

**Appendix C.1.4**

**List of Environmental Management  
Standard Operating Procedures**

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SOP INDEX 600

SECTION TITLE: HEALTH AND SANITATION (S&E DEPARTMENT)

Rev. No. 8	<b>SECTION 600</b>	Prev Rev. No. 7
Effective Date: 17.02.03		Dated: 23.08.02

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REV. NO.	SOP NO.	SOP TITLE	EFFECTIVE DATE
4	600.001	Pest & Rodent Control	27.08.02
1	600.002	<del>Programme for Employee Exclusion</del> <b>VOID</b>	17.02.03

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SOP INDEX 601

SECTION TITLE: SAFETY AND INDUSTRIAL HYGIENE (S&E DEPARTMENT)

Rev. No. 66	<b>SECTION 601</b>	Prev Rev. No. 65
Effective Date: 09.08.04		Dated: 15.04.04

REV. NO.	SOP NO.	SOP TITLE	EFFECTIVE DATE
19	601.002	Emergency Contact Telephone Numbers	19.04.04
2	601.003	Transportation of Hazardous Goods	14.06.01
1	601.006	Hazop Procedure and Follow Up <b>VOID</b>	13.09.02
3	601.007	Environment Health & Safety Training for Contractors & Transport Companies.	25.04.00
2	601.008	Safety Of Contractors.	12.03.02
0	601.009	Safety of Plant and Equipment Purchases. <b>VOID</b>	22.04.03
0	601.010	Safety Procedure for the Introduction of New Processing Equipment. <b>VOID</b>	04.02.02
2	601.013	Safety & Health of Maternity Employees	13.01.03
0	601.011	Process Safety Checklist Audit <b>VOID</b>	12.02.01
4	601.014	Internal Accident/Incident/Near Miss Reporting	07.04.04
2	601.015	Accidental Release	29.01.02
1	601.016	External Accident/Incident Reporting	07.04.04
2	601.020	Eye Screening & Procurement Of Glasses	19.06.02
0	601.021	Control of the Environmental Health & Safety Manual for Contractors & Suppliers	13.10.99
4	601.022	Control of Material Safety Data Sheets (MSDS).	13.05.03
1	601.023	Accident / Incident Response	20.08.01
0	601.024	Accident Investigation	25.02.00
0	601.025	Material Safety Data Sheet Generation	24.02.00
0	601.026	Internal Safety Auditing <b>VOID</b>	27.03.02
0	601.027	Medical Surveillance At Work	06.12.01
1	601.028	Occupational Risk Assessments	08.03.04
0	601.029	Permit To Work System	05.03.02
0	601.030	Basis of Occupational Safety And Environmental	26.06.02

SOP INDEX 601

SECTION TITLE: SAFETY AND INDUSTRIAL HYGIENE (S&E DEPARTMENT)

Rev. No. 66	<b>SECTION 601</b>	Prev Rev. No. 65
Effective Date: 09.08.04		Dated: 15.04.04

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REV. NO.	SOP NO.	SOP TITLE	EFFECTIVE DATE
		Protection	
0	601.031	Preliminary Hazard Assessment	26.06.02
0	601.032	Management of Process Safety	25.06.02
0	601.033	Management of Occupational Injury / Illness	04.12.02
0	601.034	Operation of the BA Compressor	09.08.04

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SOP INDEX 602

SECTION TITLE: ENVIRONMENTAL (S&E DEPARTMENT)

Rev. No. 54	<b>SECTION 602</b>	Prev Rev. No. 53
Effective Date: 17.06.04		Dated: 24.11.03

REV. NO.	SOP NO.	SOP TITLE	EFFECTIVE DATE
2	602.001	Use of Scrubber Air Flow Meter	02.03.01
1	602.002	Use of Scentometer	25.04.00
0	602.003	Covering /Uncovering Effluent Balancing Tank <b>VOID</b>	21.10.97
1	602.004	Checking of Discharge Drains <b>VOID</b>	06.04.00
2	602.005	Nuisance Odour Monitoring <b>VOID</b>	29.10.97
3	602.006	Determination of Turbidity, Absorbometric Method. <b>VOID</b>	20.05.97
3	602.007	Threshold Odour Test <b>VOID</b>	20.05.97
3	602.010	Determination of Phenols <b>VOID</b>	27.10.99
3	602.011	Determination of Chloride (Method A) <b>VOID</b>	27.10.99
0	602.013	Determination of Phosphate <b>VOID</b>	28.04.03
4	602.014	Operation of Windspeed and Direction Recorder <b>VOID</b>	06.02.03
4	602.015	Operation of Foxboro OVA <b>VOID</b>	04.05.00
3	602.016	Background Dust Sampling <b>VOID</b>	17.01.01
3	602.017	Respirable Dust Sampling <b>VOID</b>	17.01.01
3	602.018	Total Dust Sampling <b>VOID</b>	17.01.01
1	602.022	Solvent Removal From WWTP <b>VOID</b>	21.10.97
0	602.023	Manual Operation of WWTP Due To Alarm Activation <b>VOID</b>	21.10.97
0	602.024	Nuisance Odour At WWTP <b>VOID</b>	29.10.97
0	602.027	Sampling Groundwater From Boreholes <b>VOID</b>	24.02.99
2	602.028	Collection & Analysis of Groundwater from Boreholes	06.03.01
9	602.029	Determination of Chemical Oxygen Demand	07.10.02
7	602.030	Determination of Nitrogen Nitrate High Range	06.06.00
4	602.031	Determination of Sulphate Ion Concentration	18.11.02
7	602.032	Suspended Solids Determination	12.09.00
3	602.033	Determination Of Conductivity <b>VOID</b>	27.10.99

