STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
Title: Decontamination and Disposal of Waste Material	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

1.0 Purpose:

To describe the procedure for decontamination and disposal of waste material at Quality Control Department.

2.0 Applicable to:

This Standard Operating Procedure is applicable for decontamination and disposal of waste materials at Quality Control Department of Vaccine Formulation Plant.

3.0 Responsibility:

3.1 Officer / operator shall be responsible for the decontamination and disposal of waste material.

3.2 Head – Quality Control shall be responsible for training of the concerned persons and implementation of the SOP.

3.3 Head – Quality Assurance shall be responsible for compliance and authorization of the SOP.

4.0 Safety considerations:

4.1 Wear mask, gloves and goggles at the time of collection of waste material.

5.0 Equipment:

5.1 Decontamination autoclave

5.2 Fume hood

6.0 Materials and reagents:

6.1 Autoclavable biohazard bags

6.2 Crystal violet dye

6.3 Cable tie

6.4 Polythene bags

7.0 Preparation of solutions:

7.1 0.5% Crystal violet solution (with 5% Formaldehyde) v/v.

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8.0 Procedure:

8.1 Different waste materials generated in Quality control are categorized as:-

Type 1. General Wastes: - Head caps, Shoe covers, masks, paper waste, disposable dresses, packaging material like cartons, steripouches, blister packs, aluminium foil, broken glass wares and empty solvent bottles etc.

Type 2. Microbiological wastes: - Petri plates used for EMP, TVAC and pathogen testing, used swabs, sterility canisters, used syringes, used needles after blunting process, micro fill cups, uricol sampling bottles, reagent bottles, endotoxin vials, nalgene sampling bottles, media fill vials, prefilled syringes, stability sample containers (filled vaccine vials, Pre filled syringes, RTF bags), used vaccine vials etc.

Type 3. Immunological Wastes: - Elisa plates, SNT plates, HAI sample plates, used tips, other used cell line bottles and plastic wastes etc.

Type 4. Chemical wastes: - All the expired chemicals, Expired chemical bottles, solutions after analysis, organic solvents (Chemically hazardous waste) etc.

8.2 Type 1 waste shall be packed in polythene bags. Tie bags properly with cable tie and label it (label shown in Fig.1).

8.3 Type 2 and type 3 wastes are bio hazardous in nature and shall be packed in autoclavable biohazard bags. Tied with cable tie and decontaminated in decontamination autoclave at 121ºC for 30 minutes before being disposed off and finally handed over to M/s …….. through EOHS.

8.5 Type 4 wastes like bottles shall be packed in cartons.

8.6 When Type 4 waste like empty organic volatile solvent bottles are to be discarded, keep it overnight in fume hood in opened condition and collect it in separate containers and forward to the EOHS department (for incineration) while the decontaminated media and powder wastes which are not hazardous shall be collected in a separate container. Dissolve the material in water not less than 100 times of the material volume and disposed it to ETP through drain into the basin.

QUALITY CONTROL DEPARTMENT	
WASTE STATUS LABEL	
TYPE OF WASTE MATERIAL:	
SUPERVISED BY:	VERIFIED BY:

Figure -1

8.7 Used reagent bottles shall be marked as cross (X) on manufacturer labels with thick point marker, collected in a carton and sent to scrap yard area.

8.8 All the labeled empty vaccine product vials shall be stained with crystal violet dye in a big container, after dye treatment vials are collected in bio hazardous bags and send to microbiological department for decontamination. These vials are decontaminated as per SOP and transferred to crushing area of production department. Material crushing shall be done in the presence of Q.C. person as per SOP.

8.9 All the used syringes and needles are decontaminated as per SOP and transferred to scrap yard area after ensuring its blunting process in a separate poly bag.

8.10 **Transfer of waste:** Collect all the wastes, transfer it to housekeeping incharge, Administration department and take receiving on destruction record format between 3:00 to 4:00 p.m. on daily basis.

Type 1 wastes: to be transferred through refuge chute

Type 2, 3 and 4 wastes: to be transferred through stairs route at the back side of corridor of quality control department.

9.0 Reporting:

9.1 Record all the waste material for destruction as per Annexure – 1.

10.0 References:

10.1 SOP on SOP for preparation, issuance, revision, retrieval, obsolescence and destruction of standard operating procedure.

10.2 Schedule M.

11.0 Annexure:

Annexure No.	Form No.	Title	No. of pages
1.		Waste material destruction record.	1

12.0 Distribution:

Master Copy	Archived with Quality Assurance Department
Controlled Copy 1	Initiating Department
Subsequent controlled copies	Department (s) making requisition

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13.0 History:

Effective Date	Status	Changes/Reasons for revision

14.0 Abbreviations:

14.1 EMP : Environmental Monitoring Procedure

14.2 TVAC : Total Viable Aerobic Count

14.3 EOHS : Environment Occupational Health and Safety

14.4 SNT : Serum Neutralization Test

14.5 HAI : Haem Agglutination Inhibition

14.6 RTF : Ready To Fill

14.1 Fig. : Figure

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

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Annexure 1

S.No.	Date	Type of Waste Material	Mode of Disposal	Done By	Checked By	Remarks

Send By…..
(Quality Control Department)

Received By……
(Administration Department)