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Dedicated and Campaign wfwËK Jla Drcv`‡bi MvBWjvBb

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1| Introduction:

‡h mg¯ Pharmaceuticals Gi acute, sub-chronic/chronic, reproductive toxicity, mutagenecity, carcinogenicity, sensitization/allergy, irritency i‡q‡Q ‡m mKj High potent, High risk pharmacological/ toxicological character wewkó product Gi cross-contamination or contamination †iva Kiv Avevk¨K| DwjwLZ %ewkó wewkó Product Gi Occupational Exposure Limit (OEL)Ges Acceptable Daily Intake(ADI) Gi wfwË‡Z myb`ó Drcv`b myeav (Separate, dedicate, segregate, Isolation/containment and campaign) wbaviY Kiv Avevk¨K| cwZwU Molecule Gi Rb¨ Occupational Exposure Band (OEB) Ges Occupational Exposure Limit (OEL) Gi wfwË‡Z Facility Design Kiv c‡qvRb| Jl‡ai Molecule-Gi- DwjwLZ ˆewk‡ó¨i Dci wbfi K‡i wewfb Containment Facility-Gi Dci WHO MvBWjvB‡b wb‡`kbv i‡q‡Q|

Cross-contamination Ges Contamination†iv‡a Dchy³ HVAC Ges DUST Control mn facility design Kiv Ri¤ix| High Potent Ges Sensitizing molecule we‡kó cWv±mgn- Separate & Dedicated facility, Dedicated facility ev Campaign facility-‡Z Drcv`b Kiv n‡q _v‡K| Jla Drcv`bKvix cwZôvbmgn‡K Separate & Dedicated facility, Dedicated facility ev Campaign facility- m¤ú‡K GKwU my¯úó avivYv c`vb Ges Jla ckvm‡bi KgKZv‡`i Uniform Practice-Gi wbwg‡Ë GZØIqK GKwU MvBWjvBb Avek¨K| cYxZ MvBWjvBb gvbm¤úb Jla Drcv`‡b mnvqK n‡e|

2| Purpose:

2.1| wbivc` I gvbm¤úb Jla Drcv`b wbwðZ Kiv|
2.2| High potent, High risk pharmacological/toxicological character we‡kó product/molecule Gi Group wfwËK Zwjv cYqb Kiv|
2.3| Cross-contamination or contamination †iv‡a KvhKi e¨e¯v wbwðZ Kiv|
2.4| Jla Drcv`‡b wb‡qwRZ Rbe‡ji ¯v¯¨MZ wbivcËv wbwðZ Kiv |
2.5| cwi‡e‡ki wbivcËv wbwðZ Kiv|4
2.6| Jla Drcv`b I gvbwbqšY myeavw` gj¨vq‡bi ‡¶‡Î ckvm‡bi KgKZv‡`i Awfb Abykxjb wbwðZ Kiv|

3| Scope:

‡`‡ki Jla Drcv`bKvix cwZôvbmg‡n Drcw`Z wewfb cKvi High Potent & High Risk Jlamg‡ni cross-contamination/contamination‡iv‡a c‡qvRbxq w`K-wb‡`kbv c`v‡bi Rb¨ G Guideline c‡hvR¨ n‡e|

4| Areas:

K) B-Lactum Antibiotic (Penicillin, Cephalosporin)**:** Penicillin I Cephalosporin RvZxq c`mgn- c„_Kfv‡e ÔSeparate & Dedicated' myeavq Drcv`b Ki‡Z n‡e| Other B-Lactum (Penem, Carbacephems & Monobactum) RvZxq c` Cephalosporin GjvKvq K¨v¤úBbwfwËK Drcv`b Kiv hv‡e|

L) Hormone**:** Potent Hormone Separate & Dedicated myeavq Drcv`b Ki‡Z n‡e Ges Non-potent Hormone K¨v¤úBbwfwËK Shared Facility- ‡Z Drcv`b Kiv hv‡e |
Male Sex & Female Sex Hormone Dedicated GjvKvq Self-contained myeavq Drcv`b Ki‡Z n‡e|

M) Anti-cancer (Cytotoxic): a) Cytotoxic RvZxq Anti-cancer c`mgn- Separate & Dedicated myeavq Drcv`b Ki‡Z n‡e |
b) Non-cytotoxic Anti-cancer c`mgn-K¨v¤úBbwfwËK Shared Facility-‡Z Drcv`b Kiv hv‡e|

