

**SHILPA PHARMA LIFESCIENCES LIMITED, UNIT-2**

**WORK AREA AIR QUALITY MONITORING REPORT**

**Department:** Production

**Report No.:** RPT/PD/VOC&LEL/WA/001/23

**Ref. Protocol No.:** PC/PD/VOC&LEL/WA/001/23

Page 1 of 15

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

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


**Block** : All Production Blocks, QC & WH







**SHILPA PHARMA LIFESCIENCES LIMITED, UNIT-2****WORK AREA AIR QUALITY MONITORING REPORT****Department:** Production**Report No.:** RPT/PD/VOC&LEL/WA/001/23**Ref. Protocol No.:** PC/PD/VOC&LEL/WA/001/23


Page 2 of 15

**TITLE: REPORT FOR VOLATILE ORGANIC CARBON (VOC) AND LOWER EXPOSURE LEVEL (LEL) MONITORING IN WORK AREA****APPROVAL PAGE**

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

	<b>Name</b>	<b>Designation</b>	<b>Sign / Date</b>
Prepared by	Awnesh Kumar Goswami	Dy. Manager-PD	 13/09/23

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Approved by	N. Saravanan	AGM-QA	 16/09/23

## SHILPA PHARMA LIFESCIENCES LIMITED, UNIT-2

### WORK AREA AIR QUALITY MONITORING REPORT

**Department:** Production

**Report No.:** RPT/PD/VOC&LEL/WA/001/23

**Ref. Protocol No.:** PC/PD/VOC&LEL/WA/001/23

Page 3 of 15

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

#### 1.0 INTRODUCTION

Organic Volatile Carbon (VOC) and Lower Exposure Levels (LEL) monitoring is done in work area at specified locations as per the procedure defined in protocol (Ref. Protocol No.: PC/PD/VOC&LEL/WA/001/23).

The Organic Volatile Carbon (VOC) and Lower Exposure Levels (LEL) results of mentioned production blocks are tabulated below;

S. No.	Block	Location of monitoring	VOC in ppm	LEL in %	Remarks
1.	E	Centrifuge (E/CF-05) vent during spinning.	0	0	VOC & LEL monitored during Nor-UDC (NDA-I) batch, Process & Cleaning activities
2.		In front of Centrifuge (E/CF-05).	0	0	
3.		During unloading of wet material from Centrifuge (E/CF-05).	1	0	
4.		During opening of Sparkler Filter (E/SF-05).	0	0	
5.		During washing of Sparkler Filter (E/SF-05).	1	0	
6.		At extension area of reactor (E/RE-22) during washing.	0	0	
7.		Pharma area equipment wash room during cleaning of equipment.	1	0	
8.		Washing room-Repacking area,	0	0	
9.		Outside area-E/RC-18: during cleaning	0	0	
10.	AO	AO/RE-11 Intermediate area.	1	0	VOC & LEL monitored during Tranexamic Acid batch, Process & Cleaning activities
11.		AO/PTS-01 Pharma area.	1	0	
12.		Pharma Washing area.	1	0	
13.		AO/CF-03 area.	0	0	
14.		AO/RE-05 Intermediate Area.	0	0	
15.		AO/SF-05 Intermediate Area while opening the lid.	0	0	
16.		AO/SF-05 Intermediate washing area.	0	0	
17.		Crystallizer area between AO/RE-16 & AO/RE-16 during process activities.	0	0	
18.		Crystallizer area between AO/RE-16 & AO/RE-16 during batch to batch cleaning.	0	0	
19.		Crystallizer area AO/CF-03 during centrifugation.	1	0	

## SHILPA PHARMA LIFESCIENCES LIMITED, UNIT-2

### WORK AREA AIR QUALITY MONITORING REPORT

**Department:** Production

**Report No.:** RPT/PD/VOC&LEL/WA/001/23

**Ref. Protocol No.:** PC/PD/VOC&LEL/WA/001/23

Page 4 of 15

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

S. No.	Block	Location of monitoring	VOC in ppm	LEL in %	Remarks
20.		Crystallizer area AO/CF-03 during batch to batch cleaning.	0	0	
21.		Intermediate area near to vacuum pump AO/VP-05.	0	0	
22.		Outside area near AO/ST-11 & AO/ET-02 during NH3 solution preparation.	1	0	
23.		Outside area near AO/ST-11 & AO/ET-02 idle condition (with storage).	0	0	
24.		Outside area near AO/ST-12 & AO/ST-14A during MLs receiving.	0	0	
25.		Outside area near AO/ST-12 & AO/ST-14A idle condition (with storage).	0	0	
26.		Outside area near AO/ST-19 during water collection.	0	0	
27.		Outside area near AO/ST-19 idle condition.	0	0	
28.	AO7	At emergency exit: during batch running	0	0	VOC & LEL monitored during Tranexamic Acid batch, Process & Cleaning activities.
29.		At emergency exit (module-I): during batch running	0	0	
30.		At entry (module-2): during batch running	0	0	
31.		At AO/ cooling tower: during batch running	0	0	
32.		AO/RE-24: Batch Processing	0	0	
33.		AO/RE-24: Batch to batch cleaning.	0	0	
34.		AO/ST-64: Batch transferring	0	0	
35.		AO/ST-64: Idle	0	0	
36.		AO/ST-66: Batch transferring	0	0	
37.		AO/ST-66: Idle	0	0	
38.		AO/PNF-06: batch under processing	0	0	
39.		AO/PNF-06: batch to batch cleaning	0	0	
40.		Equipment wash area: during cleaning	1	0	

