

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. Regional and country personal protective equipment (PPE) regulations and respiratory protective equipment (RPE) assigned protection factors (APF) vary between countries and therefore the suggested PPE ensemble may not be suitable in all cases. A detailed risk assessment 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 assessment 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

	Occupational Exposure Band (OEB)					
Activity	OEB 1 and 2 (> 100 μg/m³)	OEB 3 (> 10 – 100 μg/m³)	OEB 4 (> 1 – 10 μg/m³)	OEB 5 (< 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

	Occupational Exposure Band (OEB)				
Activity	OEB 1 (> 1000 μg/m³)	OEB 2 (> 100 – 1000 μg/m³)	OEB 3 (> 10 – 100 μg/m³)	OEB 4 (< 1 μg/m³)	OEB 5 (< 1 μg/m³)
Weighing powders	Filtering Face Piece (FFP) or half mask respirator, gloves, long sleeved GMP clothing and safety equipment for the area	FFP or half mask respirator, gloves, long sleeved GMP clothing and safety equipment for the area	Turbo Hood 3 Powered Air Purifying Respirator (PAPR) with full hood or class 3/4 supplied air, gloves	Class TH3 PAPR with full hood or class ¾ supplied air, double gloves (taped cuffs), disposable or launderable coveralls (category III), and booties	Class TH3 PAPR with full hood or class ¾ supplied air, double gloves (taped cuffs), disposable or launderable coveralls (category III), and booties

Figure 2: Example – Weighing powder in OEB 3

Suggested containment control strategy for lab and areas outside manufacturing and pilot plant.

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

Table A

		Occupational Exp	oosure Band (OEB)	
Activity	OEB 1 and 2 (100 μg/m³)	OEB 3 (> 10 – 100 μg/m³)	OEB 4 (> 1 – 10 μg/m³)	OEB 5 (< 1 μg/m³)
Sample transfer	Tightly sealed conta plastic bags	iner or zip-lock	Double sealed cont (e.g. bottle in bag)	ainer
Dry powders weighing and handling (drying etc.)	Open handling <1g API permitted (Vented Balance Safety Enclosure (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 handling. Open bench permitted with spill trays. Containment hood if solvents are used or aerosolisation may occur	Open bench permitted. Containment hood if solvents are used or aerosolisation may occur		Open bench permit Containment hood or aerosolisation ma	if solvents are used
Tablets (coated uncoated) and capsules manipulation VBSE or containment hood	VBSE or containmen	nt hood	VBSE or containmen	nt 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	

Suggested PPE for lab and areas outside manufacturing and 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

	Occupational Exposure Band (OEB)				
Activity	OEB 1 and 2 (100 µg/m³)	OEB 3, 4 and 5 (< 100 μg/m³)			
Powder manipulation	Minimum required lab PPE, gloves	Minimum required lab PPE, gloves and appropriately fitted filtering facepiece respirator			
Solutions and 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 required lab PPE, gloves, lab coat and safety glasses			
Returned sample handling of broken or leaking presentations and uncoated tablets	Minimum required lab PPE, gloves	Minimum required lab PPE, gloves, lab coat and safety glasses			

