

INDUSTRIAL HYGIENE PROGRAM RECOMMENDATIONS REVIEW REPORT

FOR

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

Plot No. 33, 33A, 40 to 47, Raichur Industrial Growth Centre,
Wadloor Road, Chicksugur-584134,

Raichur District -584170

Karnataka

India

S. No.	Recommendation	Recommendation Status	Responsibility	Timelines	Remarks
1.	Carry out inspection of spill control kit once in month.	SOP is drafted and shall implement by end of August'23	Safety	30.08.23	
		Review-1: SOP is approved and spill control kit inspection is being carried-out once in every month. Latest Spill control kit inspection report is enclosed.	Safety	NA	Closed
2.	Work area monitoring for VOC & LEL shall done and based on the results suitable engineering controls / PPEs shall recommend.	Under progress and report shall be prepared by 15 th June'23	Production/WH	30.06.23	
		Review-1: Work area monitoring for VOC & LEL is completed. From the work area monitoring results it is clear that, airborne concentration of organic solvents in work area is negligible and the personnel can execute day-to-day activities without any adverse health hazard. However, PPEs as recommended in PPE matrix should flow in work area	Production/WH	NA	Closed
3.	Use Air Breathing mask (ABM) while dispensing hazardous liquid RMs	Air Breathing mask made available in the work area (Production, WH and other applicable areas) and training given for handling. PPE matrix displayed	NA	NA	Closed
4.	Work area shall monitor for LEL and based on the results suitable engineering controls / PPEs shall recommend.	Under progress and report shall be prepared by 15 th June'23	Production/WH	15.06.23	

S. No.	Recommendation	Recommendation Status	Responsibility	Timelines	Remarks
		Review-1: Work area monitoring for LEL is completed and report enclosed. From the work area monitoring results it is clear that, airborne concentration of organic solvents in work area is negligible and the personnel can execute day-to-day activities without any adverse health hazard. However, PPEs as recommended in PPE matrix should flow in work area	Production/WH	NA	Closed
5.	Carry out dust exposure monitoring for personal health safety during charging of solid RMs	To be done	Production	30.12.2023	
		Review-1: As part of dust exposure monitoring during charging of solid RMs, particulate matter is measured and the results are enclosed. From the results it is clear that, the dust exposure is negligible as the RM charging areas have adequate ventilation systems to control the exposures.	Production	NA	Closed
6.	Provide splash guards to acid liquid charging & pumping line to reactors	To be done	ENG	30.12.2023	
		Review-1: Splash guards arranged to acid liquid charging & pumping line to reactors. Photographs enclosed as an evidence.	ENG	NA	Closed
7.	Ensure the elimination of water spillages at day store area while charging the material into the reactor	Training given to concern personnel and made aware about the risk associated with the activity	Production	Ongoing	Closed

S. No.	Recommendation	Recommendation Status	Responsibility	Timelines	Remarks
8.	Provide Oxygen sensor with Low & Low-Low alarm & visual alarm for closed rooms without natural ventilation where Nitrogen gas is being used for Inertization as well as for product safety.	To be done	ENG	30.12.2024	
		Review-1: Oxygen sensor with Low & Low-Low alarm & visual alarm arranged for closed room in E-Block. Oxygen sensor installation in other blocks shall be done in phased manner	ENG	30.12.2024	
9.	Carry out work place personal monitoring for dust emission during Sifting & Milling operation.	To be done	Production	30.12.2023	
		Review-1: Sifting & Milling of Oncology products are carried-out in Isolators and the Isolators are Qualified for OEL and therefore the risk of personnel exposure to dust emissions is remote. The non-oncology API sifting & milling areas are equipped with dust extraction system to control personnel exposure to dust emissions. However, as part of work place monitoring for dust emissions during sifting & milling operations, particulate matter is measured and the results are enclosed. From the results it is clear that, the dust emission is negligible and there is no risk of health hazard to personnel working in the Sifting & Milling operations.			