## SHILPA PHARMA LIFESCIENCES LIMITED, UNIT-2

### WORK AREA AIR QUALITY MONITORING REPORT

**Department:** Production

**Report No.:** RPT/PD/VOC&LEL/WA/001/23

**Ref. Protocol No.:** PC/PD/VOC&LEL/WA/001/23

Page 5 of 15

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

S. No.	Block	Location of monitoring	VOC in ppm	LEL in %	Remarks
41.		Equipment wash area: idle	0	0	
42.		AO/RE-18: during NH <sub>3</sub> Purging	0	0	
43.		AO/RE-18: Idle with residue	0	0	
44.		AO/RE-20: during distillation	0	0	
45.		AO/RE-20: during batch to batch cleaning	0	0	
46.		AO/ANFD-03: during process	0	0	
47.		AO/ANFD-03: during batch to batch cleaning	0	0	
48.		AO/RE-19: during HMA addition	0	0	
49.		AO/RE-19: during batch to batch cleaning	0	0	
50.		C/SF-01 intermediate area.	1	0	VOC & LEL monitored during Capecitabine batch, Process & Cleaning activities
51.		At wash area, during C/SF-01 accessories washing.	1	0	
52.	C	Near reactor C/RE-14 during flushing with toluene.	1	0	
53.		Near C/RE-14A outside the block, during distilled MDC unloading	1	0	
54.		H/RE-10 (M-II) intermediate area after flushing reactor with DMF.	1	0	VOC & LEL monitored during LDM batch, Process & Cleaning activities
55.		H/SC-92 (M-II) Intermediate wash area during cleaning with methanol.	1	0	
56.		H/CF-04 (M-II) intermediate area during centrifuge unloading.	1	0	
57.	H	H/HY-02 Hydrogenator area after flushing with methanol.	1	0	
58.		H/PNF-01 Hydrogenator area during filtration.	0	0	
59.		H/PNF-01 during celite bed formation with methanol.	1	0	
60.		H/RE-12 pharma area after flushing reactor with methanol.	1	0	

## SHILPA PHARMA LIFESCIENCES LIMITED, UNIT-2

### WORK AREA AIR QUALITY MONITORING REPORT

**Department:** Production

**Report No.:** RPT/PD/VOC&LEL/WA/001/23

Page 6 of 15

**Ref. Protocol No.:** PC/PD/VOC&LEL/WA/001/23

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

S. No.	Block	Location of monitoring	VOC in ppm	LEL in %	Remarks
61.		H/CF-01 & H/GB-01 Pharma Area during centrifugation.	1	0	
62.		H/SC-95 pharma area during cleaning.	0	0	
63.		H/RE-03 Intermediate area (M-I): IPAS flushing for CF washing.	1	0	
64.		H/MLTCF-06 using in MLs collection.	0	0	
65.		Centrifuge H/CF-06 wet material unloading.	1	0	
66.		Vacuum tray drier H/VTD-01 wet material loading	1	0	
67.		Vacuum tray drier H/VTD-01 dry material unloading.	0	0	
68.		Scoop H/SC-94 after cleaning with methanol.	1	0	
69.	AM	AM/RE-15 Intermediate area after flushing the reactor with methanol.	1	0	VOC & LEL monitored during Eltrombopag Olamine batch, Process & Cleaning activities
70.		AM/PNF-05 Lid opening.	1	0	
71.		Wash area during cleaning of AM/PNF-05 accessories with methanol.	1	0	
72.		AM/VTD-06 loading.	1	0	
73.		AM/VTD-06 unloading.	1	0	
74.		AM/RE-07 Pharma area after batch charging.	1	0	
75.		AM/CF-07 Pharma area during wet material unloading.	1	0	
76.		AM/VTD-01 Pharma area during dry material unloading.	1	0	
77.		AM/RE-02 Intermediate area (M-I) after flushing the reactor with methanol.	0	0	
78.		AM/RE-04 Intermediate area (M-I) after flushing the reactor with methanol.	1	0	
79.		AM/RE-09 Intermediate area (M-I) after flushing the reactor with methanol.	0	0	
80.		AM/PNF-01 Intermediate area (M-I) open condition (MDC).	0	0	
81.		AM/SF-01 Intermediate area (M-I) open condition (MDC).	0	0	
82.		AM/RE-04 Intermediate area (M-I) after flushing the reactor with DIPE.	0	0	

## SHILPA PHARMA LIFESCIENCES LIMITED, UNIT-2

### WORK AREA AIR QUALITY MONITORING REPORT

**Department:** Production

**Report No.:** RPT/PD/VOC&LEL/WA/001/23

Page 7 of 15

**Ref. Protocol No.:** PC/PD/VOC&LEL/WA/001/23

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

S. No.	Block	Location of monitoring	VOC in ppm	LEL in %	Remarks
83.		AM/CF-06 Intermediate area (M-I) open condition (DIPE).	0	0	
84.		AM/VTD-03 Intermediate area (M-I) open condition.	0	0	
85.		Outside area: after activity	0	0	
86.		Near AJ/RE-06 reactor, during flushing of reactor with methanol.	1	0	
87.		Near AJ/CF-02, during unloading of wet material.	1	0	VOC & LEL monitored during UDA batch, Process & Cleaning activities.
88.	AJ	Near AJ/AT-02, during cleaning with methanol.	1	0	
89.		Near wash area, during cleaning of accessories with methanol.	1	0	
90.		Outside area AJ/MLTCF-01, after collection of methanol.	0	0	
91.		Outside area AJ/CFCP-01, after collection of methanol.	0	0	
92.		D/RE-16 Intermediate area, during washing time.	0	0	
93.		D/SF-01 Intermediate area, during dish opening time.	0	0	VOC & LEL monitored during Capecitabine batch, Process & Cleaning activities.
94.	D	D/SF-01 Intermediate area, during washing time.	0	0	
95.		Outside area-D/CFMLT-01: Toluene MLs collection	0	0	
96.		Pharma Area-D/CF-01 & D/GB-01: wet material unloading	0	0	
97.		Washing area- Pharma: While accessories cleaning	1	0	
98.		AI/RE-05 Intermediate Area, while IPA charging.	0	0	VOC & LEL monitored during Axitinib batch, process & cleaning activities.
99.	AI	AI/PNF-01 Intermediate Area, while reaction mass filtration.	0	0	
100.		AI/PNF-01 Intermediate Area, while opening pressure nutsche filter.	0	0	
101.		AI/PNF-01 Intermediate Area, after cleaning.	0	0	