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

		Occupational Exposure Band (OEB)				
Activity	OEB 1 (1000 μg/m³)	OEB 2 (> 100 – 1000 μg/m³)	OEB 3 (> 10 – 100 μg/m³)	OEB 4 (>1 – 10 μg/m³)	OEB 5 (< 1 μg/m³)	
Weighing	FFP or half mask respirator, gloves, long sleeved GMP clothing and safety equipment for the area	FFP or half mask respirator, gloves, long sleeved GMP clothing and safety equipment for the area	Class TH3 PAPR with full hood or class 3/4 supplied air, gloves	Class TH3 PAPR with full hood or class 3/4 supplied air, double gloves (taped cuffs), disposable or launderable coveralls (category 111), and booties	Class TH3 PAPR with full hood or class 3/4 supplied air, double gloves (taped cuffs), disposable or launderable coveralls (category 111), and booties	
QA sampling	FFP or half mask respirator, gloves, long sleeved GMP clothing and safety equipment for the area	FFP or half mask respirator, gloves, long sleeved GMP clothing and safety equipment for the area	Class TH3 PAPR with full hood or class 3/4 supplied air, gloves	Class TH3 PAPR with full hood or class 3/4 supplied air, double gloves (taped cuffs), disposable or launderable coveralls (category 111), and booties	Class TH3 PAPR with full hood or class 3/4 supplied air, double gloves (taped cuffs), disposable or launderable coveralls (category 111), and booties	
Granulation/ compounding and other powder manipulation processes area. (assuming EC not at prescribed levels)	FFP or half mask respirator, gloves, long sleeved GMP clothing and safety equipment for the area	FFP or half mask respirator, gloves, long sleeved GMP clothing and safety equipment for the area	Class TH3 PAPR with full hood or class 3/4 supplied air, gloves	Class TH3 PAPR with full hood or class 3/4 supplied air, double gloves (taped cuffs), disposable or launderable coveralls (category 111), and booties	Class TH3 PAPR with full hood or class 3/4 supplied air, double gloves (taped cuffs), disposable or launderable coveralls (category 111), and booties	

	Occupational Exposure Band (OEB)				
Activity	OEB 1 (1000 μg/m³)	OEB 2 (> 100 – 1000 μg/m³)	OEB 3 (> 10 – 100 μg/m³)	OEB 4 (>1 – 10 μg/m³)	OEB 5 (< 1 μg/m³)
Compression/ encapsulation	Gloves, long sleeved GMP clothing and safety equipment for the area	EED or holf	Class TH3 PAPR with full hood or class 3/4 supplied air, gloves	Class TH3 PAPR with full hood or class 3/4	Class TH3 PAPR with full hood or class 3/4
	Unless hand scooping is used then FFP or half mask respirator, gloves, long sleeved GMP clothing and safety equipment for the area	FFP or half mask respirator, gloves, GMP and safety equipment for the area		supplied air, double gloves (taped cuffs), disposable or launderable coveralls (category 111), and booties	supplied air, double gloves (taped cuffs), disposable or launderable coveralls (category 111), and booties
	Gloves, long	Gloves, long sleeved GMP clothing and safety equipment for the area	Working in the area before or after the pan has been changed – FFP or half mask respirator, gloves, long sleeved GMP clothing and safety equipment for the area	Working in the area before or after the pan has been changed – FFP or half mask respirator, gloves, long sleeved GMP clothing and safety equipment for the area	Class TH3 PAPR with full hood or class 3/4 supplied air, double gloves
Coating	clothing and safety equipment for the area	Charging the coating pan – FFP or half mask respirator, gloves, GMP clothing and safety equipment for the area	Charging the coater – Class TH3 PAPR with full hood or supplied air, gloves	Charging the coater – Class TH3 PAPR with full hood or class 3/4 supplied air, double gloves (taped cuffs), disposable or launderable coveralls (category 111), and booties	(taped cuffs), disposable or launderable coveralls (category 111), and booties
Solutions/ suspensions (no aerosolisation 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

	Occupational Exposure Band (OEB)				
Activity	OEB 1 (1000 μg/m³)	OEB 2 (> 100 – 1000 μg/m³)	OEB 3 (> 10 – 100 μg/m³)	OEB 4 (>1 – 10 μg/m³)	OEB 5 (< 1 μg/m³)
				FFP or half mask respirator, gloves, long sleeved GMP clothing and safety equipment for the area	Class TH3 PAPR with full hood
Packaging (uncoated tablets, hot side work)	uncoated clothing and safety equipment clothing and clothing and	During cleaning and hopper filler operator – Class TH3 PAPR with full hood or class 3/4 supplied air, double gloves (taped cuffs), disposable or launderable coveralls (category 111), and booties	or class 3/4 supplied air, double gloves (taped cuffs), disposable or launderable coveralls (category 111), 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
	BIBO (Bag In Bag Out) 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
Dust collector change out (HEPA or waste)	Class TH3 PAPR with full hood or class 3/4 supplied air, double gloves (taped cuffs), disposable or launderable coveralls (category 111), and booties	Class TH3 PAPR with full hood or class 3/4 supplied air, double gloves (taped cuffs), disposable or launderable coveralls (category 111), and booties	Class TH3 PAPR with full hood or class 3/4 supplied air, double gloves (taped cuffs), disposable or launderable coveralls (category 111), and booties	Class TH3 PAPR with full hood or class 3/4 supplied air, double gloves (taped cuffs), disposable or launderable coveralls (category 111), and booties	Class TH3 PAPR with full hood or class 3/4 supplied air, double gloves (taped cuffs), disposable or launderable coveralls (category 111), and booties

