

SHILPA PHARMA LIFESCIENCES LIMITED, UNIT-2

TITLE: PROTOCOL FOR VOLATILE ORGANIC CARBON (VOC) AND LOWER EXPOSURE LEVEL (LEL) MONITORING IN WORK AREA

Department: Production

Effective Date: 12/05/23

Document No.: PC/PD/VOC&LEL/WA/001/23

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PROTOCOL FOR MONITORING OF VOLATILE ORGANIC CARBON (VOC) AND LOWER EXPOSURE LEVEL (LEL) IN WORK AREA

Block : All Production Blocks

SHILPA PHARMA LIFESCIENCES LIMITED, UNIT-2**PROTOCOL FOR VOLATILE ORGANIC CARBON (VOC) AND LOWER EXPOSURE
LEVEL (LEL) MONITORING IN WORK AREA**

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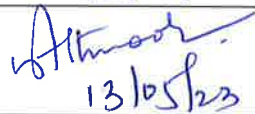


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APPROVAL PAGE

Signing of this approval page of miscellaneous study protocol indicates agreement with the methodology and the various factors captured in this protocol.

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1.0 OBJECTIVE:

To define procedure for monitoring of VOC and LEL in the work area.

The term work area means, intermediate workshops, clean rooms, equipment wash areas, etc., and the monitoring locations in these areas should represent the worst-case location w.r.t. solvent vapor.

2.0 SCOPE:

This procedure is applicable for monitoring of VOC and LEL at defined locations in the work area at Shilpa Pharma Lifesciences Limited, Unit -2.

3.0 RESPONSIBILITIES:

3.1 It is the responsibility of production Tr. Chemist and above to monitor VOC and LEL at defined locations in the work area and record the details in annexure-1.

3.2 It is the responsibility of production Sr. Executive and above to witness the activity and to provide necessary support during work area monitoring.

3.3 It is the responsibility of Head Production/Designee to ensure compliance to this protocol.

4.0 ABBREVIATIONS:

SD	: Spherical Dryer	Sr.	: Senior
LEL	: Lower Exposure Level	Tr.	: Trainee
VOC	: Volatile Organic Carbon	WA	: Work Area
PNF	: Pressure Nutsche Filter	PC	: Protocol
RCVD	: Rotacone Vacuum Dryer	PD	: Production
ANFD	: Agitated Nutsche Filter and Dryer	CIP	: Clean in Place

5.0 REASON FOR THE STUDY:

The chemicals used in the manufacturing process shall be handled as per the SOP "Raw material charging into reactor" SOP No.: SOP/U-2/PD/GEN/003/15, The solvents used in the manufacturing process shall be handled as per the SOP "Procedure for handling of bulk quantity of solvents" SOP No.: SOP/U-2/PD/GEN/084/01 transferred solvents into reactors and filters through process pumps/vacuum. However during handling, there is a risk of leakage/spillage of solvents/chemicals and during cleaning of process filters used for solvent transfer, there is a risk of personnel exposure to traces of solvent vapor.

Similarly, the process equipment, filters, components and ancillary equipment (scoop/sampler/bucket/hosepipes, etc.,) shall undergo cleaning with suitable cleaning solvent

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after usage. The closed equipment such are Reactors/RCVDs/ANFDs/SDs were equipped with spray balls for CIP cleaning where the risk of solvent exposure to personnel and to the environment during cleaning of equipment's is less.

However, the equipment components, filters, powder process equipment and ancillary equipment's (scoop/sampler/bucket/hosepipes etc.) shall be transferred to equipment wash area and cleaning is carried-out in cleaning area. Since, solvents are used for cleaning; there is a risk of personnel exposure to traces of solvent vapor.

Hence, it is plan to monitor of VOC and LEL in the work area, to know trace levels of solvent vapors in work area, which can be a safety hazard.

6.0 PROCEDURE:

- 6.1 Personnel working in the production area must wear the necessary PPEs namely safety shoes, goggles, organic vapor mask and hardhat as applicable.
- 6.2 VOC and LEL shall be monitored at work place while performing manufacturing and equipment cleaning operations and the results shall record in the annexure-1.
- 6.3 VOC and LEL monitoring shall done whenever the open handling of solvents for process and cleaning operations is in-progress.
- 6.4 VOC and LEL monitoring is not required when the work area is idle.
- 6.5 Production Sr. Executive and above shall provide necessary support for monitoring of VOC and LEL and the results shall be reviewed for safe environment to continue the manufacturing and cleaning operations.
- 6.6 The low/negligible results of VOC (or) LEL indicate that, there is no risk of exposure to solvent vapor.
 - 6.6.1 If the VOC result is high, the operator should wear the necessary respirator before commencing the work.
 - 6.6.2 If the LEL result is high, the operations should be stopped immediately and inform to Production Head and EHS Head for necessary actions. The LEL must reduce to low/negligible level by providing adequate ventilation (or) flushing the work area with water.
- 6.7 The locations for monitoring of VOC in work area defined based on the process knowledge and work experience. Following locations were consider for monitoring of VOC.

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Location ID	Description of sample location
Location-1	Center of reactor area at working height during manufacturing and cleaning operations of reactors.
Location-2	Centrifuge area at working height during unloading of wet material and cleaning of centrifuge.
Location-3	Near solvent transfer line filter while opening the filter for cleaning/replacement.
Location-4	In equipment wash area at working height while cleaning of equipment/accessories

6.8 The locations for monitoring of LEL in work area defined based on the process knowledge and work experience. Following locations were consider for monitoring of LEL.