## SHILPA PHARMA LIFESCIENCES LIMITED, UNIT-2

### WORK AREA AIR QUALITY MONITORING REPORT

**Department:** Production

**Report No.:** RPT/PD/VOC&LEL/WA/001/23

**Ref. Protocol No.:** PC/PD/VOC&LEL/WA/001/23

Page 8 of 15

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

S. No.	Block	Location of monitoring	VOC in ppm	LEL in %	Remarks
102.		AI/RC-02 Outside Area, while unloading distilled IPA from receiver.	0	0	
103.		AI/PNFMLT-01 Outside Area, while unloading filtrate MLs.	0	0	
104.		Pharma area-AI/GT-10: While sucking methanol.			
105.		Pharma area-AI/MF-04: While opening the micron filter.			
106.		Pharma area-AI/MF-04: While cleaning the micron filter.			
107.	I	I/RE-05 Intermediate Area (Module-I), while flushing with MDC.	1	0	VOC & LEL monitored during Bendamustine Hydrochloride batch, Process & Cleaning activities.
108.		I/RF-04 Intermediate Area (Module-I), open condition MDC traces.	1	0	
109.		I/CF-01 Intermediate Area (Module-I), while wet material unloading.	1	0	
110.		I/VTD-02 Intermediate Area (Module-II), while loading wet material.	1	0	
111.		I/VTD-02 Intermediate Area (Module-II), while unloading dry material.	0	0	
112.		Washing Area Intermediate Area (Module-II), after accessories cleaning.	0	0	
113.		I/RE-17 Intermediate Area (Module-I), while flushing with water.	0	0	
114.		I/RF-04 Intermediate Area (Module-I), open condition MDC traces.	1	0	
115.		I/CF-02 Intermediate Area (Module-I), while wet material unloading.	1	0	
116.		I/VTD-01 Intermediate Area (Module-I), while loading wet material.	1	0	
117.		I/VTD-01 Intermediate Area (Module-I), while unloading dry material.	0	0	
118.		Washing Area Intermediate Area (Module-I), after accessories cleaning.	0	0	
119.		Outside area I/MLTNF-01, drying with nitrogen.	0	0	
120.		Pharma area I/RE-12, flushing with methanol.	1	0	



## SHILPA PHARMA LIFESCIENCES LIMITED, UNIT-2

### WORK AREA AIR QUALITY MONITORING REPORT

**Department:** Production

**Report No.:** RPT/PD/VOC&LEL/WA/001/23

**Ref. Protocol No.:** PC/PD/VOC&LEL/WA/001/23

Page 9 of 15

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

S. No.	Block	Location of monitoring	VOC in ppm	LEL in %	Remarks
121.		Pharma area- accessories cleaning with methanol.	1	0	
122.	G	G/RE-05 First Floor, After flushing with Acetone	1	0	VOC & LEL monitored during UDCA batch, Process & cleaning activities.
123.		G/RE-05 First Floor, under Acetone charging	1	0	
124.		G/CF-01 Ground Floor, under wet material unloading.	1	0	
125.		G/TD-01 Second Floor, under wet material loading.	1	0	
126.		G/TD-01 Second Floor, under dry material unloading.	0	0	
127.		Washing Area, after accessories cleaning with methanol.	0	0	
128.		G/MLTCF-01 Outside area - during collection of acetone MLs.	0	0	
129.		G/MLTCF-02 Outside area - during collection of ethyl acetate MLs	0	0	
130.		G/HMC-01 Outside area – during solvent collection.	0	0	
131.		G/FST-01 Outside area – during solvent collection.	0	0	
132.		G/RST-01 Outside area – during solvent collection.	0	0	
133.	WH	Dispensing Area-01, with operation.	0	0	Warehouse during activities VOC & LEL levels.
134.		Dispensing Area-02, with operation.	0	0	
135.		Sampling Area, with operation.	0	0	
136.		Acid Dispensing Booth, with operation.	0	0	
137.		Drum Storage Yard-01, with operation.	1	0	
138.		Drum Storage Yard-02, with operation.	0	0	
139.		Solvent Dispensing Area, with operation.	1	0	
140.		Solvent Tanks outside area, with operation.	N/A	0	
141.		Dispensing Area-01, without operation.	0	0	Warehouse without activities VOC
142.		Dispensing Area-02, without operation.	0	0	

SHILPA PHARMA LIFESCIENCES LIMITED, UNIT-2					
WORK AREA AIR QUALITY MONITORING REPORT					
Department: Production					Page 10 of 15
Report No.: RPT/PD/VOC&LEL/WA/001/23					
Ref. Protocol No.: PC/PD/VOC&LEL/WA/001/23					
TITLE: REPORT FOR VOLATILE ORGANIC CARBON (VOC) AND LOWER EXPOSURE LEVEL (LEL) MONITORING IN WORK AREA					
S. No.	Block	Location of monitoring	VOC in ppm	LEL in %	Remarks
143.		Sampling Area, without operation.	0	0	& LEL levels
144.		Acid Dispensing Booth, without operation.	0	0	
145.		Drum Storage Yard-01, without operation.	0	0	
146.		Drum Storage Yard-02, without operation.	0	0	
147.		Solvent Dispensing Area, without operation.	0	0	
148.		Solvent Tanks outside area, without operation.	1	0	
149.	QC	Weighing balance SPL2/QC/SB/001 during CPC material weighing.	0	0	Quality Control during activities & cleaning VOC & LEL levels
150.		Mobile preparation Capecitabine.	1	0	
151.		Weighing balance SPL2/QC/WB/007 during Tranexamic acid material weighing.	0	0	
152.		Washing area accessories, test tube, pipet cleaning with methanol.	1	0	

From the above results, it is clear that, the airborne concentration of organic solvents (hazardous material) in the work area is negligible and the personnel can execute day-to-day operations without any adverse health effect.

However, the obtained LEL results were correlated with theoretical Threshold Limit Values (TLV) of majority of organic solvents used in the site and accordingly conclusions are draw as follows.

**Threshold Limit Value (TLV):** The maximum average airborne concentration of a hazardous material to which healthy adult workers can be exposed during an 8-hour workday and 40-hour workweek—over a working lifetime—without experiencing significant adverse health effects.

**Immediately Dangerous to Life and Health Limits (IDLHs):** The concentration of a chemical in the air to which healthy adult workers could be exposed (if their respirators fail) without suffering permanent or escape-impairing health effects.