S. No.	Recommendation	Recommendation Status	Responsibility	Timelines	Remarks
10.	Carry out Work place monitoring for Ammonia gas emission near reactor vent area and ammonia scrubber vent area.	To be done	Production Team	30.07.2023	
		Review-1: Ammonia sensors are available near reactor vent and scrubber vent to monitor ammonia gas emissions.	Production Team	NA	Closed

ATTACHMENTS:

Attachment-1: Spill control kit inspection report







Attachment-2: Work area Air Quality monitoring Report

Attachment-3: Dust Exposure monitoring report while charging RMs into Reactors

Attachment-4: Photographs of Splash guards for Acid & Liquid charging

Attachment-5: Dust Exposure monitoring in sifting & milling area

APPROVALS:

Names of Members	Mr. Chandra Shekar Dudani (Manager - WH)	Reviewer	 20/12/23
	Mr. Govindappa Galagali (AGM - PD)	Reviewer	 20/12/23
	Mr. R. Elangovan (DGM – EHS)	Reviewer	R. Elangovan 20/12/23
	Mr. AK Singh (DGM - HR)	Reviewer	 20/12/23
	Mr. Jay Kumar Kotwal (GM – ENG)	Reviewer	 20/12/23
	Mr. Veereshappa (Senior GM - PD)	Reviewer	 20/12/23
	Mr. K. Sharath Reddy (Director-Projects)	Approver	 20/12/23



MSV Analytical Laboratories

Recognition by MoEF under Environment (Protection) Act, 1986

(Certified by ISO 14001:2015, ISO 45001:2018, ISO 9001:2015, ISO 22000:2018)

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MSVAL/AA/RF/01/00

ANALYSIS REPORT OF INDOOR AIR QUALITY

Test report No: MSVAL/2023/5448

1.	Name and Address of Industry	:	M/S.Shilpa Medicare Ltd (unit – II), Plot No. 33, 33A, 40-47,Raichur Industrial Growth Center, Chicksugur village, Raichur
2.	Sample Collected By	:	MSV Analytical Laboratories, Bellary.
3.	Particulars of the sampling Equipments	:	Sample collected with Handy Sampler
4.	Date of Monitoring	:	03.11.2023
5.	Date of Sample Receipt	:	04.11.2023
6.	Sample Code	:	8108
7.	Analysis Starting Date	:	04.11.2023
8.	Analysis Completion Date	:	06.11.2023
9.	Report Issue Date	:	07.11.2023

S.No	Block	Name of the Location	Parameter	Protocols	Units	Results
1	E-Block	Near Reactor Manhole	Particulate Matter as PM _{2.5}	MSVAL/SOP/IAQ/006	µg/m ³	36.4
2	AO Block	Near Reactor Manhole	Particulate Matter as PM _{2.5}		µg/m ³	42.7
3	AO7	Near Reactor Manhole	Particulate Matter as PM _{2.5}		µg/m ³	40.8
4	C-Block	Near Reactor Manhole	Particulate Matter as PM _{2.5}		µg/m ³	35.4
5	H-Block	Near Reactor Manhole	Particulate Matter as PM _{2.5}		µg/m ³	50.2
6	AM-Block	Near Reactor Manhole	Particulate Matter as PM _{2.5}		µg/m ³	38.7
7	AJ-Block	Near Reactor Manhole	Particulate Matter as PM _{2.5}		µg/m ³	44.2
8	D-Block	Near Reactor Manhole	Particulate Matter as PM _{2.5}		µg/m ³	40.6
9	AI-Block	Near Reactor Manhole	Particulate Matter as PM _{2.5}		µg/m ³	41.8
10	I-Block	Near Reactor Manhole	Particulate Matter as PM _{2.5}		µg/m ³	43.5
11	G-Block	Near Reactor Manhole	Particulate Matter as PM _{2.5}		µg/m ³	44.2
12	E-Block	Sifting & Milling Area	Particulate Matter as PM _{2.5}		µg/m ³	50.4
		Near Dust collection System exhaust	Particulate Matter as PM _{2.5}		µg/m ³	46.7
13	AO Block	Sifting & Milling Area	Particulate Matter as PM _{2.5}	µg/m ³	43.8	
NAAQS/EPA-Limit						65

Analysed by

Authorized Signatory

Hanumanthaiah P
Technical Manager

*** End of Report ***



Note: 1. The results listed only to the tested samples & applicable parameters.

2. Water, Pollution & Environment & Food samples will be discarded after 10 days. Ores and minerals Filter papers & Thimbles will be discarded in 3 months from the date of issue of test reports, unless otherwise specified. ILC samples will be discarded after 1 month from the date of test reports.

3. This report is not to be reproduced wholly or in part & cannot be used as evidence in the court of law & should not be used in any advertising media without our special permission in writing.

4. Total liability of our laboratory is limited to the invoice amount. Any dispute arising out of this report is subject to Bellary jurisdiction only.

5. Sampling is not done by us unless otherwise specified.