N) Vaccine:
i) Human Vaccine: Live Vaccine 'Separate & Dedicated' myeavq Drcv`b Ki‡Z n‡e| Dedicated GjvKvq Bacteria Ges Virus RvZxq Killed Vaccine K¨v¤úBbwfwËK Drcv`b Kiv hv‡e|

ii) Animal & Poultry Vaccine: Animal & Poultry Live Vaccine c„K c„K 'Separate & Dedicated' myeavq Drcv`b Ki‡Z n‡e|
Animal & Poultry RvZxq Killed Vaccine Dedicated GjvKvq Self-contained myeavq Drcv`b Kiv hv‡e|

O) Steroid: Steroid RvZxq c` K¨v‡¤úBbwfwËK Shared Facility-‡Z Drcv`b Kiv hv‡e|

P) Biosimilar Drug (Vaccine e¨ZxZ): Critical ev‡qvwmwgjvi WvM (Hazardous in nature) Separate & Dedicated Drcv`b myeavq Drcv`b Ki‡Z n‡e| Non-critical RvZxq c` K¨v‡¤úBbwfwËK Shared Facility-‡Z Drcv`b Kiv hv‡e| Immunoglobulin-Antitoxin, Dedicated Drcv`b myeavq Drcv`b Ki‡Z n‡e|

Q) Blood products: Blood products Separate & Dedicated Drcv`b myeavq Drcv`b Ki‡Z n‡e |

R) External/Topical Liquids: Segregated Facility ‡Z m¤úY© c„K †gwkb e¨envi K‡i Drcv`b Ki‡Z n‡e|

S) Radioactive Pharmaceuticals: Radioactive Pharmaceuticals Separate & Dedicated Drcv`b myeavq Drcv`b Ki‡Z n‡e |

T) Medical devices & Diagnostics: Medical devices & Diagnostics Separate & Dedicated Drcv`b myeavq Drcv`b Ki‡Z n‡e |

U) Medical Gases: Medical Gases Separate & Dedicated Drcv`b myeavq Drcv`b Ki‡Z n‡e|

V) Veterinary Drug: ‡h mKj f¨v‡Uwibvix Jl‡ai gvbe †`‡n e¨envi bvB Ges ïaygvÎ f¨v‡Uwibvix ‡M‡Wi KuPvgvj Øviv Drcw`Z Jlamgn- Dedicated Drcv`b myeavq Drcv`b Ki‡Z n‡e|

5| Test & Analysis: Sensitizing Drug & Live Vaccine mg‡ni cix¶v I we‡klY Kvhw` c„K c„K j¨v‡e m¤úb Ki‡Z n‡e|

6| Definitions:

a) Contamination:
The undesired introduction of impurities of a chemical or microbiological nature, or of foreign matter, into or onto a raw material, intermediate, or API during production, sampling, packaging or repackaging, storage or transport.

b) Cross-contamination:
Contamination of a starting material, intermediate product, or finished product with another starting material or product during production.

Cross-contamination can results from, e.g.

1. Poorly designed, operated or maintained air-handling systems and dust extraction systems
2. Inadequate procedures for, and movement of personnel, materials and equipment insufficiently cleaned equipment.

c) Campaign Production:

Campaign Production is defined as a manufacturing of a product in row with use of equipment with proper cleaning validation.

d) Containment/Isolation:

Isolation/Containment is defined as use of equipment and application of special Technology (PPE & Ventilation, Closed System Containment, CIP & WIP, HVAC and others).

The action of confining Biological, Sensitizing & Highly Potent drug substance or other entity within a defined space.

i) Primary containment:

A system of containment which prevents the escape of a Biological, Sensitizing & Highly Potent agent into the immediate working environment. It involves the use of closed containers or safety biological cabinets along with appropriate standard operating procedures.

ii) **Secondary containment:**

A system of containment which prevents the escape of a Biological, Sensitizing & Highly Potent agent into the external environment or into other working areas. It involves the use of rooms with specially designed air handling, the existence of airlocks and/or pass box for the exit of materials and appropriate standard operating procedures. In many cases it may add to the effectiveness of primary containment.

e) Dedicated Facility:

Dedicated Facility is defined as Facility within same building with no common access and with separate HVAC and having common Utilities and Waste treatment. It may be in the same floor or may be in different floor**.**

f) Separate Facility:

Separate facility is defined as totally dedicated and self-contained building which is isolated from other buildings in the site.