**SHILPA PHARMA LIFESCIENCES LIMITED, UNIT-2**

**WORK AREA AIR QUALITY MONITORING REPORT**

**Department:** Production

**Report No.:** RPT/PD/VOC&LEL/WA/001/23

Page 11 of 15

**Ref. Protocol No.:** PC/PD/VOC&LEL/WA/001/23

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

S. No.	Name of the Organic Solvent	TLV (ppm)	IDLH (ppm)	Block	Maximum volume (L) of Solvent used block wise in Process & Cleaning			
					Product	Stage	Process	Cleaning
1.	Acetic Anhydride	5	200	AJ	RK	II	714.286	0
				AI	Axitinib	IV	16.0	0
2.	Acetic Acid	10	50	AM	Eltrombopag (EBA)	III	16.046	0
				AI	Fingolimod HCl	I	14.4	0
				AO	Oxcarbazepine	I	128.08	0
				E	Montelukast Sodium	I	300.0	0
				D	Bicalutamide	II	550.048	0
				C	Capecitabine	III	84.5	0
				H	Melphalan HCl	I	252.0	0
				I	Lenvatinib Mesylate	IV	16.0	0
3.	Acetonitrile	20	500	I	Lenvatinib Mesylate / LNT	III	123.05	0
				E	Tenofovir Disoproxil Fumarate	I	1305.0	0
				H	Busulfan	I	5.5	0
				AM	Lenvatinib Mesylate / LVT	II	74.25	0
				AI	Pomalidomide	I	170.6	0
				C	TP1RM	I	2250.0	0

## SHILPA PHARMA LIFESCIENCES LIMITED, UNIT-2

### WORK AREA AIR QUALITY MONITORING REPORT

**Department:** Production

**Report No.:** RPT/PD/VOC&LEL/WA/001/23

Page 12 of 15

**Ref. Protocol No.:** PC/PD/VOC&LEL/WA/001/23

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

S. No.	Name of the Organic Solvent	TLV (ppm)	IDLH (ppm)	Block	Maximum volume (L) of Solvent used block wise in Process & Cleaning			
					Product	Stage	Process	Cleaning
4.	Acetone	500	2500	AO	Tranexamic Acid (TXO)	VI	5147.0	0
				E	Montelukast Sodium	I	80.051	0
				C	Capecitabine	I	20.0	0
				D	Azacitidine (AZD)	I	2985.0	0
				H	Busulfan	I	372.0	0
				AM	Eltrombopag (EBA)	III	861.0	0
				AI	Zoledronic Acid	III	103.12	0
5.	n-Butanol	100	1400	E	Tenofovir Alafenamide Fumarate	I	6.48	0
6.	Cyclohexane	100	1300	G	K / Rectified 2-Butanol	6K	100.0	0
				E	TF7	I	2305.0	0
7.	Dichloro methane (DCM)	50	2,300	D	Imatinib Mesylate	I	9160.0	0
				C	Capecitabine	III	4200.0	0
				G	Rectified MDC from PC-III	-	17.045	0
				AJ	K	5	325.758	0
				I	Lenvatinib Mesylate	III	2235.682	0
				AI	Carmustine	I	140.152	0
				AM	Target-A	II	0	127.5
				E	TF7	I	2025.0	0
				H	Pemetrexed Disodium	I	1074.15	0
AO	Oxcarbazepine	III	295.15	0				

## SHILPA PHARMA LIFESCIENCES LIMITED, UNIT-2

### WORK AREA AIR QUALITY MONITORING REPORT

**Department:** Production

**Report No.:** RPT/PD/VOC&LEL/WA/001/23

Page 13 of 15

**Ref. Protocol No.:** PC/PD/VOC&LEL/WA/001/23

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

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					Product	Stage	Process	Cleaning
8.	Dimethyl Formamide (DMF)	10	500	AI	Pomalidomide	I	120.0	0
				AM	Eltrombopag (EBA) Int	III	82.503	0
				C	TP1RM	I	223.01	0
				D	Imatinib Mesylate	I	1210.0	0
				H	Pemetrexed Disodium	I	250.15	0
				I	Pemetrexed Disodium Heptahydrate	I	96.07	0
9.	Ethanol	1000	3300	H	Abiraterone Acetate	IV	442.0	0
				AM	Eltrombopag Olamine	I	68.1	0
				AI	Fingolimod HCl	I	84.6	0
				I	Pemetrexed Disodium Heptahydrate	II	148.3	0
10.	Hexane	500	1100	AI	Clofarabine	I	40.6	0
				AM	Varenicline Tartrate	I	42.6	0
				E	Montelukast Sodium	I	1085.07	0
				H	Abiraterone Acetate	III	739.0	0
				C	Enzalutamide KSM-III/ICT	I	523.0	0
11.	n-Heptane	400	750	AI	Carmustine	I	101.778	0
				C	Capecitabine	II	84.0	0
				D	Capecitabine (J)	II	60.0	0
				E	Montelukast Sodium	II	498.074	0
				I	Bendamustine HCl	II	240.889	0

**SHILPA PHARMA LIFESCIENCES LIMITED, UNIT-2**

**WORK AREA AIR QUALITY MONITORING REPORT**

**Department:** Production

**Report No.:** RPT/PD/VOC&LEL/WA/001/23

Page 14 of 15

**Ref. Protocol No.:** PC/PD/VOC&LEL/WA/001/23

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

S. No.	Name of the Organic Solvent	TLV (ppm)	IDLH (ppm)	Block	Maximum volume (L) of Solvent used block wise in Process & Cleaning			
					Product	Stage	Process	Cleaning
12.	Isopropyl Alcohol	400	2000	AM	Prucalopride Succinate	III	91.72	0
				AI	Azacitidine (AZA)	I	56.41	0
				D	Imatinib Mesylate	II	2945.0	0
				H	Imatinib Mesylate (DMN)	I	850.0	0
				E	Tenofovir Disoproxil Fumarate	I	2455.0	0
				I	Azacitidine (ATZ)	I	328.0	0
				AO	Citicoline Sodium	I	1575.0	0
13.	Methanol	200	6000	AM	Eltrombopag olamine	I	---	779.0
				AI	Bortezomib	II	---	587.0
				AJ	K	5	---	2565.0
				G	K	6	---	1790.0
				AO	Tranexamic Acid (TXO)	V	---	1022.0
				C	Capecitabine	III	---	4720.0
				D	Capecitabine (PCJ)	I	---	2898.0
				E	Nor-Ursodeoxycholic Acid	I	---	2405.5
				H	Ibrutinib	IV	---	1028.0
				I	Lenvatinib Mesylate	III	---	1453.0
14.	n-Propanol	100	800	AM	Propyl Gallate	I	1680.4	0
15.	Tetrahydrofuran (THF)	50	2000	AI	Axitinib	III	53.7	0
				AM	Eltrombopag olamine	I	149.6	0
				H	Ibrutinib	I	710.0	0
16.	Toluene	50	500	AI	Bortezomib	II	19.1	0
				C	Capecitabine	III	2358.0	0
				D	Capecitabine (J)	III	3000.0	0
				H	Erlotinib HCl	III	2295.5	0
				E	Montelukast Sodium	I	2895.0	0

