Pharmaceutical Industry Best Practice

Suggested Containment Control Strategy and Personal Protective Equipment based on Active Pharmaceutical Ingredient Occupational Exposure Banding

In order to properly use the information contained in the tables below, active pharmaceutical ingredients (API) must be evaluated and placed into an Occupational Exposure Band (OEB).

Occupational exposure banding, also known as hazard banding, or health hazard banding, is a process intended to quickly and accurately assign chemicals into specific categories (bands), which correspond to a range of exposure concentrations designed to protect worker health. These bands are assigned based on a chemical's toxicological potency and the adverse health effects associated with exposure to the chemical. The output of this process is an **occupational exposure band.** [McKernan L, Seaton M, Gilbert S [2016]. The NIOSH Decision Logic for OEBs: Applying Occupational Exposure Bands. The Synergist (March 2016)].

Each band describes a distinct range of Occupational Exposure Limits (OELs), grouped so that a single recommendation for exposure control technology and personal protective equipment (PPE) can adequately protect employees engaged in similar tasks or process.

Information and tables included in this document are not intended to cover all tasks or situations, and may not be applicable for some or all of a company's specific operations. A detailed analysis should be conducted to determine applicability.

How to Use This Best Practice Guide

Use of this guide and suggestions herein are not a substitute for a complete and robust risk assessment and exposure assess-ment program. Good industrial hygiene and occupational exposure banding practices should be implemented and followed.

Suggested Containment Control Strategy

1) Identify the operation/activity to be performed in the far-left column of the chart.
2) Identify the OEB of the API handled or processed during the operation/activity in the top row of the chart.
3) Find the intersection point of the identified OEB and activity. This is the suggested containment control strategy for the activity performed.

Activity	Occupational Exposure Band (OEB)			
	OEB 1 & 2	OEB 3	OEB 4	OEB 5
	(≥ 100 µg/m³)	(>10 - 100 µg/m³)	(> 1 - 10 µg/m³)	(≤ 1 µg/m³)
Dispensing / Weighing – Wet Powders	NA	LEV	LEV or Down flow booth	Down flow booth with barriers or curtains or isolator with contained transfer ports

Figure 1: EXAMPLE – Dispensing/weighing wet powder in OEB 4

Suggested Personal Protective Equipment

1) Identify the operation/activity to be performed in the far-left column of the chart.
2) Identify the OEB of the API handled or processed during the operation/activity in the top row of the chart.
3) Find the intersection point of the identified OEB and activity. This is the suggested personal protective equipment for the activity performed, without regard to engineering controls/containment.

Activity	Occupational Exposure Band (OEB)				
	OEB 1	OEB 2	OEB 3	OEB 4	OEB 5
	(≥ 1000 µg/m³)	(>100 - 1000 µg/m³)	(>10 - 100 µg/m³)	(> 1 - 10 µg/m³)	(≤ 1 µg/m³)
Weighing	½ mask respirator, gloves, long sleeved GMP clothing and safety equipment for the area.	½ mask respirator, gloves, long sleeved GMP clothing and safety equipment for the area.	PAPR w/ full hood with max APF and HEPA filter or supplied air, gloves	PAPR w/ full hood with max APF and HEPA filter or supplied air, double gloves (Taped cuffs), disposable or launderable coveralls (Category III), and booties.	PAPR w/ full hood with max APF and HEPA filter or supplied air, double gloves (Taped cuffs), disposable or launderable coveralls (Category III), and booties.

Figure 2: EXAMPLE – Weighing powder in OEB 3

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Suggested Containment Control Strategy for Lab & Areas Outside Manufacturing & Pilot Plant

This chart offers suggestions only and should not be used without verifying that the technology works for your unique situation.

Table A.