## SOP INDEX 602

## SECTION TITLE: ENVIRONMENTAL (S&amp;E DEPARTMENT)

Rev. No. 54	<b>SECTION 602</b>	Prev Rev. No. 53
Effective Date: 17.06.04		Dated: 24.11.03

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REV. NO.	SOP NO.	SOP TITLE	EFFECTIVE DATE
0	602.034	Determination Of COD in Wastewater <b>VOID</b>	04.11.97
4	602.044	Hazardous Waste Disposal Within The State <b>VOID</b>	21.10.97
4	602.045	The pH Determination of a solution	15.11.02
2	602.046	Visual Inspection Of Effluent Solution <b>VOID</b>	27.10.99
2	602.047	Occupational Monitoring for Organic Solvents	06.03.01
3	602.048	Monitoring Emission of Organic Solvents	09.08.02
1	602.049	Calibration of Air Sampling Pumps	28.10.99
3	602.050	Preparation Of Drummed Waste For Shipment <b>VOID</b>	21.10.97
3	602.051	Preparation Of Bulk Waste For Shipment <b>VOID</b>	21.10.97
1	602.052	Determination of Chloride Ion Concentration	18.11.02
1	602.053	Determination of Nitrogen, Nitrite, High Range.	28.10.99
0	602.054	Safety Of Contractors <b>VOID</b>	18.04.96
0	602.055	Safety Training For Outside Contractors <b>VOID</b>	18.04.96
0	602.057	Dealing With Members Of The Public making Enquiries On Environmental Performance <b>VOID</b>	29.09.99
2	602.060	Surface Water Monitoring	15.09.03
0	602.061	Handling Of Hazardous Lab Waste <b>VOID</b>	21.10.97
0	602.062	Non-Chem. Process Waste Collection <b>VOID</b>	14.11.96
2	602.066	Use and Operation of the Labtoc TOC Water Analysis System	12.09.00
2	602.067	Occupational Noise Monitoring	29.10.02
3	602.068	Use and operation of the on line toc	12.09.00
2	602.069	determination of total ammonia	29.10.99
1	602.070	Air Flow Measurement in Vents	20.11.00
2	602.071	Measurement of HCl, Ammonia, Bromine, SO <sub>x</sub> , NO <sub>x</sub> and Acetic Acid in Air	23.03.00
1	602.072	Pperation of fixed solvent monitor <b>VOID</b>	14.02.03

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## SECTION TITLE: ENVIRONMENTAL (S&amp;E DEPARTMENT)

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Effective Date: 17.06.04		Dated: 24.11.03

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REV. NO.	SOP NO.	SOP TITLE	EFFECTIVE DATE
1	602.073	Environmental Requirments on EPA Visits from Air or Water Monitoring Units	09.04.03
0	602.074	<del>Sampling And Inspection Of Sodium Acetate</del> <b>VOID</b>	18.02.00
2	602.075	Environmental Noise Management	18.04.03
1	602.076	Operation of Flow Meters and Automatic Samplers Bay 130 and Mainsite	07.10.02
1	602.077	Response To FOC Alarm Activation	31.01.02
0	602.078	Procedure for Calibrating Laboratory Balance	29.10.99
0	602.079	Calibration of DR/2000 Spectrophotometer	28.10.99
0	602.080	Calibration of Gallenkamp Vacuum Oven	28.10.99
1	602.081	Calibration of Sound Level Meter & Acoustic Calibrator	26.11.03
0	602.082	Use & Calibration of Digital Water bath	28.10.99
0	602.083	Sampling & analysis requirements for Toluene & Xylene in effluent	22.06.00
0	602.084	Total Nitrogen Determination	15.03.01
0	602.085	Total Phosphorous Determination	01.06.01
0	602.086	D.O. Meter Calibration & Determination	31.01.02
0	602.087	Determination of Bromide Ion	09.08.02
0	602.088	MLVSS Determination	09.08.02
0	602.089	Operation of the 3000HM Heated Total Hydrocarbon Analyser	21.06.04

SOP INDEX 603

SECTION TITLE: SECURITY (S&E DEPARTMENT)

Rev. No. 24	<b>SECTION 603</b>	Prev Rev. No. 23
Effective Date: 17.04.02		Dated: 03.10.01