SHILPA PHARMA LIFESCIENCES LIMITED, UNIT-2								
WORK AREA AIR QUALITY MONITORING REPORT								
Department: Production							Page 15 of 15	
Report No.: RPT/PD/VOC&LEL/WA/001/23								
Ref. Protocol No.: PC/PD/VOC&LEL/WA/001/23								
TITLE: REPORT FOR VOLATILE ORGANIC CARBON (VOC) AND LOWER EXPOSURE LEVEL (LEL) MONITORING IN WORK AREA								
S. No.	Name of the Organic Solvent	TLV (ppm)	IDLH (ppm)	Block	Maximum volume (L) of Solvent used block wise in Process & Cleaning			
					Product	Stage	Process	Cleaning
17.	Triethyl Amine	10	200	AI	Pomalidomide	I	5.076	0
				AM	Prucalopride Succinate	I	6.8	0
				G	Ursodeoxycholic Acid	II	55	0
				AJ	RK	II	1074.4	0
				C	TP1RM	I	180	0
				E	Praziquantel	I	447.7	0
				H	Lenalidomide	I	27.931	0

**2.0 CONCLUSION:**

From the work area monitoring (VOC & LEL) results, it is clear that, the airborne concentration of organic solvents (hazardous material) in the work area is negligible and the personnel can execute day-to-day operations without any adverse health effect. Moreover, the obtained results are far less than the TLV limits of respective organic solvents (hazardous material).

Hence, the risk of personnel exposure to organic vapors of hazardous chemicals is remote and the use of PPEs while handling organic solvents will give even more protection to personnel working in manufacturing area.

**3.0 ATTACHMENTS:**

3.1 Attachment-I : VOC & LEL monitoring raw data

# **ATTACHMENT-I**

**[VOC & LEL MONITORING RAW DATA]**







**SHILPA PHARMA LIFESCIENCES LIMITED (UNIT-2)**

**VOC & LEL MONITORING LOG IN WORK AREA**

**ANNEXURE-1**

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

Effective date: 13/05/23

Page 1 of 1

Work Area ID

A0-Block Crystallizer Area

Date & Time: 24/07/23, 14/25

VOC Meter ID

541096102-002

LEL Meter ID

MA221-040248

Location for monitoring of VOC	VOC Result	Remarks	Location for monitoring of LEL	LEL Result	Remarks
In between A0/RE-16 & A0/RE-17	0 ppm	Batch processing	In process area b/w A0/RE-16 & A0/RE-17	0%	During process activity
In between A0/RE-16 & A0/RE-17	0 ppm	Batch to Batch cleaning	In process area b/w A0/RE-16 & A0/RE-17	0%	During B2B cleaning
During centrifugation	1 ppm	Batch processing	During centrifugation	0%	During process activity
During centrifuge Batch to Batch cleaning	0 ppm	Batch to Batch cleaning	During centrifuge Batch to Batch cleaning	0%	During B2B cleaning
NA					




Sign & Date (monitored by):

 24/07/23

Reviewer Comments:

Reviewer Sign & Date:

M. Lamm 24/07/23

	Prepared By	Reviewed By	Approved by
Name	Mr. Awnesh Kumar Goswami	Mr. Govindappa Galagali	Mr. N. Saravanan
Designation	Dy. Manager-PD	AGM-PD	AGM-QA
Sign & Date	 13/05/23	 13/05/23	 13/05/23

**SHILPA PHARMA LIFESCIENCS LIMITED (UNIT-2)**

**VOC & LEL MONITORING LOG IN WORK AREA**

**ANNEXURE-1**

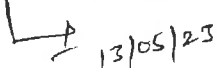
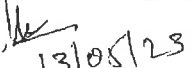
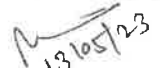
Protocol No.: PC/PD/VOC&LEL/WA/001/23		Effective date: 13/05/23
		Page 1 of 1
Work Area ID	A0-Block outside area	Date & Time: 24/07/23, 14/45
VOC Meter ID	541096102-002	
LEL Meter ID	1A221-040248	

Location for monitoring of VOC	VOC Result	Remarks	Location for monitoring of LEL	LEL Result	Remarks
Near A0/ST-11, A0/ET-02 Area	1 ppm	During ml's Solution preparation	Near A0/ST-11, A0/ET-02 Area	0%	During ml's Solution prep
Near A0/ST-11, A0/ET-02 Area	0 ppm	Idle condition (with storage)	Near A0/ST-11, A0/ET-02 Area	0%	Idle condition (with storage)
A0/ST-12, A0/ST-14A Area	0 ppm	During ml's receiving	A0/ST-12, A0/ST-14A Area	0%	During ml's receiving
A0/ST-12, A0/ST-14A Area	0 ppm	Idle condition (with storage)	A0/ST-12, A0/ST-14A Area	0%	Idle condition (with storage)
A0/ST-19 Area	0 ppm	During water collection	A0/ST-19 Area	0%	During water collection
A0/ST-19 Area	0 ppm	During Idle condition	A0/ST-19 Area	0%	During Idle condition
NA					
① 24/07/23					

Sign & Date (monitored by):  24/07/23

Reviewer Comments: -

Reviewer Sign & Date:  M. Ramu 24/07/23

	Prepared By	Reviewed By	Approved by
Name	Mr. Awnesh Kumar Goswami	Mr. Govindappa Galagali	Mr. N. Saravanan
Designation	Dy. Manager-PD	AGM-PD	AGM-QA
Sign & Date	 13/05/23	 13/05/23	 13/05/23

**SHILPA PHARMA LIFESCIENCS LIMITED (UNIT-2)**

**VOC & LEL MONITORING LOG IN WORK AREA**

**ANNEXURE-1**

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

Effective date: 13/05/23

Page 1 of 1

Work Area ID

A0 Intermediate Area (A07)

Date & Time: 22/07/23 & 13/08

VOC Meter ID

541096102-002

LEL Meter ID

MA221-040248

Location for monitoring of VOC	VOC Result	Remarks	Location for monitoring of LEL	LEL Result	Remarks
A0/PNF-06	0 PPM	Batch up processing	A0/PNF-06	0%	Batch up processing
A0/PNF-06	0 PPM	Batch to Batch cleaning	A0/PNF-06	0%	Batch to Batch cleaning
Equipment wash Area	1.0 PPM	During cleaning	Equipment wash Area	0%	During cleaning
Equipment wash Area	0 PPM	Idle	Equipment wash Area	0%	Idle
A0/RE-18	1.0 PPM	During NH3 purging	A0/RE-18	0%	During NH3 purging
A0/RE-18	0 PPM	Idle with residue	A0/RE-18	0%	Idle with residue
A0/RE-20	0 PPM	During distillation	A0/RE-20	0%	During distillation
A0/RE-20	0 PPM	During Batch to Batch cleaning	A0/RE-20	0%	During Batch to Batch cleaning
A0/ANFD-03	0 PPM	During process	A0/ANFD-03	0%	During process
A0/ANFD-03	0 PPM	During B to B cleaning	A0/ANFD-03	0%	During Batch to Batch cleaning
A0/RE-19	0 PPM	During HMA addition	A0/RE-19	0%	During HMA addition
A0/RE-19	0 PPM	During Batch to Batch cleaning	A0/RE-19	0%	During Batch to Batch cleaning

