBC

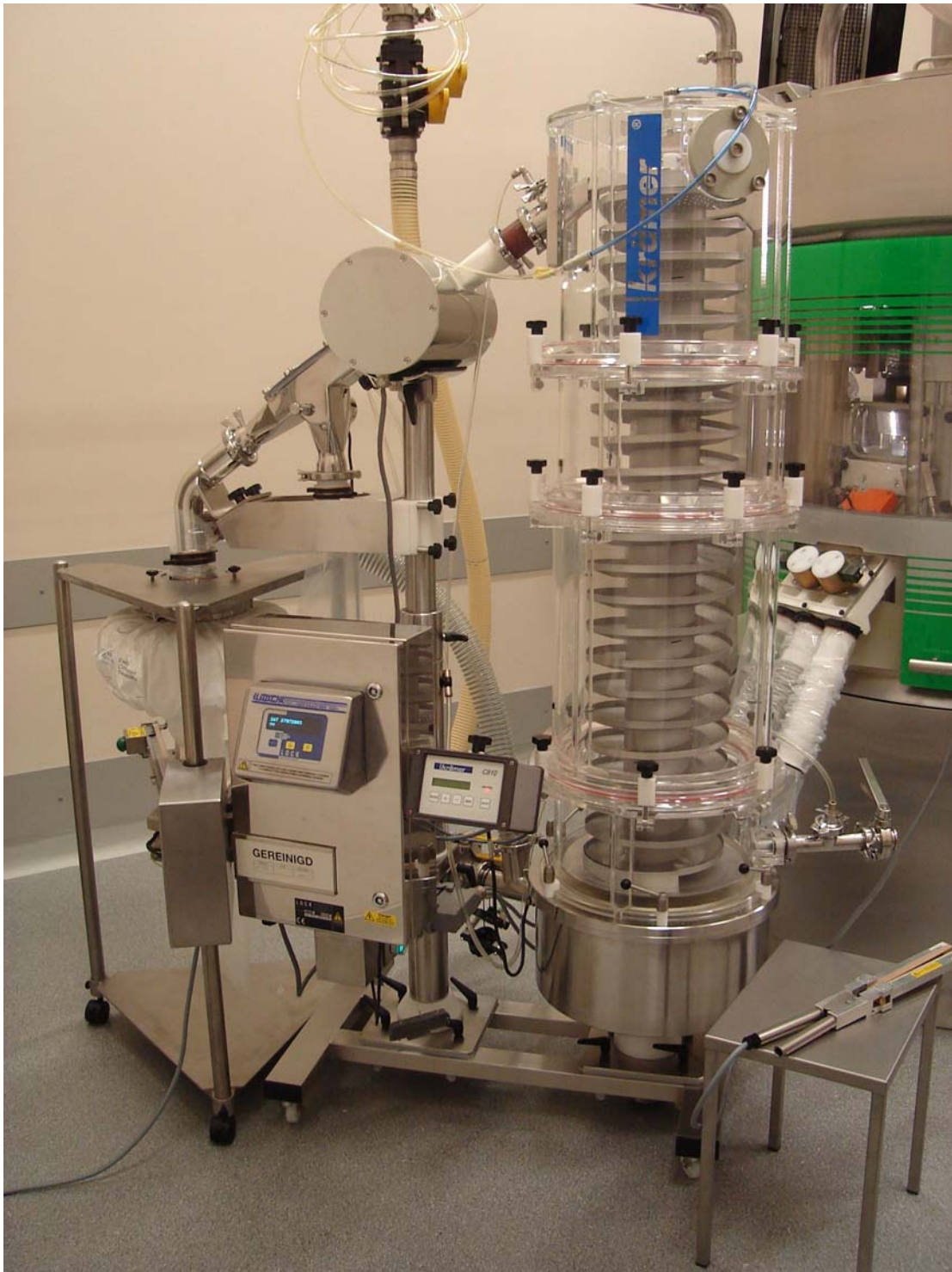


PHOTO 4: Washable combined deduster/metal-checker



PHOTO 5: Contained tablet recipient based on LDPE continuous liner