Department	Environmental, Health and Safety		Document no	EHS-080	
Title	Industrial Hygiene Sampling for Airborne Contaminants				
Prepared by:		Date:		Supersedes:	
Checked by:		Date:		Date Issued:	
Approved by:		Date:		Review Date:	

1.0 AFFECTED PARTIES

All Environment, Health and Safety personnel

2.0 PURPOSE

To provide guidance on sampling for airborne contaminants in the workplace and the communication of results to affected staff.

3.0 SCOPE

This SOP is applicable to manufacturing operations at a GMP site.

4.0 RESPONSIBILITY \ BUSINESS RULES

4.1 Calibration of Sampling Pumps

Sampling must be performed with a calibrated sampling pump. Calibrations must be performed before and after sampling, for each sampling pump, with the sampling media (filter cassette or sorbent tube) in line.

5.0 PROCEDURE

5.1 General Guidance

5.1.1 Obtaining Sampling Equipment

Sampling supplies such as pumps, calibrators and other sampling accessories can be obtained on a rental basis.

5.1.2 Obtaining Sampling Supplies

Questions regarding the sampling of drug substance or industrial chemical and information regarding obtaining sampling supplies may be found on the local EHS procedure.

5.1.3 Collection of Samples

When placing the sample pump on an individual for personal monitoring or when taking an area sample, the sampling media / holder (filter cassette or sorbent tube) must face downward to avoid collection of settling contaminants from the air. (Impingers should be placed in a manner to prevent spillage of the solution.)

For personal samples, the sampling media / holder should be placed near the individual's breathing zone, within a 0.3 meter radius, such as attached to the shirt collar.

Generally, if the person is right-handed, attach the sample media to the left side of the lapel. If left-handed, attach to the right lapel.

Unless validating a respirator protection factor, the sample media is generally worn on the outside of any protective clothing or respiratory protection.

Tubing should extend from the sample media, over or under the shoulder, down the back and to the pump attached to the belt.

If permitted, tape the slack tubing to the clothing to minimize possible interference of the tubing with work activities.

Ensure the individual is comfortable and able to easily move both arms without dislodging the pump, tubing or sampling media.

For area samples, fix the location of the sampling train to within 1m of the operation using a tripod.

Where possible remain in the work area for the duration of the sampling period recording observations such as:

- The operation being carried out
- Product dosage strength
- Quantities of materials being handled
- Containers being used for charging and unloading equipment
- Transition pieces being used at the charging and unloading points
- Local exhaust ventilation at the charging and unloading points and
- Personal protective equipment being used.

5.1.4 **Number of Samples to Collect**

If possible, at least three samples should be collected at the workplace. These can be personal, area or a combination of personal / area samples; full shift or unit operation depending on sampling strategy.

5.1.5 **Sampling for Solids**

When sampling for a full shift, change the filter cassettes periodically based on the expected airborne concentration of the contaminant. For task or unit operations use one filter cassette for the duration of each task.

5.1.6 **Sampling Gases and Vapours**

When sampling for a full shift, change the sample media periodically based on the expected airborne concentration of the contaminant. Generally, sorbent tubes and badges should be changed regularly (at least twice over the course of an 8 hour day) to prevent breakthrough of the analyte(s). Breakthrough is assumed to occur when >25% of an analyte is found on the back section of the tube. Impinger solutions may require more frequent changing of solution.

5.1.7 **Sending Samples for Analysis**

Details of the current laboratory used for sample analysis is available on site EHS procedure. Samples should be sent by courier, using enough packaging materials to protect the samples.

A completed Industrial Hygiene Sampling Report (Appendix 1) and MSDS for each material sampled should also be submitted to the laboratory. A small (approx 1g) sample of a recent delivery of each substance should also be included in the shipment to be used as a reference standard.

5.1.8 **Communication of Results to Employees and Management**

Results should be communicated to the employee who was present at the time of sampling and to their team leader, manager and department head as soon as practical. It is the Manager's responsibility to communicate the results to same exposure groups. Depending on the nature of the results, Form "Industrial Hygiene Sampling Result - Communication to Site Colleague" (Appendix 2) or Form "Industrial Hygiene Sampling Result - Communication to Site Management" (Appendix 3) should be used to communicate these results.