Sign & Date (monitored by):

*(Signature)*  
22/07/23

Reviewer Comments: -

*(Signature)*  
M. Ramesh  
22/07/23

Reviewer Sign & Date:

	Prepared By	Reviewed By	Approved by
Name	Mr. Awnesh Kumar Goswami	Mr. Govindappa Galagali	Mr. N. Saravanan
Designation	Dy. Manager-PD	AGM-PD	AGM-QA
Sign & Date	<i>(Signature)</i> 13/05/23	<i>(Signature)</i> 13/05/23	<i>(Signature)</i> 13/05/23

**SHILPA PHARMA LIFESCIENCS LIMITED (UNIT-2)**

**VOC & LEL MONITORING LOG IN WORK AREA**

**ANNEXURE-1**

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

Effective date: 13/05/23

Page 1 of 1

Work Area ID

A0 Intermediate Area (A0A)

Date & Time: 22/07/23 & 13/08

VOC Meter ID

541096102-002

LEL Meter ID

KA221-040248

Location for monitoring of VOC	VOC Result	Remarks	Location for monitoring of LEL	LEL Result	Remarks
A0/RE-24	0 PPM	Batch processing	A0/RE-24	0%	Batch processing
A0/RE-24	0 PPM	Batch to Batch cleaning	A0/RE-24	0%	Batch to Batch cleaning
A0/ST-64	0 PPM	Batch transferring	A0/ST-64	0%	Batch transferring
A0/ST-64	0 PPM	Idle	A0/ST-64	0%	Idle
A0/ST-66	0 PPM	Batch transferring	A0/ST-66	0%	Batch transferring
A0/ST-66	0 PPM	Batch Idle	A0/ST-66	0%	Idle
NA					

Sign & Date (monitored by):

*(Signature)*  
22/07/23

Reviewer Comments:

Reviewer Sign & Date:

*M. Ramu*  
22/07/23

	Prepared By	Reviewed By	Approved by
Name	Mr. Awnesh Kumar Goswami	Mr. Govindappa Galagali	Mr. N. Saravanan
Designation	Dy. Manager-PD	AGM-PD	AGM-QA
Sign & Date	<i>(Signature)</i> 13/05/23	<i>(Signature)</i> 13/05/23	<i>(Signature)</i> 13/05/23

**SHILPA PHARMA LIFESCIENCS LIMITED (UNIT-2)**

**VOC & LEL MONITORING LOG IN WORK AREA**

**ANNEXURE-1**

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

Effective date: 13/05/23

Page 1 of 1

Work Area ID

Ap-Intermediate Area (A07)

Date & Time: 22/07/23, 13/00

VOC Meter ID

541096102-002

LEL Meter ID

MA221-040248

Location for monitoring of VOC	VOC Result	Remarks	Location for monitoring of LEL	LEL Result	Remarks
At Emergency Exit	0 PPM	At batch running time	At Emergency Exit	0.0%	At batch running time
At Emergency Exit (Module-1)	0 PPM	At batch running time	At Entrance area (Module-1)	0.0%	At batch running time
At Entry A07 (Module-2)	0 PPM	At batch running time	At Entrance area (Module-2)	0.0%	At batch running time
At A0/cooling tower	0 PPM	At batch running time	At cooling tower	0.0%	At batch running time
NA					

Sign & Date (monitored by):

(M)  
22/07/23

Reviewer Comments: -

Reviewer Sign & Date:

M. Ramu  
22/07/23

	Prepared By	Reviewed By	Approved by
Name	Mr. Awnesh Kumar Goswami	Mr. Govindappa Galagali	Mr. N. Saravanan
Designation	Dy. Manager-PD	AGM-PD	AGM-QA
Sign & Date	<u>(M)</u> 13/05/23	<u>(G)</u> 13/05/23	<u>(N)</u> 13/05/23

<b>SHILPA PHARMA LIFESCIENCS LIMITED (UNIT)</b>	
<b>VOC &amp; LEL MONITORING LOG IN WORK AREA</b>	
<b>ANNEXURE-1</b>	
Protocol No.: PC/PD/VOC&LEL/WA/001/23	Effective date: 13/05/23
	Page 1 of 1
Work Area ID	H
VOC Meter ID	S41096102-002
LEL Meter ID	MA221-040248
	Date & Time:

Location for monitoring of VOC	VOC Result	Remarks	Location for monitoring of LEL	LEL Result	Remarks
SS Reactor H/RE-03	1 PPM	SPAS closing & def washing	SS Reactor H/RE-03	0%	SPAS closing & def washing
H/MLTCF-06	0 PPM	during mil collection	H/MLTCF-06	0%	during mil collection
centrifuge H/CF-06	1 PPM	wet material unloading	Centrifuge H/CF-06 13/07/23	0%	wet material unloading
Drying H/UTD-01	1 PPM	wet material loading	Drying H/UTD-01	0%	wet material loading
Drying H/UTD-01	0%	dry material unloading	Drying H/UTD-01	0%	dry material unloading
washing area ACC OFFONIL	1 PPM	dry material unloading	Scoop #15C-99	0%	after cleaning method
NA					
/C 16/07/23					

Sign & Date (monitored by): 16/07/23

Reviewer Comments: outside area & inside equipments H/RE-03  
 Reviewer Sign & Date: H/MLTCF-06, H/CF-06, H/UTD-01 VOC & LEL verified  
 17/07/23

	Prepared By	Reviewed By	Approved by
Name	Mr. Awnesh Kumar Goswami	Mr. Govindappa Galagali	Mr. N. Saravanan
Designation	Dy. Manager-PD	AGM-PD	AGM-QA
Sign & Date	13/05/23	13/05/23	13/05/23