Activity	Occupational Exposure Band (OEB)			
	OEB 1 & 2	OEB 3	OEB 4	OEB 5
	(100 µg/m^3)	(>10 - 100 µg/m^3)	(> 1 - 10 µg/m^3)	(< 1 µg/m^3)
Sample transfer	Tightly sealed container or zip-lock plastic bags		Double sealed container (e.g. bottle in bag)	
Dry Powders weighing and handling (Drying etc.)	Open Handing <1g API permitted (VBSE recommended) >1g VBSE required	VBSE	VBSE or Isolator (if quantity >10g) with appropriate contained transfer device.	VBSE or Isolator (if quantity >1g) with appropriate contained transfer device.
Wet Powders handling (weighing, filtration and cake handling)	Containment Hood		Containment Hood, For quantities >100 g, use VBSE or Isolator	Containment Hood. For quantities >10 g, use VBSE or Isolator
Solution/Suspension handlingOpen Bench permitted with spill trays. Containment Hood if solvents are used or aerosolization may occur	Open Bench permitted. Containment Hood if solvents are used or aerosolization may occur		Open Bench permitted with spill trays Containment Hood if solvents are used or aerosolization may occur	
Tablets (coated / uncoated) and capsules manipulation VBSE or Containment Hood	VBSE or Containment Hood		VBSE or Containment Hood	
Returned Sample Handling of broken or leaking presentations and uncoated tablets VBSE Recommended	VBSE Recommended		VBSE Recommended	
Returned Sample Handling of intact:Coated tablets, capsules, vials, patches, bottles Open Handling	Open Handling		Open Handling	

VBSE = Vented Balance Safety Enclosure

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Suggested PPE for Lab & Areas Outside Manufacturing & Pilot Plant. For operations with insufficient and/or unverified engineering controls

For operations with insufficient and/or unverified engineering controls.

This chart offers suggestions only and should not be used without verifying that the Personal Protective Equipment (PPE) is appropriate for your unique situation.

Table B.

Activity	Occupational Exposure Band (OEB)	
	OEB 1 & 2	OEB 3, 4 & 5
	(100 µg/m^3)	(< 100 µg/m^3)
Powder Manipulation	Min required lab PPE, gloves	Minimum lab PPE, gloves and appropriately fitted ½ facepiece particulate respirator
Solutions & Suspensions (No aerosols)	Minimum required Lab PPE, gloves	Minimum required lab PPE, gloves, lab coat, safety glasses and spill trays
Potentially Contaminated Batch Record Handling	NA	Minimum lab PPE, gloves, lab coat, safety glasses
Returned Sample Handling of broken or leaking presentations and uncoated tablets	Min required lab PPE, gloves	Minimum lab PPE, gloves, lab coat, safety glasses

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Suggested Personal Protection Equipment for Production/Pilot Plant (without regards to engineering controls/containment strategy)

This chart offers suggestions only and should not be used without verifying that the technology works for your unique situation.

Table C.

Activity	Occupational Exposure Band (OEB)				
	OEB 1	OEB 2	OEB 3	OEB 4	OEB 5
	(1000 µg/m^3)	(>100 - 1000 µg/m^3)	(>10 - 100 µg/m^3)	(> 1 - 10 µg/m^3)	(< 1 µg/m^3)
Weighing	½ mask respirator, gloves, long sleeved GMP clothing and safety equipment for the area.	½ mask respirator, gloves, long sleeved GMP clothing and safety equipment for the area.	PAPR w/ full hood with max APF and HEPA filter or supplied air, gloves	PAPR w/ full hood with max APF and HEPA filter or supplied air, double gloves (Taped cuffs), disposable or launderable coveralls (Category III), and booties.	PAPR w/ full hood with max APF and HEPA filter or supplied air, double gloves (Taped cuffs), disposable or launderable coveralls (Category III), and booties.
QA Sampling	½ mask respirator, gloves, long sleeved GMP clothing and safety equipment for the area.	½ mask respirator, gloves, long sleeved GMP clothing and safety equipment for the area.	PAPR w/ full hood with max APF and HEPA filter or supplied air, gloves	PAPR w/ full hood with max APF and HEPA filter or supplied air, double gloves (Taped cuffs), disposable or launderable coveralls (Category III), and booties.	PAPR w/ full hood with max APF and HEPA filter or supplied air, double gloves (Taped cuffs), disposable or launderable coveralls (Category III), and booties.
Granulation/ Compounding & Other Powder Manipulation Processes (assuming EC not at prescribed levels)	½ mask respirator, gloves, long sleeved GMP clothing and safety equipment for the area.	½ mask respirator, gloves, long sleeved GMP clothing and safety equipment for the area	PAPR w/ full hood with max APF and HEPA filter or supplied air, gloves.	PAPR w/ full hood with max APF and HEPA filter or supplied air, double gloves (Taped cuffs), disposable or launderable coveralls (Category III), and booties.	PAPR w/ full hood with max APF and HEPA filter or supplied air, double gloves (Taped cuffs), disposable or launderable coveralls (Category III), and booties.

GMP = Good Manufacturing Process
APF = Assigned Protection Factor
PAPR = Powered Air Purifying Respirator
HEPA = High Efficiency Particulate Air

Table C. Continued...