Location ID	Description of sample location
Location-1	Just above centrifuge at working height while unloading the wet material and cleaning of centrifuge.
Location-2	Near filters (Micron/Sparkler/Leaf/PNF, etc.,) while opening the filter for cleaning/replacement.
Location-3	Just above trays at working height while loading the wet material into trays and cleaning of trays.
Location-4	Near process equipment (reactor, centrifuge, drier, filter, sifter, miller, etc.,) at working height while cleaning.
Location-5	In equipment wash area at working height while cleaning of equipment/accessories.

6.9 The PPE matrix to follow while handling organic solvents in manufacturing and cleaning operations established based on scientific knowledge and literature. The recommended PPEs as per matrix should follow while handling of organic solvents. For PPE matrix, refer annexure-2.

7.0 DATA COMPILATION AND EVALUATION:

Data shall be compiled in report and conclusion shall be drawn based on,

- VOC results
- LEL results

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8.0 CONCLUSION:

Based on the VOC and LEL results, conclusions shall be made on trace levels of solvents present in the work environment.

9.0 ATTACHMENTS:

Annexure-1 : VOC & LEL Monitoring Log in Work Area

Annexure-II : Personal Protective Equipment Matrix

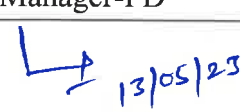
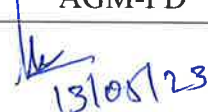
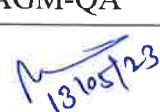
SHILPA PHARMA LIFESCIENCS LIMITED (UNIT-2)	
VOC & LEL MONITORING LOG IN WORK AREA	
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Work Area ID	Date & Time:
VOC Meter ID	
LEL Meter ID	

Location for monitoring of VOC	VOC Result	Remarks	Location for monitoring of LEL	LEL Result	Remarks

Sign & Date (monitored by):

Reviewer Comments:

Reviewer Sign & Date:

	Prepared By	Reviewed By	Approved by
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Sign & Date	 13/05/23	 13/05/23	 13/05/23

SHILPA PHARMA LIFESCIENCES LIMITED (UNIT-2)

PERSONAL PROTECTIVE EQUIPMENT MATRIX

ANNEXURE-II




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Personal Protective Equipment (PPE) Matrix:

Personal Protective Equipment (PPE)	Job Task	Protected to									
		Head	Hands	Whole Body	Eyes	Face	Ears	Lungs	Foot		
Helmet	After Enter in to the Factory premises. Its protecting head from injuries	√	x	x	x	x	x	x	x	x	x
PVC apron	Loading and unloading corrosive chemicals (acids, bases)	x	x	√	x	x	x	x	x	x	x
Air Pressure Suit	Handling toxic chemicals	x	x	√	x	x	x	x	x	x	x
PVC Hand gloves	Handling corrosive chemicals and Solvents	x	√	x	x	x	x	x	x	x	x
Neoprene Hand gloves	Handling of all Solvents	x	√	x	x	x	x	x	x	x	x
Nitrile Hand gloves	Handling powder chemical at Pharma room (controlling latex allergies)	x	√	x	x	x	x	x	x	x	x
Heat resistant Hand gloves	Water proof and high resistance against temperature	x	√	x	x	x	x	x	x	x	x
Chemical splash goggles	Handling corrosive chemicals and Solvents	x	x	x	√	x	x	x	x	x	x

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SHILPA PHARMA LIFESCIENCES LIMITED (UNIT-2)
PERSONAL PROTECTIVE EQUIPMENT MATRIX

ANNEXURE-II

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Personal Protective Equipment (PPE)	Job Task	Protected to							
		Head	Hands	Whole Body	Eyes	Face	Ears	Lungs	Foot
Welding Goggles	Its protecting eyes while some forms of welding and cutting are being done. They are intended to protect the eyes not only from the heat and optical radiation produced by the welding, cutting, such as the intense ultraviolet light produced by an electric arc, but also from sparks or debris	x	x	x	√	x	x	x	x
Face shield	Protect wearer's entire face (or part of it) from impact hazard such as flying objects and, chemical splashes	x	x	x	√	√	x	x	x
Ear Muffs and Plugs	Its protecting ears for high sounds	x	x	x	x	x	√	x	x
Organic Nose Mask	Its protecting to organic vapors at handling of solvents	x	x	x	x	x	x	√	x
Respirator with cartridge nose mask	Its protecting to different air contaminating vapors	x	x	x	x	x	x	√	x

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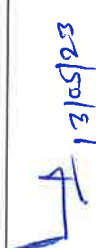

PERSONAL PROTECTIVE EQUIPMENT MATRIX

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Personal Protective Equipment (PPE)	Job Task	Protected to									
		Head	Hands	Whole Body	Eyes	Face	Ears	Lungs	Foot		
Dust and disposal nose mask	Its protecting against dust and chemical powder	x	x	x	x	x	x	√			x
Safety shoes	Steel-capped boot or safety shoe) is a durable boot or shoe that has a protective reinforcement in the toe which protects the foot from falling objects	x	x	x	x	x	x	x			√
Safety Gumboots	They are usually worn when walking on wet or Chemical muddy ground.	x	x	x	x	x	x	x			√
Fire suit	Protect a firefighter from high temperatures, especially near fires of extreme temperature such as chemical fires.	x	x	√	x	x	x	x			x
SCBA (self-contained breathing apparatus)	Rescue workers, firefighters, and others to provide breathable air in an immediately dangerous to life	x	x	x	√	√	x	√			x

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