**SHILPA PHARMA LIFESCIENCS LIMITED (UNIT-**

**VOC & LEL MONITORING LOG IN WORK AREA**

**ANNEXURE-1**


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


Effective date: 13/05/23

Page 1 of 1


Work Area ID	Am-Block (Intermediate Bay-I)	Date & Time: 17/07/23 8:12:50
VOC Meter ID	5U1096102 - 002	
LEL Meter ID	MA 221 - 040248	




Location for monitoring of VOC	VOC Result	Remarks	Location for monitoring of LEL	LEL Result	Remarks
AMIRE-02 (Inter Area)	0 ppm	After flushing	AMIRE-02 (Inter Area)	0-1	After flushing with meth
AMIRE-04 (Inter Area)	1.0 ppm	After flushing	AMIRE-04 (Inter Area)	0-1	After flushing with meth
AMIRE-09 (Inter Area)	0 ppm	After flushing	AMIRE-09 (Inter Area)	0-1	After flushing with meth
AMIPNF-01 (Inter Area)	0 ppm	open condition	AMIPNF-01 (Inter Area)	0-1	After flushing with meth open condition mbc
AMISF-01 (Inter Area)	0.1 ppm	open condition	AMISF-01 (Inter Area)	0-1	open condition mbc
AMIRE-04 (Inter Area)	0 ppm	After flushing	AMIRE-04 (Inter Area)	0-1	After flushing with DIPE
AMICF-06 (Inter Area)	0 ppm	open condition	AMICF-06 (Inter Area)	0-1	open condition DIPE
AMVTD-03 (Inter Area)	0 ppm	open condition	AMVTD-03 (Inter Area)	0-1	open condition
/					
N/A					

Sign & Date (monitored by):  17/07/23

 17/07/23

Reviewer Comments:

Reviewer Sign & Date:  17/07/23

	Prepared By	Reviewed By	Approved by
Name	Mr. Awnesh Kumar Goswami	Mr. Govindappa Galagali	Mr. N. Saravanan
Designation	Dy. Manager-PD	AGM-PD	AGM-QA
Sign & Date	 13/05/23	 13/05/23	 13/05/23

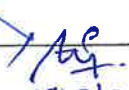


**SHILPA PHARMA LIFESCIENCS LIMITED (UNIT)**

**VOC & LEL MONITORING LOG IN WORK AREA**

**ANNEXURE-1**

Protocol No.: PC/PD/VOC&LEL/WA/001/23		Effective date: 13/05/23
		Page 1 of 1
Work Area ID	AJ Block (outside Area)	Date & Time: 18/07/23 09:50
VOC Meter ID	54109102 - 002	
LEL Meter ID	MA221 - 040248	

Location for monitoring of VOC	VOC Result	Remarks	Location for monitoring of LEL	LEL Result	Remarks
outside Area AJLMTCP-01	0ppm	After collection of methanol	outside Area AJLMTCP-01	0%	After collection of methanol
outside Area AJLMTCP-01	0ppm	After collection of methanol	outside Area AJLMTCP-01	0%	After collection of methanol
No					
 18/07/23					

Sign & Date (monitored by):




*A.J.*  
18/07/23

Reviewer Comments:

AJ block outside area VOC & LEL result

Reviewer Sign & Date:

verified on 18/07/23

	Prepared By	Reviewed By	Approved by
Name	Mr. Awnesh Kumar Goswami	Mr. Govindappa Galagali	Mr. N. Saravanan
Designation	Dy. Manager-PD	AGM-PD	AGM-QA
Sign & Date	 13/05/23	 13/05/23	 13/05/23

<b>SHILPA PHARMA LIFESCIENCS LIMITED (UNIT)</b>		
<b>VOC &amp; LEL MONITORING LOG IN WORK AREA</b>		
<b>ANNEXURE-1</b>		
Protocol No.: PC/PD/VOC&LEL/WA/001/23		Effective date: 13/05/23
		Page 1 of 1
Work Area ID	D	Date & Time: 31/07/23; 09:30
VOC Meter ID	541096102-002	
LEL Meter ID	MA221-040248	

Location for monitoring of VOC	VOC Result	Remarks	Location for monitoring of LEL	LEL Result	Remarks
DICFMLT-01	0 PPM	Toluene ML's collection	DICFMLT-01	0%	Toluene ML's collection
Centrifuge DICF-01 & DICB-01	0 PPM	wet material containing	Centrifuge DICF-01 & DICB-01	0%	wet material containing
washing area Accessories	1 PPM	white accessories cleaning	washing area Accessories	0%	white accessories cleaning

Sign & Date (monitored by):

*[Signature]*  
31/07/23

Reviewer Comments:

*DICFMLT-01 & DICF-01 & DICB-01 and Accessories area VOC & LEL verified.*

Reviewer Sign & Date:

*[Signature]*  
31/07/23

	Prepared By	Reviewed By	Approved by
Name	Mr. Awnesh Kumar Goswami	Mr. Govindappa Galagali	Mr. N. Saravanan
Designation	Dy. Manager-PD	AGM-PD	AGM-QA
Sign & Date	<i>[Signature]</i> 13/05/23	<i>[Signature]</i> 13/05/23	<i>[Signature]</i> 13/05/23

**SHILPA PHARMA LIFESCIENCS LIMITED (UNIT)**

**VOC & LEL MONITORING LOG IN WORK AREA**

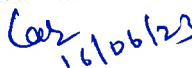
**ANNEXURE-1**




Protocol No.: PC/PD/VOC&LEL/WA/001/23		Effective date: 13/05/23
		Page 1 of 1
Work Area ID	AI Block pharma Area	Date & Time: 16/06/23 2:09/15
VOC Meter ID	541096/02 002	
LEL Meter ID	MA 221 - 040248	

Location for monitoring of VOC	VOC Result	Remarks	Location for monitoring of LEL	LEL Result	Remarks
AI/GAT-10	0 PPM	while sucking methanol in AI/GAT-10	AI/GAT-10	0	while sucking methanol in AI/GAT-10
AI/MF-04	0 PPM	while opening AI/MF-04	AI/MF-04	0	while opening AI/MF-04
AI/MF-04	0 PPM	while After cleaning AI/MF-04	AI/MF-04	0	while After cleaning AI/MF-04
N/A					
EM 16/06/23					

Sign & Date (monitored by):  16/06/23

Reviewer Comments: LEL & VOC checked during Arikunib bathnao. ATB4230003  
16/06/23

Reviewer Sign & Date:  16/06/23

	Prepared By	Reviewed By	Approved by
Name	Mr. Awnesh Kumar Goswami	Mr. Govindappa Galagali	Mr. N. Saravanan
Designation	Dy. Manager-PD	AGM-PD	AGM-QA
Sign & Date	 13/05/23	 13/05/23	 13/05/23