Separate facility must have:

- Separate HVAC System
- Purified Water and Water for Injection Loop Distribution System
- Separate Utilities
- Waste Treatment
- Change Room & Change Facilities and
- Also the Quality Control Laboratory may be separated based on the toxicity and sensitivity of the molecules.

g) Segregated Facility:

Segregated facility is defined as facility in same building but with dedication in a modular formation having common access with separate HVAC, common Utilities and Waste Treatment**.**

h) Self Containment Facility:

Self-Containment Facilities is defined as facility in the same building as another facility but Should be separated by a physical barrier and have separate entrance, staff facilities and air-handling systems.

i) Occupational Exposure Limit (OEL):

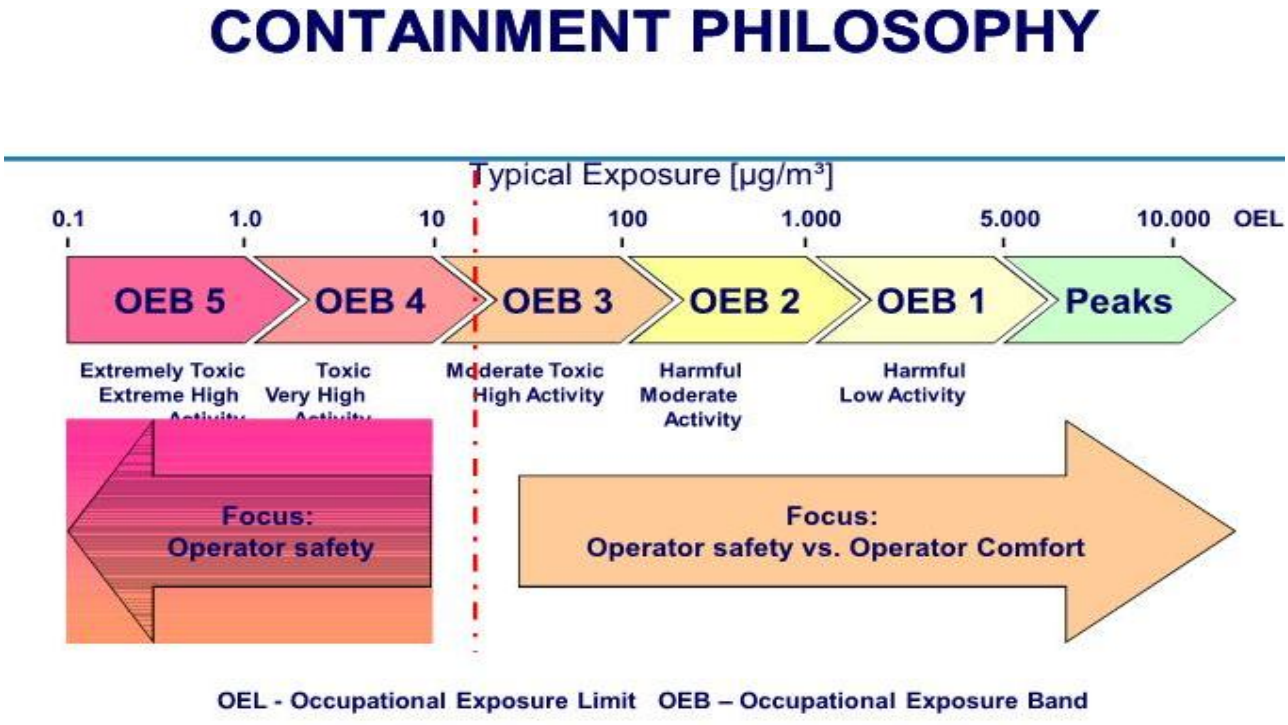
OEL is safe level of air borne exposure for an 8 hour workday, which does not impair health day after day at work (mg/m^3).

An **occupational exposure limit** is an upper limit on the acceptable concentration of a hazardous substance in workplace air for a particular material or class of materials. It is typically set by competent national authorities and enforced by legislation to protect health. It can be a tool in risk assesment and in the management of activities involving handling of dangerous substances.[1]

There are many dangerous substances for which there are no formal occupational exposure limits. In these cases, control banding strategies can be used to ensure safe handling. The "Hierarchy of OELs" provides a continuum of occupational exposure limit values that allow assessment of the risk of exposure in order to apply adequate controls.

ii) Occupational Exposure Band (OEB):

Occupational ExposureBand enables use of Hazard classification data to develop OEL ranges.Control banding is a process of assigning a compound to a hazard category that corresponds to a range of airborne concentrations – and the engineering controls, administrative controls, and personal protective equipment – needed to ensure safe handling. While the terminology used was different, the high potency of some pharmaceutical compounds required the use of alternatives to setting numerical occupational exposure limits (OELs), e.g., performance-based exposure control limits (PB-ECLs) or occupational exposure bands(OEBs).



j) Acceptable Daily Intake (ADI):

ADI is the amount of a drug or chemical residue to which person can be exposed daily for a lifetime without suffering a deleterious or injurious effect, on the basis of all of the facts known at the time.

References:

1. WHO GMP Guideline
2. PICs Guideline
3. ICH Guideline
4. NIOSH Guideline