

# A.C.M.

Application Cleaning Methodology  
Evaluation Form



**DOBER**

Pharmaceutical Division

*Directions for Completing the ACM Form: The information we gather in this ACM Submission Form will help us to better replicate your soiling and cleaning processes in our laboratory. Please complete the tables and answer the questions that follow as completely as possible. Attach other pages or support information as appropriate.*

Contact Information			
Company Name		Phone (Office)	
Primary Contact		Phone (Mobile)	
Address		E-mail	
		Fax	
		Alternate Contact	
		Phone	
Country		Email	

Date of sample submission / shipment:  Requested completion date:

Product Information – Sample Submission				
Product Name / Sample ID <small>(Names are used in the reporting of your results. Active ingredient names or internal names may also be used provided that they relate to the MSDS submitted.)</small>	Sample Size <small>(400mL or 400g to be submitted if possible to permit for maximum experimentation)</small>	MSDS <small>(check to show that MSDS is attached)</small>	SOP * <small>(check to show that SOP is attached, when required)</small>	Hazard Class & Disposal * <small>(List Hazard class and define (or attach) the disposal instructions)</small>

\* SOP submission is desirable when there are details of the cleaning process, the manufacturing process or the sample preparation that need to be communicated to the Dober laboratory.

**How does residue get on the surface?**

The following section is designed to help us better understand what happens to the residue during the manufacturing process and how it adheres to the equipment in order to accurately depict your soil conditions prior to cleaning. A copy of the process SOPs may be helpful.

Equipment		
Equipment Name / Type	Size (e.g., capacity and/or dimensions)	Materials of Construction

**Production Details to Assist in Our Simulation of Your Process**

Estimate of the number of times the equipment is cleaned annually: \_\_\_\_\_

Do you campaign production? If so, how many batches are produced before a thorough cleaning of residues from the surface? If yes, #: \_\_\_\_\_

Yes	No
<input type="checkbox"/>	<input type="checkbox"/>

What is the maximum time equipment remains soiled before it is cleaned? \_\_\_\_\_

If residues remain on the equipment prior to cleaning, do they dry? Pick up moisture? Become gummy or sticky? Describe. \_\_\_\_\_

What is the temperature available to you for cleaning? \_\_\_\_\_

Is the residue exposed to heat or significant friction during the manufacturing process? Describe. \_\_\_\_\_

If your product is a liquid form (or if your dry product is moistened during processing, such as a wet granulation) and the product you submit is not in the same form, what ingredient(s) / solvent(s) are used to produce the solution or slurry? What ratio? Have you provided samples of those fluids? (Attach directions as required): \_\_\_\_\_

Describe other process attributes or steps prior to cleaning that have an effect on the residue or that might affect your cleaning (e.g., wastewater limitations, available cleaning time, etc.).

**Objectives**

Dober wants to ensure that we tailor the cleaning process to meet your goals. Please check the reasons for improving the cleaning process:

*Check all that apply:*

- |  |   |
|--|---|
| <input type="checkbox"/> Save labor                                    | <input type="checkbox"/> Save money                 |
| <input type="checkbox"/> Reduced reliance on solvents / green cleaning | <input type="checkbox"/> Move to automated cleaning |
| <input type="checkbox"/> Address a difficult residue                   | <input type="checkbox"/> Other: _____               |

List any additional product characteristics, comments or information that might assist us in our studies:

*If you have any questions about any of the high quality GMP products manufactured by Dober, do not hesitate to ask.*

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