**SHILPA PHARMA LIFESCIENCS LIMITED (UNIT)**

**VOC & LEL MONITORING LOG IN WORK AREA**

**ANNEXURE-1**

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

Effective date: 13/05/23

Page 1 of 1

Work Area ID: 1-Block Pharma Area

Date & Time: 17/08/23 9:15:00

VOC Meter ID: 541096102-002

LEL Meter ID: MA 221-040248

Location for monitoring of VOC	VOC Result	Remarks	Location for monitoring of LEL	LEL Result	Remarks
Pharma area Reactor IIRF-12	1 ppm	Flushing with methanol	Pharma area reactor IIRF-12	0%	Flushing with methanol
Pharma area Accessories cleaning	1 ppm	Flushing with methanol	Pharma Area Accessories cleaning	0%	Flushing with methanol
NA					
1/2/23 20/08/23					

Sign & Date (monitored by): *[Signature]* 20/08/23

Reviewer Comments: 1-Block Pharma area ready routinely by VOC and LEL result found ok

Reviewer Sign & Date: *[Signature]* 20/08/23

	Prepared By	Reviewed By	Approved by
Name	Mr. Awnesh Kumar Goswami	Mr. Govindappa Galagali	Mr. N. Saravanan
Designation	Dy. Manager-PD	AGM-PD	AGM-QA
Sign & Date	<i>[Signature]</i> 13/05/23	<i>[Signature]</i> 13/05/23	<i>[Signature]</i> 13/05/23

Issued By QA  
I.Jagannadham  
D/T:05/08/23 16:05

<b>SHILPA PHARMA LIFESCIENCS LIMITED (UNION)</b>		
<b>VOC &amp; LEL MONITORING LOG IN WORK AREA</b>		
<b>ANNEXURE-1</b>		
Protocol No.: PC/PD/VOC&LEL/WA/001/23		Effective date: 13/05/23
		Page 1 of 1
Work Area ID	2-Block outside area	Date & Time: 17/08/23 @ 14:55
VOC Meter ID	541096102-002	
LEL Meter ID	MA221-040248	

Location for monitoring of VOC	VOC Result	Remarks	Location for monitoring of LEL	LEL Result	Remarks
outside area 2/MLTAR-01	0 ppm	Drying with nitrogen	outside area 2/MLTAR-01	0 %	Drying with nitrogen

Sign & Date (monitored by):

*XLS*  
17/08/23

Reviewer Comments: 1-Block outside area Rendamustone Hdy VOC and LEL

Reviewer Sign & Date: result found OK

*[Signature]*  
17/08/23

	Prepared By	Reviewed By	Approved by
Name	Mr. Awnesh Kumar Goswami	Mr. Govindappa Galagali	Mr. N. Saravanan
Designation	Dy. Manager-PD	AGM-PD	AGM-QA
Sign & Date	<i>[Signature]</i> 13/05/23	<i>[Signature]</i> 13/05/23	<i>[Signature]</i> 13/05/23

**SHILPA PHARMA LIFESCIENCS LIMITED (UNIT)**

**VOC & LEL MONITORING LOG IN WORK AREA**

**ANNEXURE-1**

Protocol No.: PC/PD/VOC&LEL/WA/001/23 Effective date: 13/05/23

Page 1 of 1

Work Area ID: G-Block (outside area) Date & Time: 18/07/23 11:00

VOC Meter ID: 541096102-002

LEL Meter ID: MA221-040248

Location for monitoring of VOC	VOC Result	Remarks	Location for monitoring of LEL	LEL Result	Remarks
outside area G/MLTCF-01	0 ppm	during collection of Acetone ML's	outside area G/MLTCF-01	0.1	during collection of Acetone ML's
outside area G/MLTCF-02	0 ppm	during collect of E/A mix	outside area G/MLTCF-02	0.1	during collect of E/A mix
outside area G/HMC-01	0 ppm	during solvent collection	outside area G/HMC-01	0.1	during solvent collection
outside area G/FST-01	0 ppm	during solvent collection	outside area G/FST-01	0.1	during solvent collection
outside -area G/FST-01	0 ppm	during solvent collection	outside area G/FST-01	0.1	during solvent collection
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Sign & Date (monitored by): [Signature] 18/07/23

Reviewer Comments: G-block outside area VOC & LEL results

Reviewer Sign & Date: [Signature] 18/07/23

	Prepared By	Reviewed By	Approved by
Name	Mr. Awnesh Kumar Goswami	Mr. Govindappa Galagali	Mr. N. Saravanan
Designation	Dy. Manager-PD	AGM-PD	AGM-QA
Sign & Date	<u>[Signature]</u> 13/05/23	<u>[Signature]</u> 13/05/23	<u>[Signature]</u> 13/05/23



**SHILPA PHARMA LIFESCIENCS LIMITED (UNIT**

**VOC & LEL MONITORING LOG IN WORK AREA**

**ANNEXURE-1**

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

Effective date: 13/05/23

Page 1 of 1

Work Area ID

Quality control

Date & Time: 18/06/23

VOC Meter ID

541096102-002

LEL Meter ID

MA 221-040248


Location for monitoring of VOC	VOC Result	Remarks	Location for monitoring of LEL	LEL Result	Remarks
Weighing balance SPL2101 S1001 Capentabine weighing	0 ppm	During weighing	Weighing balance SPL2101 S1001 Capentabine weighing	0 ppm	During weighing
Mobile preparation Capentabine	1 ppm	HPLC mobile phase	Mobile preparation Capentabine	0 ppm	During weighing
Weighing Balance SPL2101 S1001 Fraxiparin sodium	0 ppm	During weighing	Weighing Balance SPL2101 S1001 Fraxiparin sodium	0 ppm	During weighing
Washing Area Accessories Test Tube, Pipet	1 ppm	cleaning Area	Washing Area Accessories Test Tube, Pipet	0 ppm	cleaning after with meth
200 18/06/23					




Sign & Date (monitored by):

  
18/06/23

Reviewer Comments:

Reviewer Sign & Date:

  
18/06/23

	Prepared By	Reviewed By	Approved by
Name	Mr. Awnesh Kumar Goswami	Mr. Govindappa Galagali	Mr. N. Saravanan
Designation	Dy. Manager-PD	AGM-PD	AGM-QA
Sign & Date	 13/05/23	 13/05/23	 13/05/23