REV. NO.	SOP NO.	SOP TITLE	EFFECTIVE DATE
1	603.001	Boundary Fence Alarm Operation <b>VOID</b>	15.01.97
1	603.002	Safe Delivery And collection Of Goods <b>VOID</b>	20.02.98
0	603.003	Logging SIFA Personnel <b>VOID</b>	20.02.98
1	603.004	Duties Of Security In Locking/Unlocking Site <b>VOID</b>	04.11.97
1	603.005	Receiving Contractors <b>VOID</b>	20.02.98
0	603.006	Passenger Vehicles On Site <b>VOID</b>	20.02.98
0	603.007	Site Entrance Unmanned By Security <b>VOID</b>	21.10.97
1	603.008	Receiving Visitors <b>VOID</b>	21.10.97
1	603.009	Issuing And Return Of Keys <b>VOID</b>	21.10.97
2	603.010	Site Beat Patrol & Nuisance Odour Monitoring Patrol for Security. <b>VOID</b>	26.09.00
1	603.012	Effluent And Balancing Tank Shutdown <b>VOID</b>	04.11.97
0	603.013	On/Off Site Odours <b>VOID</b>	26.09.00
3	603.014	Emergency Instructions for Security Personnel. <b>VOID</b>	17.04.02
1	603.015	Alcohol & Narcotic Drugs On Site <b>VOID</b>	30.10.97
1	603.016	Children On Site <b>VOID</b>	21.10.97
1	603.017	Instructions For Equipment Unattended <b>VOID</b>	21.10.97
1	603.018	SIFA Property Leaving The Site <b>VOID</b>	21.10.97
0	603.019	Silencing & Resetting Boundary Fence Alarm <b>VOID</b>	15.10.97
0	603.021	Directing members Of The Public Marking Enquiries On Environmental Performance <b>VOID</b>	29.09.99



SOP INDEX 604

SECTION TITLE: TRAINING (S&E DEPARTMENT)

Rev. No. 8	<b>SECTION 604</b>	Prev Rev. No. 7
Effective Date: 11.05.00		Dated: 10.06.97

REV. NO.	SOP NO.	SOP TITLE	EFFECTIVE DATE
3	604.001	<del>Training</del> VOID	07.05.97

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SOP INDEX 605

SECTION TITLE: WASTE DISPOSAL (S&E DEPARTMENT)

Rev. No. 11	<b>SECTION 605</b>	Prev Rev. No. 10
Effective Date: 04.04.03		Dated: 02.04.03

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REV. NO.	SOP NO.	SOP TITLE	EFFECTIVE DATE
2	605.002	Waste Disposal Contractor Control	04.04.03
2	605.044	Hazardous Waste Disposal	04.04.03
3	605.050	Preparation of Drummed Waste for Shipment	08.04.03
2	605.051	Preparation of Bulk Waste for Shipment	08.04.03
0	605.061	Handling of Hazardous Laboratory Waste. VOID	26.09.00
2	605.062	Non-Process Waste Collection	08.04.03

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## SECTION TITLE: GENERAL ENVIRONMENT (S&amp;E DEPARTMENT)

Rev. No. 20	<b>SECTION 606</b>	Prev Rev. No. 19
Effective Date: 02.07.04		Dated: 01.07.04

REV. NO.	SOP NO.	SOP TITLE	EFFECTIVE DATE
1	606.001	External Environmental Complaints <b>VOID</b>	29.09.99
0	606.003	Covering/Uncovering the Effluent Balancing Tanks. <b>VOID</b>	26.09.00
1	606.005	Nuisance Odour Monitoring	16.05.00
1	606.022	Solvent Removal from Wastewater Treatment Plant (Solvent Traps, Neutralisation Tank and Balancing Tank.)	29.11.00
2	606.023	Manual Operation of Old ETP due to alarm activation	16.02.00
0	606.024	Nuisance Odour at Wastewater Treatment Plant. <b>VOID</b>	16.02.01
4	606.025	Bund Management	02.07.04
0	606.026	Response to Emergency Conditions in the Waste Water Treatment Plant	14.10.99
0	606.027	SCADA Operation at the Waste Water Treatment Plant	25.09.99
1	606.028	Waste Water Treatment Plant Description / Operation	14.11.02
0	606.029	Control of Critical Equipment For Effluent And Air	27.09.02
0	606.030	Critical Environmental Laboratory & Field Equipment & Reagents	27.09.02
0	606.031	External Environmental Complaints	05.07.04

**SOP INDEX 607**

**SECTION TITLE: GENERAL DOCUMENTATION (S&E DEPARTMENT)**

Rev. No. 4	<b>SECTION 607</b>	Prev Rev. No. 3
Effective Date: 06.09.02		Dated: 27.04.00

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<b>REV. NO.</b>	<b>SOP NO.</b>	<b>SOP TITLE</b>	<b>EFFECTIVE DATE</b>
1	607.001	Numbering of Safety Environmental Standard Operating Procedures (SOPs)	10.09.02
1	607.002	Preparation of Safety and Environmental SOP's	02.05.00

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SOP INDEX 610

SECTION TITLE: ENVIRONMENT MANAGEMENT SYSTEM (S&E DEPARTMENT)

Rev. No. 28	<b>SECTION 610</b>	Prev Rev. No. 27
Effective Date: 08.04.04		Dated: 05.04.04

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REV. NO.	SOP NO.	SOP TITLE	EFFECTIVE DATE
4	610.001	Internal Environmental Health and Safety Auditing	07.04.04
3	610.002	Control of Safety & Env. Management System Records	07.04.04
3	610.003	Monitoring & Analysis Requirements	14.10.02
4	610.004	Identification & Evaluation of Environmental Aspects & Impacts	19.03.03
3	610.005	Management Review of the EMS	27.09.00
0	610.010	Tracking Of EMP Projects <b>VOID</b>	27.10.99
1	610.011	Setting & Monitoring of Environmental Objective & Targets	25.02.00
1	610.012	Register of Environmental Legal and other Requirements	16.09.02
1	610.014	Environmental Health and Safety Change Control <b>VOID</b>	31.03.03
0	610.015	Internal and External Environmental Communications	19.07.99
1	610.016	Calibration of Environmental Measuring & Monitoring Equipment	07.10.02
1	610.017	Control of the Environmental Management System Manual	28.10.99
2	610.018	Environmental Health and Safety Corrective and Preventative Actions	13.04.04