Note that the communication to management includes scope for recommendations to improve the control of airborne contaminants.

Copies of these results must also be filed with the employee's medical records.

5.2 **Procedure Step**

5.2.1 Sampling for Solids Remove the plastic cassette plugs prior to switching on the sampling pump.

Record observations during the operation / activity and record them on Form "Industrial Hygiene Sampling Report" (Appendix 1).

Periodically check the pump to ensure it continues to function properly.

Re-seal filter cassettes with supplied plastic plugs immediately at the conclusion of sampling.

Recheck the pump calibration and note flow rates and sampling times on the observation form.

Place cassettes in a plastic bag and store in a refrigerator (for up to ten days) prior to shipping to the laboratory.

Transport sampling media to the laboratory by courier, with cassettes packaged tightly in an upright position and padded for shipment to the laboratory to minimize shock and damage. See the General Guidance section above (Section 5.1).

5.2.2 Sampling Gases and Vapours

Remove the sealing plugs prior to switching on the sampling pump.

Record observations during the operation / activity and record them on Form "Industrial Hygiene Sampling Report" (Appendix 1).

Periodically check the pump to ensure it continues to function properly.

At the conclusion of sampling:

- Re-seal sorbent tubes with supplied plastic plugs and place in plastic bags.
- Dosimeters: Remove the diffusion membrane and replace the supplied plastic cover. Make sure all of the plugs are in place to snap on the cover. Place the dosimeter in its original container for shipment to the laboratory.
- Impingers: Redilute the impinger to the initial volume, if necessary. Transfer this solution to scintillation vials with polyseal cone liners for shipment to the laboratory.

Recheck the pump calibration and note flow rates and sampling times on the observation form.

Transport sampling media to the laboratory by courier. See the General Guidance section above (Section 5.1).

6.0 **DEFINITIONS / ACRONYMS**

EHS	Environmental Health and Safety
MSDS	Material Safety Data Sheet

7.0 SUMMARY OF CHANGES

Version #	Revision History
EHS-080	New

Department	Environmental, Health and Safety		Document no	Supersedes:	EHS-080
Title	Industrial Hygiene Sampling for Airborne Contaminants				
Prepared by:		Date:		Date Issued:	
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Appendix 1: Industrial Hygiene Sampling Report

TASK INFORMATION			
ROOM NO.	DESCRIPTION		
PRODUCT NAME	LOT NO.	ACTIVE / CONCENTRATION	OEL (MG/M^3)
			OEB
OPERATION			ANTICIPATED DURATION
EQUIPMENT NO.	DESCRIPTION		
OPERATOR NAME			TASK(S)

PPE			
CLOTHING	RESPIRATOR / MODEL	GLOVES	SHOES
WORKPLACE CONTROLS			
PROCESS / EQUIPMENT	VENTILATION	ADMINISTRATIVE	
QUALITATIVE RISK / EXPOSURE ASSESSMENT			
HIGH	MEDIUM	LOW	

SAMPLE IDENTIFICATION	SAMPLING START TIME	SAMPLING END TIME	TOTAL SAMPLING TIME	INITIAL FLOW RATE (LPM)	FINAL FLOW RATE (LPM)	AVERAGE FLOW RATE (LPM)	AIR VOLUME (L)	PIMP SERIAL NO.	SAMPLERS INITIALS

Section 2: Sample Results

SAMPLE _____ IDENTIFICATION

AIR CONTAMINANT	SAMPLE RESULTS (MG / M^3)	TIME WEIGHTED AVERAGE (TWA) OR PERMISSIBLE EXPOSURE LIMIT	OCCUPATIONAL EXPOSURE LIMIT (OEL)

Section 3: Actions Facility staff should complete the conclusions and summary of actions to be taken based on the air sample results.

Conclusions:

- ☐ **IN ALL CASES:** COMMUNICATED RESULTS TO MEDICAL STAFF AND AFFECTED EMPLOYEES AND RETAIN RECORDS.
- ☐ **TWA > OEL:** Special precautions required: reduced air contaminant levels, using hierarchy of controls, review respiratory/personal protective equipment, develop action plan.
- ☐ **Sample Results > OEL:** Develop action plan, review controls, review respiratory/personal protective equipment, review protection factor for respirators.
- ☐ **½ OEL < TWA < OEL:** Verify adequacy of engineering controls with additional air monitoring.
- ☐ **TWA < ½ OEL:** No special precautions required.