Activity	Occupational Exposure Band (OEB)				
	OEB 1	OEB 2	OEB 3	OEB 4	OEB 5
	(1000 µg/m^3)	(>100 - 1000 µg/m^3)	(>10 - 100 µg/m^3)	(> 1 - 10 µg/m^3)	(< 1 µg/m^3)
Compression/ Encapsulation	Gloves, long sleeved GMP clothing and safety equipment for the area. Unless hand scooping is used then ½ mask respirator, gloves, long sleeved GMP clothing and safety equipment for the area.	½ mask respirator, gloves, GMP and safety equipment for the area.	PAPR w/ full hood with max APF and HEPA filter or supplied air, gloves.	PAPR w/ full hood with max APF and HEPA filter or supplied air, double gloves (Taped cuffs), disposable or launderable coveralls (Category III), and booties.	PAPR w/ full hood with max APF and HEPA filter or supplied air, double gloves (Taped cuffs), disposable or launderable coveralls (Category III), and booties.
Coating	Gloves, long sleeved GMP clothing and safety equipment for the area.	Gloves, long sleeved GMP clothing and safety equipment for the area.	Working in the area before or after the pan has been charged - ½ mask respirator, gloves, long sleeved GMP clothing and safety equipment for the area.	Working in the area before or after the pan has been charged - ½ mask respirator, gloves, long sleeved GMP clothing and safety equipment for the area.	PAPR w/ full hood with max APF and HEPA filter or supplied air, double gloves (Taped cuffs), disposable or launderable coveralls (Category III), and booties.
		Charging the coating pan - ½ mask respirator, gloves, long sleeved GMP clothing and safety equipment for the area.	Charging the coater - PAPR w/ full hood with max APF and HEPA filter or supplied air, gloves.	Charging the coater - PAPR w/ full hood with max APF and HEPA filter or supplied air, double gloves (Taped cuffs), disposable or launderable coveralls (Category III), and booties.	
Solutions/ Suspensions (no aerosolization or powders.	Gloves, long sleeved GMP clothing and safety equipment for the area.	Gloves, long sleeved GMP clothing and safety equipment for the area.	Gloves, long sleeved GMP clothing and safety equipment for the area.	Gloves, long sleeved GMP clothing and safety equipment for the area.	Gloves, long sleeved GMP clothing and safety equipment for the area.

Table C. Continued...

Activity	Occupational Exposure Band (OEB)				
	OEB 1	OEB 2	OEB 3	OEB 4	OEB 5
	(1000 µg/m^3)	(>100 - 1000 µg/m^3)	(>10 - 100 µg/m^3)	(> 1 - 10 µg/m^3)	(< 1 µg/m^3)
Packaging (uncoated tablets, hot side work)	Gloves, long sleeved GMP clothing and safety equipment for the area.	½ mask respirator, gloves, long sleeved GMP clothing and safety equipment for the area.	½ mask respirator, gloves, long sleeved GMP clothing and safety equipment for the area.	½ mask respirator, gloves, long sleeved GMP clothing and safety equipment for the area.	PAPR w/ full hood with max APF and HEPA filter or supplied air, double gloves (Taped cuffs), disposable or launderable coveralls (Category III), and booties.
				During cleaning and hopper filler operator - PAPR w/ full hood with max APF and HEPA filter or supplied air, double gloves (Taped cuffs), disposable or launderable coveralls (Category III), and booties.	
Packaging coated tablets, capsules, liquids, or cold side work	Gloves, long sleeved GMP clothing and safety equipment for the area.	Gloves, long sleeved GMP clothing and safety equipment for the area.	Gloves, long sleeved GMP clothing and safety equipment for the area.	Gloves, long sleeved GMP clothing and safety equipment for the area.	Gloves, long sleeved GMP clothing and safety equipment for the area.
Dust Collector Change Out (HEPA or waste)	BIBO HEPA's should be used.	BIBO HEPA's should be used.	BIBO HEPA's should be used for HEPA cartridge change out.	BIBO HEPA's should be used for HEPA cartridge change out.	BIBO HEPA's should be used for HEPA cartridge change out.
	PAPR w/ full hood with max APF and HEPA filter or supplied air, double gloves (Taped cuffs), disposable or launderable coveralls (Category III), and booties.	PAPR w/ full hood with max APF and HEPA filter or supplied air, double gloves (Taped cuffs), disposable or launderable coveralls (Category III), and booties.	PAPR w/ full hood with max APF and HEPA filter or supplied air, double gloves (Taped cuffs), disposable or launderable coveralls (Category III), and booties.	PAPR w/ full hood with max APF and HEPA filter or supplied air, double gloves (Taped cuffs), disposable or launderable coveralls (Category III), and booties.	PAPR w/ full hood with max APF and HEPA filter or supplied air, double gloves (Taped cuffs), disposable or launderable coveralls (Category III), and booties.