SOP INDEX 630

SECTION TITLE: ENVIRONMENTAL MANAGEMENT SYSTEM (S&E DEPARTMENT)

Rev. No. 8	<b>SECTION 620</b>	Prev Rev. No. 7
Effective Date: 05.04.04		Dated: 12.06.03

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REV. NO.	SOP NO.	SOP TITLE	EFFECTIVE DATE
1	620.001	Emergency Equipment	09.06.00
0	620.002	Equipment Isolation	22.09.99
2	620.003	Emergency Response Team	16.06.03
2	620.004	Emergency Plan	07.04.04
0	620.005	Emergency Equipment Inventory	01.09.99
2	620.006	Efficiency Testing of the Emergency Evacuation Procedure	09.10.01

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SOP INDEX 630

SECTION TITLE: OCCUPATIONAL HYGIENE (S&E DEPARTMENT)

Rev. No. 3	<b>SECTION 630</b>	Prev Rev. No. 2
Effective Date: 24.09.02		Dated: 14.09.01

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REV. NO.	SOP NO.	SOP TITLE	EFFECTIVE DATE
0	630.001	Background Dust Sampling	18.01.01
0	630.002	Respirable Dust Sampling	18.01.01
0	630.003	Total Dust Sampling	18.01.01
1	630.004	Calibration of Air Flows Through Laboratory Fume Cupboards	26.09.02

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## Appendix C.1.5

# Environmental, Health and Safety Policy Statement

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## Environment & Safety Policy

SCHWARZ PHARMA Limited is a market leader in the development and manufacture of a wide variety of Fine Chemicals and Pharmaceutical products, which are primarily used for the treatment of cardiovascular disease, urology & neurology. As an organisation SCHWARZ PHARMA Limited considers the effective management of the natural and workplace environment to be one of its highest organisational priorities as reflected through its commitment to Environmental Health and Safety compliance.

### Our Commitment to Environment, Health and Safety

SCHWARZ PHARMA Limited regards provision of a Safe workplace and protection of the Environment as an integral part of its business. It undertakes to conduct its activities in a manner which adheres to the highest Environmental Health and Safety standards and strives towards ensuring the protection of its employees, contractors, members of the public and the Environment in which it operates. The company's Environmental Health & Safety Management System Manual outlines the framework for implementing these objectives.

### Specifically we commit to the following:-


- **Continual Improvement.** We are committed to improving our overall Environmental Health and Safety performance and we will strive to demonstrate this commitment to continual improvement through the setting and reviewing of objectives and targets.
- **Accident Prevention.** We will strive to prevent accidents through learning from our own previous experiences and by adherence to risk assessment programmes and safe systems of work to ensure a safer work environment.
- **Compliance.** We will comply with all applicable Environmental Health and Safety regulatory and legislative requirements.
- **Major Accident and Emergency Planning.** We will comply with the requirements of the SEVESO II Directive by adhering to the provisions of the Major Accident Prevention Plan (MAPP) and the implementation of all other safety systems required under the conditions of the Directive.
- **Employees.** We will ensure that all our employees are made fully aware of their Environmental Health and Safety responsibilities and that they are provided with the training and information necessary to ensure that they perform their work in a manner which ensures their safety, the safety of others and protection of the environment. The updated sections of the company's Safety Statement will be communicated to relevant employees when revised.
- **Conservation.** We will strive to conserve natural resources through the responsible and efficient use of raw materials and energy, and through the development of onsite waste reduction programmes.
- **Pollution Control.** We will strive to prevent pollution through a combination of substitution, elimination, engineering controls and monitoring, while abiding by the principles of Cleaner Technology and BATNEEC (Best Available Technology Not Entailing Excessive Cost).
- **Communication.** We will maintain good relations with the local community and local industry in relation to all Environmental Health and Safety issues.
- **Suppliers and Contractors.** We will work with our suppliers and contractors to enhance Environmental Health and Safety performance.
- **Availability.** Our Environmental Health and Safety policy is available to all our employees & contractors in designated areas of the plant. We will make the policy available to the public on request.

The General Manager is responsible for the effective implementation of the Environmental, Health and Safety policy throughout the sites. Policy implementation is achieved through the Departmental Managers and company line management structure, with the Safety and Environment Department playing a specialist role in providing advice, direction and support to assist management and employees fulfil the policy objectives. All employees and users of the site are responsible for environmental protection and for ensuring they work and contribute to a healthy and safe workplace.

  
Dr. Bernie Harten  
Managing Director

03 09 04  
Date

Rev. No. 2  
Dated: 29/07/2004

  
Ivor Willis  
QA & Support Services

05/09/04  
Date

Prev. Rev.: 1  
Dated: 22/07/2003

**Appendix C.1.6**  
**Duties under Responsible Care**

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## DUTIES UNDER RESPONSIBLE CARE

### *Example 1*

- Operate plant and facilities in a manner that preserves the environment and protects the health and safety of employees and the public.
- Develop and produce products that can be manufactured, transported, used and disposed of safely.
- Give health, safety and environmental considerations priority in planning for new products and processes.
- Report relevant health and environmental information to appropriate stakeholders
- Ensure that relevant health safety and environmental hazards are identified and protective measures taken to prevent accidents
- Provide advice to customers on the safe use, transportation and disposal of chemical products
- Increase knowledge by conducting and supporting research on the health, safety and environmental effects for our products, processes and waste materials.
- Co-operate with customers, authorities and affected groups and individuals to resolve problems created by the handling and disposal of chemical substances considered hazardous.
- Co-operate with government in developing laws and regulations to safeguard the community, the workplace and the environment.