Summary of actions

CONTROL MEASURES CURRENTLY USED:

- ☐ Process Changes
- ☐ Engineering
- ☐ Administrative controls
- ☐ Training
- ☐ Safe Work Practices
- ☐ Supervision
- ☐ Respiratory / Personal Protective Equipment

PLANNED ACTIONS:

Immediate

- ☐ Further Investigation
- ☐ Perform Resampling
- ☐ Upgrade Respiratory / Personal Protective Equipment
- ☐ Medical Support

Long Term

- ☐ Process Changes
- ☐ Additional Engineering Controls
- ☐ Additional Administrative Controls
- ☐ Health Surveillance Practices.

Date Results Received by EHS:	Date Form Delivered to Medical Staff:
EHS Signature:	Medical Staff Signature:

To medical staff: A copy of this record must be kept in colleague exposure record. This record must be available to the Examiner at each medical examination. This record must be updated when; the colleague changes jobs; the job changes; or when the job hazard assessment / workplace risk characterization changes.

Appendix 2: Industrial Hygiene Sampling Result - Communication to Site Colleague

MEMORANDUM

DATE:

COPIES TO: **Senior Manager, Area Manager, Team Leader, EHS Manager, Medical Coordinator**

FROM: **EHS Coordinator**

SUBJECT: **Results of Air Sampling**

As part of the Site chemicals in the Workplace program, we periodically take measurements of potential employee exposure to compounds. This letter is to advise you of the results obtained while you were performing the following task.

Date:	
Product:	
Batch Number:	
Room:	
Process:	
Respiratory / Personal Protective Equipment you were wearing	

Compound	Sampling Time (minutes)	Results (mg/m^2)	8 hour TWA (mg/m^2) (see notes below)	OEL (mg/m^2) (see notes below)

Note: The 8 hour TWA (time Weighted Average) is the calculated exposure to the compound for the full work day based on the tasks you performed on the above date. The OEL is the published occupational exposure limit for the compound.

The results obtained are (below or above) the compound OEL, indicating that there was no overexposure to COMPOUND during the above task.

Thank you for your assistance in collecting there samples. Please contact EHS department if you have any questions about this letter.

Appendix 3: Industrial Hygiene Sampling Result - Communication to Site Management

MEMORANDUM

DATE:

COPIES TO: **Senior Manager, EHS Manager, Medical Coordinator**

FROM: **EHS Coordinator**

SUBJECT: **Action Required based on results of air sampling**

As part of the Site chemicals in the Workplace program, we periodically take measurements of potential employee exposure to compounds. This letter is to advise you of the results obtained while you were performing the following task and the recommended actions necessary to reduce occupational exposures during the task.

Date:	
Product:	
Batch Number:	
Room:	
Process:	
Respiratory / Personal Protective Equipment you were wearing	

Compound	Sampling Time (minutes)	Results (mg/m^2)	8 hour TWA (mg/m^2) (see notes below)	OEL (mg/m^2) (see notes below)

Note: The 8 hour TWA (time Weighted Average) is the calculated exposure to the compound for the full work day based on the tasks you performed on the above date. The OEL is the published occupational exposure limit for the compound.

The results obtained are (below or above) the compound OEL. However, as employee was wearing a RESPIRATORY MODEL, there was no overexposure to the compound during the above task. A RESPIRATORY MODEL or an equivalent as advised by the EHS staff must continue to be worn whenever this task is being performed.

Control measures currently used for the task are:

- ✓ Engineering
- ✓ Administrative Practices
- ✓ Training
- ✓ Safe Work Practices
- ✓ Supervision
- ✓ Respiratory / Personal Protective Equipment

Based on the current control measures and the results obtained the following actions are recommended to be taken as per the immediate and/or longer term.

Immediate	Responsible
√ X Further investigation	
√ X Perform Re-sampling	
√ X Upgrade Respiratory / Personal Protective Equipment	
√ X Medical Support	

Long Term	Responsible
√ X Process Changes	
√ X Additional Engineering Controls	
√ X Additional Administrative Practice	
√ X Health Surveillance Practices	

Thanks you for your assistance in collecting these samples. Please contact EHS department if you have any questions about this letter.