BIBO = Bag In Bag Out

Table C. Continued...

Activity	Occupational Exposure Band (OEB)				
	OEB 1	OEB 2	OEB 3	OEB 4	OEB 5
	(1000 µg/m^3)	(>100 - 1000 µg/m^3)	(>10 - 100 µg/m^3)	(> 1 - 10 µg/m^3)	(< 1 µg/m^3)
Personnel Decontamination	Decontamination procedure required	Decontamination procedure required	Decontamination procedure required	Decontamination procedure required	Decontamination procedure required
			PPE decontamination is required upon leaving the area.	PPE decontamination is required upon leaving the area.	PPE decontamination is required prior to leaving the area.
			Ensure contamination doesn't occur or isn't spread outside the area (personnel and equipment, materials etc.)	Ensure contamination doesn't occur or isn't spread outside the area (personnel and equipment, materials etc.)	Ensure contamination doesn't occur or isn't spread outside the area (personnel and equipment, materials etc.)
Emergency Containment Breaches	½ mask respirator, gloves, long sleeved GMP clothing and safety equipment for the area.	½ mask respirator, gloves, long sleeved GMP clothing and safety equipment for the area.	PAPR w/ full hooded head top with max APF and HEPA filter or supplied air, gloves	PAPR w/ full hooded head toped head top with max APF and HEPA filter or supplied air, double gloves (Taped cuffs), disposable or launderable coveralls (Category III equivalent), and booties.	PAPR w/ full hooded head top with max APF and HEPA filter or supplied air, double gloves (Taped cuffs), disposable or launderable coveralls (Category III equivalent), and booties.

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Suggested Containment Control Strategy for Production or Pilot Plant

This chart offers suggestions only and should not be used without verifying that the technology works for your unique situation.

Table D.

Activity	Occupational Exposure Band (OEB)			
	OEB 1 & 2	OEB 3	OEB 4	OEB 5
	(≥100 µg/m^3)	(>10 - 100 µg/m^3)	(>1 - 10 µg/m^3)	(≤1 µg/m^3)
Dispensing/ Weighing -Wet Powders	NA	LEV	LEV or Down flow booth	Down flow booth with barriers or curtains or isolator with contained transfer ports
Dispensing/ Weighing -Dry Powders	LEV	LEV or Down flow booth or ventilated enclosure	Down flow booth with barriers or curtains or isolator with contained transfer ports	Isolator with contained transfer ports
Dispensing dry powders into liquids Appropriate contained transfer technology, (e.g. SBV, PTS, DCS, etc.), direct connection between processing units or isolator Solids/liquids disperser/ homogenizer - recommended	Solids/liquids disperser/ homogenizer - recommended		Appropriate contained transfer technology, (e.g. SBV, PTS, DCS, etc) , direct connection between processing units or Isolator Solids/liquids disperser/homogenizer - recommended	
Powder Sampling (when dedicated sampling port is not available)	LEV	LEV or Down flow booth	Down flow booth	PAT, isolator or through appropriate contained transfer device
TD Centrifuge Discharge Isolator/ glove bag or change technology	NA		Isolator/glove bag or change technology	
BD Centrifuge Discharge	NA	Suitable enclosure (e.g. inflatable seal)	Suitable continuous liner	Appropriate contained transfer device or isolator with contained transfer ports

Table D. Continued...