### *Example 2*

WE demonstrate our commitment by adhering to the following principles

- **Operational Safety:** We will manage all activities to minimise the risk to employees, the community and the environment to deliver expected performance to the public at large.
- **Product Stewardship:** We will assess the risks associated with our products and seek to ensure these risks are properly managed throughout their life cycle, always striving to eliminate all risks.
- **Resource Conservation:** We will conserve resources and reduce waste in all our activities.
- **Community Engagement:** We will talk to our local communities about our activities and products and listen and respond to their concerns. We will report our health, safety and environmental performance to our local communities.
- **Industry Collaboration:** We will share expertise with our industry colleagues and incorporate best practices into our own activities.

*Example 3*

- Ensure that operations do not present an unacceptable level of risk to employees, customers, the public or the environment. Provide relevant information on the hazard of chemicals to customers urging them to use and dispose of product in a safe manner and make such information available to the public on request.
- Make responsible care an early and integral part of the planning process leading to new products processes or plants
- Increase the emphasis on the understanding of existing product and their uses and ensure that a high level of understanding of new products and their potential hazards is achieved prior to and throughout commercial development
- Comply with all legal requirements, which affect its operations and products.
- Be responsive and sensitive to legitimate community concerns.
- Work actively with and assist government and selected organisations to foster and encourage equitable and attainable standards.

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**Appendix C 1.7 –  
Scrubber Abatement System SOPs**

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<b>OPERATIONS PROCEDURE</b>	<b>S O P</b> 201.013	<b>Page 1 of 5</b>
<b>TITLE: ATMOSPHERIC EMISSIONS CONTROL MANAGEMENT SYSTEM.</b>		<b>Effective Date:</b> _____ <b>Revision No:</b> <u>0</u> <b>Date:</b> <u>26.04.2005</u> <b>Prev Rev No:</b> _____ <b>Dated:</b> _____

## 1 PURPOSE

To define the method by which Production Operations will be managed and operated to minimise the potential for air emissions through the licensed main process emission points for each production building exceeding the limits set in the site Environmental License.

## 2 RESPONSIBILITY

It is the responsibility of the General Manager to ensure that the relevant individuals are familiarised with this SOP and to ensure that all activities relating to operation are carried out in accordance with this document.

It is the responsibility of all Heads of Department and Department Managers to ensure that processes are operated accorded to implemented procedures and that operators and other responsible persons adhere to these procedures.

## 3 APPROVAL

This SOP and any changes must be approved by the General Manager, Head of Operations, Head of Supply Chain Management, Environment and Safety Manager and Q.A./Validation Specialist.

## 4 SCOPE

This SOP describes the actions and operations that must take place to minimise the potential for air emissions from production building to exceed the limits set in the site IPC/IPPC License at SCHWARZ PHARMA Ltd, Shannon during production of Active Pharmaceutical Ingredients.

## 5 PROCEDURE

Process emissions occur as a result of venting waste gases from equipment during routine production. To ensure that the waste gases are discharged in a controlled manner, either to assist in the prevention of pressure build-up in equipment or to assist in the drying of product, this procedure sets out the process to be followed to facilitate production operations whilst minimising the potential to emit to atmosphere quantities of material that would exceed the levels set out in current Environmental License conditions.

Written By:	Approved By:	Approved By:	Approved By:	Approved By:	Approved By:
_____ Ivor Wills Head of QA & Support Services	_____ Dorothea Diewald QA/Validation Specialist	_____ Marcus Dohmann Head of SCM	_____ Dermot Hanrahan Environment & Safety Manager	_____ Bernie Harten General Manager	_____ TJ Coen Production Manager
Date : _____	Date : _____	Date : _____	Date : _____	Date : _____	Date : _____



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<b>TITLE: ATMOSPHERIC EMISSIONS CONTROL MANAGEMENT SYSTEM.</b>		<b>Effective Date:</b> _____ <b>Revision No:</b> <u>0</u> <b>Date:</b> <u>26.04.2005</u> <b>Prev Rev No:</b> _____ <b>Dated:</b> _____

### 5.1 *STEP 1 - Planning Production*

Production planning is a combination of matching the requirements of Supply Chain Management with the availability of production equipment. Planning of production therefore will involve the following:

- Determination of API Material requirements and timeline for delivery.
- Synchronisation of processes so as to avoid overload of the abatement system.
- Synchronisation of processes to ensure the optimisation of critical utility supply.
- Synchronisation of processes so as to avoid incompatibility of Waste Gases that could result in secondary reactions in the process vent system. (e.g. strong base and acid vapour mixtures).
- Identification of safety critical steps which cannot be immediately stopped in an Alarm condition and must be moved forward to a safe hold point.
- Identification / selection of scrubber configuration, scrubbing media and venting arrangements.