BIBO= Bag In Bag Out

		Occupational Exposure Band (OEB)				
Activity	OEB 1 (1000 μg/m³)	OEB 2 (> 100 – 1000 μg/m³)	OEB 3 (> 10 – 100 μg/m³)	OEB 4 (> 1 – 10 μg/m³)	OEB 5 (< 1 μg/m³)	
			Decontamination procedure required	Decontamination procedure required	Decontamination procedure required	
Personal production	Decontamination	Decontamination procedure required	PPE decontamination is required upon leaving the area	PPE decontamination is required upon leaving the area	PPE decontamination is required upon 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	FFP or half mask respirator, gloves, long sleeved GMP clothing and safety equipment for the area	FFP or half mask respirator, gloves, long sleeved GMP clothing and safety equipment for the area	BIBO HEPA's should be used for HEPA cartridge change out	Class TH3 PAPR with full hood or supplied air, double gloves (taped cuffs), disposable or launderable coveralls (category 111), and booties	Class TH3 PAPR with full hood or class 3/4 supplied air, double gloves (taped cuffs), disposable or launderable coveralls (category 111), and booties	

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

	Occupational Exposure Band (OEB)			
Activity	OEB 1 and 2 (> 100 μg/m³)	OEB 3 (> 10 – 100 μg/m³)	OEB 4 (>1 – 10 μg/m³)	OEB 5 (< 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
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/homogeniser - recommended	Solids/liquids disperser/homogeniser – recommended		Appropriate contained transfer technology, (e.g. SBV, PTS, DCS, etc), direct connection between processing units or isolator Solids/liquids disperser/homogeniser – 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 enclosue (e.g. inflatable seal)	Suitable continuous liner	Appropriate contained transfer device or isolator with contained transfer ports

	Occupational Exposure Band (OEB)			
Activity	OEB 1 and 2 (> 100 μg/m³)	OEB 3 (> 10 – 100 μg/m³)	OEB 4 (> 1 – 10 μg/m³)	OEB 5 (< 1 μg/m³)
Hor. centrifuge discharge	NA	Suitable enclosue (e.g. inflatable seal)	Suitable continuous liner	Appropriate contained transfer device or isolator with contained transfer ports
Inv. basket centrifuge discharge	NA	Suitable enclosue (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. Us 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 enclosue	Suitable enclosue (e.g. inflatable seal)	Suitable continuous liner or other appropriate contained transfer technology	
Fluidised 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)	
Fluidised 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)	
Fluidised bed dryer or spray dryer cleaning WIP or glove bag/box isolator	HEPA vacuum and v	vet methods	WIP or glove bag/b	ox isolator
Tray dryer change. NA if material is wet enough if not see discharge below	LEV recommended		NA if material is we if not see discharge	_
Tray dryer discharge down flow booth with barriers or 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.)	
Lyophilising/freeze drying discharge down flow booth with barriers or curtains or isolator	LEV		Down flow booth w curtains or isolator	ith barriers or
Lyophilising/freeze drying cleaning WIP, vial wash down or glove bag/box isolator	HEPA vacuum and v	vet methods	WIP, vial wash down or glove bag/box isolator	