Activity	Occupational Exposure Band (OEB)			
	OEB 1 & 2	OEB 3	OEB 4	OEB 5
	(≥100 µg/m^3)	(>10 - 100 µg/m^3)	(>1 - 10 µg/m^3)	(≤1 µg/m^3)
Hor. Centrifuge Discharge	NA	Suitable enclosure (e.g. inflatable seal)	Suitable continuous liner	Appropriate contained transfer device or isolator with contained transfer ports
Inv. Basket Centrifuge Discharge	NA	Suitable enclosure (e.g. inflatable seal)	Suitable continuous liner	Appropriate contained transfer device or isolator with contained transfer ports
Other Liquid Filtration systems when solids are waste	NA	Thoroughly wash out the unit before opening for disposal	Safely dispose after proper wetting. Use disposable bags/ cartridges if possible. Dispose in contained manner, e.g. while using “Bag in Bag” or “Cartridge in Bag” technology	
Filter Dryer Discharge	LEV or Suitable enclosure	Suitable enclosure (e.g. inflatable seal)	Suitable continuous liner or other appropriate contained transfer technology	
Fluidized Bed Dryer or Spray Dryer Charging	LEV	LEV and direct connection or remote charging	Appropriate contained transfer using vacuum, gravity or both. (SBV or similar if disconnections are required)	
Fluidized Bed Dryer or Spray Dryer Discharging	LEV	LEV and direct connection	Contained transfer technology (Vacuum system for side discharge or bottom gravity discharge with SBV)	
Fluidized Bed Dryer or Spray Dryer CleaningWIP or Glove Bag/Box Isolator	HEPA vacuum and wet methods		WIP or Glove Bag/Box Isolator	
Tray Dryer Charge NA if material is wet enough If not see discharge below	LEV recommended		NA if material is wet enough If not see discharge below	
Tray Dryer Discharge Down flow booth with barriers or curtains, isolator or change technology (one Pot etc.)	LEV or down flow booth		Down flow booth with barriers or curtains, isolator or change technology (one Pot etc.)	
Lyophilizing/ Freeze Drying Discharge Down flow booth with barriers or curtains or isolator	LEV		Down flow booth with barriers or curtains or Isolator	
Lyophilizing/ Freeze Drying Cleaning WIP, Vial wash down or Glove Bag/Box Isolator	HEPA vacuum and wet methods		WIP, Vial wash down or Glove Bag/Box Isolator	

Table D. Continued...

Activity	Occupational Exposure Band (OEB)			
	OEB 1 & 2	OEB 3	OEB 4	OEB 5
	(≥100 µg/m^3)	(>10 - 100 µg/m^3)	(>1 - 10 µg/m^3)	(≤1 µg/m^3)
Vacuum Dryers Charge/DischargeDirect connection with appropriate contained transfer device	Direct connection		**Direct connection with appropriate contained transfer device**	
Vacuum Dryers CleaningWIP or CIP through appropriate contained transfer device or built in	Direct connection		**WIP or CIP through appropriate contained transfer device or built in**	
Tumble Blending (V, Bin, Cone), Charging/ Discharging	LEV	LEV and direct connection	Appropriate contained transfer device	
Tumble Blending (V, Bin, Cone), Cleaning WIP or CIP through appropriate contained transfer device or built in	HEPA vacuum and wet methods		WIP or CIP through appropriate contained transfer device or built in	
High Sheer Mixing/ Granulating Charge/Discharge	LEV	LEV and direct connection	Appropriate contained transfer device	
High Sheer Mixing/ Granulating Heel Removal	LEV	LEV and direct connection	Isolator/glove bag for product heel removal or one pot processor	
High Sheer Mixing/ Granulating Cleaning WIP or CIP through appropriate contained transfer device or built in	HEPA vacuum and wet methods		WIP or CIP through appropriate contained transfer device or built in	
Tablet Coating Charge Appropriate contained transfer device	LEV (may be built in)		Appropriate Contained transfer device	
Tablet Coating Cleaning WIP (may be built in)	HEPA vacuum and wet methods		WIP (may be built in)	
Roller Compactor Charge/Discharge	LEV or down flow booth	LEV and direct connections or down flow booth	Appropriate contained transfer device, leak proof seals	

Table D. Continued...

Activity	Occupational Exposure Band (OEB)			
	OEB 1 & 2	OEB 3	OEB 4	OEB 5
	(≥100 µg/m^3)	(>10 - 100 µg/m^3)	(>1 - 10 µg/m^3)	(≤1 µg/m^3)
Roller Compactor CleaningWIP/CIP or Isolator	HEPA vacuum and wet methods		WIP/CIP or Isolator	
Milling CleaningWIP/CIP or Isolator	HEPA vacuum and wet methods		WIP/CIP or Isolator	
Milling Charge, Discharge & Operation	LEV or down flow booth	LEV and direct connections or down flow booth	Appropriate contained transfer device, leak proof seals	
Sieving/Screening Charge/Discharge	LEV or down flow booth	LEV and direct connections or down flow booth	Appropriate contained transfer device, leak proof seals	
Seiving/Screening CleaningWIP/CIP or isolator	HEPA vacuum and wet methods		WIP/CIP or isolator	
Packaging Hopper Filling & Operation (uncoated tablets or powder filling) Appropriate contained transfer device for the hopper (if possible), and contained ventilated filler	LEV at hopper and filler		Appropriate contained transfer device for the hopper (if possible), and contained ventilated filler	
Packaging Hopper/Filler Cleaning (uncoated tablets or powder filling) WIP, Mist in Place or Isolator	HEPA vacuum		WIP, Mist in Place or Isolator	
Compression & Encapsulation Charging	LEV	LEV & drum lift & direct connection	Appropriate contained transfer device	
Compression & Encapsulation In Process Checks Automated or contained (VBSE, etc.)	NA		Automated or contained (VBSE, etc.).	
Compression/ Encapsulation Product Recovery	LEV	LEV and direct connection	Safe change Vacuum system or Cyclone with contained transfer device and WIP or CIP	