### 5.2 *STEP 2 - Process Operation/Control*

Step 2 of the process, which is designed to reduce the emissions at source, is developed as follows and includes a documented pre-campaign check of equipment that will be completed in order to ensure:

- The equipment is suitable for use and all PM (Preventative Maintenance) work has been carried out prior to start-up.
- The Process equipment set up is accordance with Batch Manufacturing Instructions.
- That the Process Vents from the equipment are connected to the correct Vent Headers/Abatement system.

Standard Operating Procedures (SOP's) are used for both the operation and maintenance of equipment in production. The scope of these procedure types is outlined as follows:

- SOP's used as part of routine manufacturing will reference the operation of equipment and abatement systems to control emissions.
- SOP's used for maintaining equipment will reference checks on critical emission control equipment (e.g. fitting of orifice plates).

<b>OPERATIONS PROCEDURE</b>		Page 3 of 5
<b>TITLE: ATMOSPHERIC EMISSIONS CONTROL MANAGEMENT SYSTEM.</b>	<b>S O P 201.013</b>	<b>Effective Date:</b> _____ <b>Revision No:</b> <u>0</u> <b>Date:</b> <u>26.04.2005</u> <b>Prev Rev No:</b> _____ <b>Dated:</b> _____

Batch manufacturing instructions (BMI's) are used for control and document the manufacture of the individual products. To maintain control of the processing these instruction sheets contain the following information:

- Safe holding points for processes in the event of an emergency.
- Details of the condenser set up and cooling media required for the condensing of gases.
- Details of the liquid to be used in liquid ring vacuum pumps and the destination of the waste liquor from the pump.
- Details of the set point for the over temperature protection fitted to the outlet of condensers.
- Details of the level of vacuum to be used during processing.
- Detail instructions for loading material to reaction/isolation/drying equipment.
- Details of the temperature for operating distillations/reactions/drying.
- Details of which abatement system the process vent is connected to.
- Approval that it is safe to commence a distillation/reflux.
- Details of the use and pressure of Nitrogen for purging/Blanketing and inter vessel transfers.
- Details of any addition that might cause an increase in emissions or pressure in system and control of that addition.
- Details of in-process vacuum/pressure checks.

Cleaning Protocols are used as instructions to ensure that equipment that is being used for a given product is free from any previous materials that might affect the quality of the product. These protocols contain the following:

- Details of the condenser set up and cooling media required for the condensing of gases.
- Details of the liquid to be used in liquid ring vacuum pumps and the destination of the waste liquor from the pump.
- Details of the set point for the over temperature protection fitted to the outlet of condensers.
- Details on the level of vacuum to be used.
- Detail instructions for drying equipment.
- Details on the temperature for operating distillations/drying.
- Details on which abatement system the process vent is connected to.
- Approval that it is safe to commence a distillation/reflux.
- Details on the use and pressure of Nitrogen for purging/Blanketing/Transferring.
- Details on in-process vacuum/pressure checks.



<b>OPERATIONS PROCEDURE</b>		Page 4 of 5
<b>TITLE: ATMOSPHERIC EMISSIONS CONTROL MANAGEMENT SYSTEM.</b>	<b>S O P 201.013</b>	<b>Effective Date:</b> _____ <b>Revision No:</b> <u>0</u> <b>Date:</b> <u>26.04.2005</u> <b>Prev Rev No:</b> _____ <b>Dated:</b> _____

### 5.3 STEP 3 - Abatement and Monitoring

The abatement and monitoring systems form the last stage of the emissions control system. The operation and maintenance of these systems are covered by operational procedures.

The Emission Control Systems for the site production buildings are summarised as follows:

1. **BPC** – This system consists of dual General Process Vent and Specific Process Vent solvent headers. These headers carry air emissions from the plants operations to the scrubbers. The operation of this system is procedurally controlled.
2. **Nitration** – this is a single piping system with 2 scrubbing systems in series. The operation of this system is procedurally controlled.

The Monitoring of Emission and Testing of the Scrubber fluid is summarised as follows:

1. Monitoring – monitoring of emissions is carried out by using identical analytical methods for both the BPC and Nitration buildings. Grab samples will be taken during operations to check emission levels and an in-line Flame Ionising Detector (FID) will be used to monitor emissions on a continuous basis. The operation of this system is described in SOP602.048 - Monitoring Emissions of Organic Solvents.
2. Testing of scrubber fluid – the scrubbing fluid will be tested at defined intervals in order to determine when the set saturation limit has been reached. At this point the solution will be replenished. The change out level is determined by lab test and calculation. STEP 4 - Alarms

To assist in preventing emission limits being exceeded, the FID units are linked to an alarm system which is continuously monitored by SCADA in both the BPC and Nitration Control Rooms. Audible Alarms will be activated upon reaching the preset limits thereby initiating the necessary management intervention. The set points of these alarms are as follows:

- 50% of a 2Kg TOC reading of the solvent with the least carbon content in that class used on site.
- 75% of a 2Kg TOC reading of the solvent with the least carbon content in that class used on site.

<b>OPERATIONS PROCEDURE</b>		Page 5 of 5	
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		<b>Prev Rev No:</b> _____	<b>Dated:</b> _____

These limits will apply to both BPC and Nitration

Calculation Example:

If Methanol is identified as the solvent in the Air emissions stream with the lowest carbon content the FID limits would be set as follows:

For a 2Kg Mass Emission of Methanol the equivalent Carbon content would be 0.75 Kgs.

The limits for the FID would therefore be set at 50% and 75% of this value i.e. 0.37 and 0.56 Kg of Carbon respectively. This assumes a pure stream of the worst case material and so provides a significant protection factor for other higher carbon content materials.