	Occupational Exposure Band (OEB)			
Activity	OEB 1 and 2 (> 100 μg/m³)	OEB 3 (> 10 – 100 μg/m³)	OEB 4 (> 1 – 10 μg/m³)	OEB 5 (< 1 μg/m³)
Vacuum dryers charge/ discharge direct connection with appropriate contained transfer device	Direct connection		Direct connection with appropriate contained transfer device	
Vacuum dryers cleaning WIP or CIP through appropriate contained transfer device	Direct connection		WIP or CIP through 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 contained transfer device or built in	
High sheer mixing/ granulating charge/discharge	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 v	vet methods	WIP or CIP through device or built in	contained transfer
Tablet coating charge appropriate contained transfer device	LEV (may be built in)		Appropriate contain	ned 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 connection or down flow booth	Appropriate contain	ned transfer device,

	Occupational Exposure Band (OEB)			
Activity	OEB 1 and 2 (> 100 μg/m³)	OEB 3 (> 10 – 100 μg/m³)	OEB 4 (> 1 – 10 μg/m³)	OEB 5 (< 1 μg/m³)
Roller compactor cleaning WIP/CIP or isolator	HEPA vacuum and v	vet methods	WIP or CIP or isolate	or
Milling cleaning WIP/CIP or isolator	HEPA vacuum and v	vet methods	WIP or CIP or isolat	or
Milling charge, discharge and operation	LEV or down flow booth	LEV and direct connection or down flow booth	Appropriate contained transfer device leak proof seals	
Sieving/screening charge/discharge	LEV or down flow booth	LEV and direct connection or down flow booth	Appropriate contained transfer device, leak proof seals	
Sieving/screening cleaning WIP/CIP or isolator	HEPA vacuum and wet methods		WIP or CIP or isolator	
Packaging hopper filling and 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 contair for the hopper (if po contained ventilated	ssible), and
Packaging hopper/filler cleaning (uncoated tablets or powder filling) WIP, mist in place or isolator	HEPA vacuum		WIP, mist in place o	r isolator
Compression and encapsulation charging	LEV	LEV and drum lift and direct connection	Appropriate contained transfer device	
Compression and encapsulation in process checks automated or contained (VBSE, etc.)	NA		Automated or conta	ained (VBSE, etc.).
Compression/encapsulation product recovery	LEV	LEV and direct connection	Safe change vacuur Cyclone with conta device and WIP or 0	ined transfer

	Occupational Exposure Band (OEB)			
Activity	OEB 1 and 2 (> 100 μg/m³)	OEB 3 (> 10 – 100 μg/m³)	OEB 4 (> 1 – 10 μg/m³)	OEB 5 (< 1 μg/m³)
Compression/encapsulation cleaning WIP or CIP or isolator	HEPA vacuum		WIP or CIP or isolator	
Extruding and spheronising charging/discharging appropriate contained transfer device	LEV		Appropriate contained transfer device	
Extruding and spheronising 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 typer suitable container – required	Suitable container – recommended		Suitable container – required	
Transdermal film coating additional specific local ventilation or containment recommended 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 recommended 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	
Batch record handling electronic batch records or glove box or recording done in a 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		Local Exhaust Ventilation	
API	Active Pharmaceutical Ingredient	NA	Not Applicable	
BIBO	D Bag In Bag Out		Occupational Exposure Band	
BD	Bottom Discharge	OEL	Occupational Exposure Limit	
BSC	Bio-safety Cabinet	PAT	Process Analytical Technology	
CIP	Clean In Place	PPE	Personal Protective Equipment	
DCS	Distributed Control System	PTS	Powder Transfer System	
FA	Fresh Air	SBV	Split Butterfly Valve	
FBD	Fluidised Bed Dryer	TD	Top Discharge	
GMP	Good Manufacturing Process	V	V-shaped style tumble blender	
HEPA	High Efficiency Particulate Air IPI – Isolated Process Intermediate Isolator – Glove Box or Flexible Glove Bag		Ventilated Balance Safety Enclosure	
			Wash In Place	

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