Table D. Continued...

Activity	Occupational Exposure Band (OEB)			
	OEB 1 & 2	OEB 3	OEB 4	OEB 5
	(≥100 µg/m^3)	(>10 - 100 µg/m^3)	(>1 - 10 µg/m^3)	(≤1 µg/m^3)
Compression/ Encapsulation Cleaning WIP or CIP or Isolator	HEPA vacuum		**WIP or CIP or Isolator**	
Extruding & Spheronizing Charging/ Discharging Appropriate Contained transfer device	LEV		Appropriate Contained transfer device	
Extruding & Spheronizing Cleaning WIP or CIP or Isolator	HEPA vacuum and wet methods		WIP or CIP or Isolator	
Vacuum Cleaner Bag Change Out BIBO Filter change and appropriate contained transfer device	LEV		BIBO Filter change and appropriate contained transfer device	
Container TyperSuitable Contained - required	Suitable Container - recommended		Suitable Container - required	
Transdermal Film Coating Additional specific local ventilation or containment required to control volatile APIs or solvents	Additional specific local ventilation or containment recommended to control volatile APIs or solvents		Additional specific local ventilation or containment Required to control volatile APIs or solvents	
Personnel Decontamination Methods Required - Misting Shower for decontamination of Personnel PPE, etc., policy and training Unless, In Controlled containment: Recommended	NA		Required - Misting Shower for decontamination of Personnel PPE, etc., policy and training **Unless, In Controlled containment: Recommended.**	
Equipment/ Material Transfer Contaminated items must be cleaned or contained prior to transfer. Cleaning with Compressed Air is not allowed	Contaminated items must be cleaned or contained prior to transfer. Cleaning with Compressed Air is not allowed.		Contaminated items must be cleaned or contained prior to transfer. Cleaning with Compressed Air is not allowed.	

Table D. Continued...

Activity	Occupational Exposure Band (OEB)			
	OEB 1 & 2	OEB 3	OEB 4	OEB 5
	(≥100 µg/m^3)	(>10 - 100 µg/m^3)	(>1 - 10 µg/m^3)	(≤1 µg/m^3)
Batch Record Handling Electronic Batch Records or Glove Box or Recording done in an uncontaminated area Unless, In Controlled containment: NA	NA		Electronic Batch Records or Glove Box or Recording done in a uncontaminated area **Unless, In Controlled containment – NA**	

APF – Assigned Protection Factor

API – Active Pharmaceutical Ingredient

BIBO – Bag In Bag Out

BD – Bottom Discharge

BSC – Bio-safety Cabinet

CIP – Clean In Place

DCS – Distributed Control System

FA – Fresh Air

FBD – Fluidized Bed Dryer

GMP – Good Manufacturing Process

HEPA – High Efficiency Particulate Air IPI – Isolated Process Intermediate Isolator – Glove Box or Flexible Glove Bag

LEV – Local Exhaust Ventilation

NA – Not Applicable

OEB – Occupational Exposure Band

OEL – Occupational Exposure Limit

PAT – Process Analytical Technology

PPE – Personal Protective Equipment

PTS – Powder Transfer System

SBV – Split Butterfly Valve

TD – Top Discharge

V – V-shaped style tumble blender

VBSE – Ventilated Balance Safety Enclosure

WIP - Wash In Place

Disclaimer

3M disclaims any and all liability, loss, or risk resulting directly or indirectly from the use of the suggestions presented in this document. Moreover, it is ultimately the employer's responsibility to provide a place of employment which is free from recog-nized hazards that are causing or are likely to cause death or serious physical harm to his employees, and to comply with local occupational safety and health standards and regulations.

Compliance with suggestions made in this document does not certify compliance with federal, state or local regulations. No warranties are made, as these documents only present suggestions that may be applicable for work in these environments.

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