### 5.3.1 Response to Scrubber Fluid Test Results

As described the scrubbing solutions will be sampled and analysed during the course of normal operation in order to determine when the necessary change out point has been reached. Based on the trend analysis of the test results the scrubber liquid will be changed once the defined saturation point achieved. If test results indicate an abnormal drop in absorption capacity a root cause analysis of operations at that time would be performed and a decision on ceasing offending operations or proceeding with production until a safe point is reached would be taken based on a safety risk assessment.

### 5.3.2 Response to FID Alarms

As described the FID alarm system will be monitored continuously by the SCADA Systems in both the BPC and Nitration Control Rooms. The Alarm system is based on a two stage activation. The first warning limit is set at 50% of the maximum allowable carbon output (based on emission calculations) and the second is set a 75% of this value. Following the activation of the first warning limit a root cause analysis of operations at that time would be performed to identify the offending operations and put the necessary corrective actions to reduce emission levels. If the 75% alarm is activated then a decision on ceasing offending operations or proceeding with production until a safe point is reached would be taken based on a safety risk assessment.

## 6 REVISION

This SOP is reviewed according to SOP 100.007. Any necessary changes will be documented in a new revision of this SOP.

<b>OPERATIONS PROCEDURE</b>  <b>TITLE: ATMOSPHERIC EMISSIONS CONTROL MANAGEMENT SYSTEM.</b>	<b>S O P</b> <b>201.013</b>	<b>Page 5 of 5</b> <b>Effective Date:</b> _____ <b>Revision No:</b> <u>0</u> <b>Date:</b> <u>26.04.2005</u> <b>Prev Rev No:</b> _____ <b>Dated:</b> _____
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### REVISION LOG

**SOP TITLE: ATMOSPHERIC EMISSIONS CONTROL  
MANAGEMENT SYSTEM.**

**SOP NUMBER/CODE: 201.013**

<b>REVISION NO.</b>	<b>REQUESTED BY:</b>	<b>REASON FOR REVISION</b>	<b>EFFECTIVE DATE</b>
0	Ivor Wills	To introduce a new SOP.	

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**RECEIPT OF SOP CONFIRMATION**

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<b>Signed:</b>	<b>Department:</b>	<b>Date:</b>

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<b>NITRATES MANUFACTURING PROCEDURE</b>	<b>S O P</b>	Page 1 of 2
<b>TITLE: NITRATION PRODUCTION SHUTDOWN SYSTEM IN THE EVENT OF AN AIR EMISSIONS ALARM</b>	<b>507.003</b>	<b>Effective Date:</b> _____ <b>Revision No:</b> <u>0</u> <b>Date:</b> <u>29.04.05</u>

**1.0 PURPOSE:**

To describe the nitration shutdown system in the event of an air emissions alarm.

**2.0 PROCEDURE:**

- 2.1 The air emissions values are located on the SCADA screen on the PC's in the control room, under: plant overview/vent emissions /mass flow percent.
- 2.2 The air emissions alarm will be generated at 50% and 75%, the alarm will pop up on the SCADA screen on the PC's in the control room, see attachment I for an example of the pop up alarm. All alarms must be acted on immediately.
- 2.3 A MASS FLOW HI ALARM – REDUCE EMISSIONS will be generated at 50%, A MASS FLOW HI HI ALARM – STOP EMISSIONS will be generated at 75%, these alarms will not be removed until they are acknowledged and the alarm conditions have been removed.
- 2.4 There are other alarms generated by the system which also must be acknowledged and will not be removed until the alarm conditions have been removed. Such as a TOC HI LEVEL.

**Action at 50% MASS FLOW HI ALARM – REDUCE EMISSIONS:**

- 2.5 When the 50% alarm is triggered call the site co-ordinator immediately.
- 2.6 The site co-ordinator will acknowledge the alarm.
- 2.7 The site co-ordinator will investigate the following to reduce the emissions and remove the alarm condition: all processes in-operation, condenser temperatures set to 2°C, CV 's at process vents, nitrogen feed valves, saturation of scrubbing solutions, level of scrubbing solutions, and leaks.

**Action at 75% MASS FLOW HI HI ALARM – STOP EMISSIONS:**

- 2.8 When the 75% alarm is triggered call the site co-ordinator immediately
- 2.9 The site co-ordinator will acknowledge the alarm.
- 2.10 The site co-ordinator will begin the plant shutdown as per attachment II to reduce the emissions and remove the alarm condition. Attachment II is a list of the processes which could cause air emissions alarm to trigger. The sequence of shutdown and the steps at which it is safe to shutdown each of the processes is also included.

Written By:	Approved By:	Approved By:
_____	_____	_____
S. Burke Technical Adviser Nitration	T.J. Coen Production Manager	M. McCarthy Technical Specialist
Date: _____	Date: _____	Date: _____



<p>NITRATES MANUFACTURING PROCEDURE</p> <p>TITLE: NITRATION PRODUCTION SHUTDOWN SYSTEM IN THE EVENT OF AN AIR EMISSIONS ALARM</p>	<p>S O P</p> <p>507.003</p>	<p>Page 2 of 2</p> <p>Effective Date: _____ Revision No: <u>0</u>      Date: <u>29.04.05</u></p>
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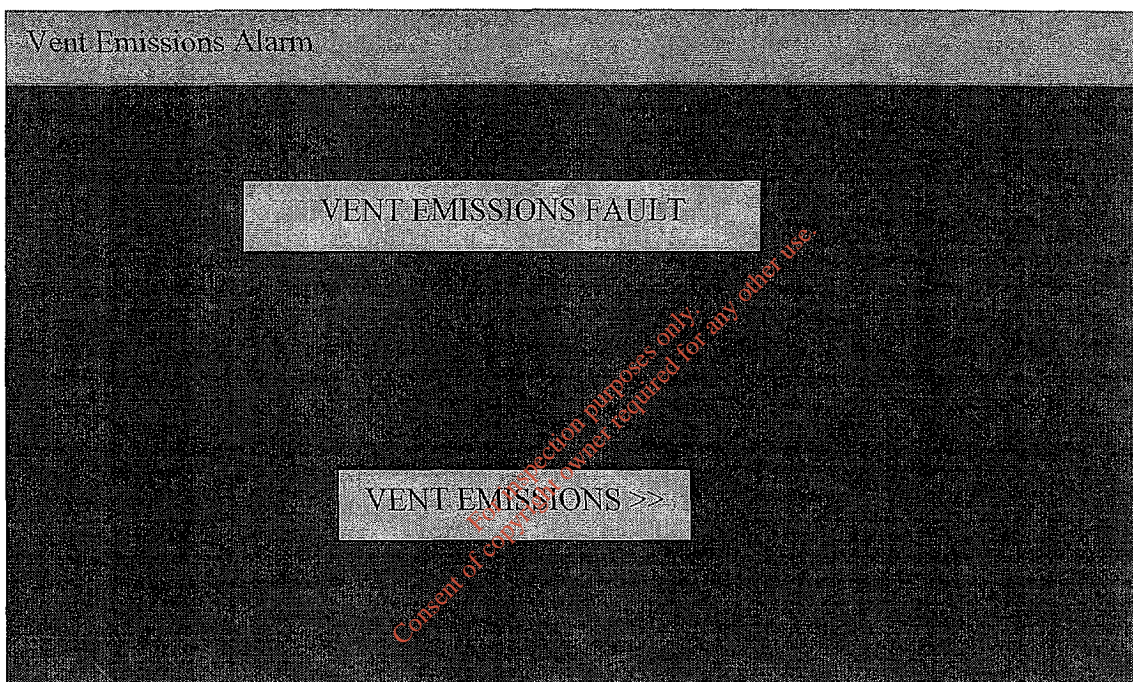
- 2.11 There is a complete history of the air emissions on the control system under: desktop/air emissions log.
- 2.12 Fill out attachment III for each process and step being carried out at the time of the 75% alarm.

**3.0 DOCUMENTATION:**

- Attachment I - Example of air emissions alarm pop up screen
- Attachment II - Shutdown sequence in the event of a 75% air emissions alarm
- Attachment III - List of process running at trigger of 75% air emissions alarm

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<p><b>NITRATES MANUFACTURING ATTACHMENT I</b></p> <p><b>Title:</b> Example of air emissions alarm pop up screen</p>	<p><b>SOP</b></p> <p>507.003</p>	<p><b>Page 1 of 1</b></p> <p><b>Effective Date:</b> _____</p> <p><b>Revision No:</b> <u>0</u>      <b>Date:</b> <u>29.04.05</u></p>
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MASS FLOW HI ALARM - REDUCE EMISSIONS

MASS FLOW HI HI ALARM- STOP EMISSIONS



<b>NITRATES MANUFACTURING ATTACHMENT II</b>	<b>SOP</b>	<b>Page 1 of 1</b>
<b>Title:</b> Shutdown sequence in the event of a 75% air emissions alarm	<b>507.003</b>	<b>Effective Date:</b> _____ <b>Revision No:</b> <u>0</u> <b>Date:</b> <u>29.04.05</u>

Reactor	Process	Shutdown Priority	Sequence
RE-6101	Nitration Solution	9	If the alarm occurs during the loading of Nitric Acid or Acetic Anhydride this should be the last reaction to be shutdown due to the dangerous nature of the reaction. Only shutdown if before the addition of Nitric Acid or after addition of Anhydrous Sodium Acetate.
RE-6111	Hydrolysed Nitration Solution	3	This reaction should only cause a problem during the toluene separations. It is safe to shut it down at this point but drop the temp to 20 and keep the agitator running. Also safe to shutdown at all other times, keep agitator running and temperature at 20. Product will crystallise out if maintained at this temperature over 12hours.
EC-6121	MIBK Extraction	6	Cannot leave anything in TA-6121 otherwise it will solidify. So it is not safe to shutdown this reaction. If necessary move the solution in TA-6121 to a heated agitated vessel.
RE-6131	MIBK Distillation	4	Safe to shutdown at anytime cool to 20 and keep agitating. Can stop agitation if necessary, product will crystallise out if maintained without agitation over 12 hours
EC-6141	Toluene Extraction	5	Cannot leave anything in TA-6141 otherwise it will solidify. So it is not safe to shutdown this reaction. If necessary move the solution in TA-6141 to a heated agitated vessel, close the CV on the process vent, and turn back the Nitrogen.
RE-6201	Crude 5-ISM	2	Only issue should be during the toluene distillation. Can be shutdown at anytime and held at 20. Product will crystallise out if maintained at this temperature after all the toluene has been distilled.
CR-6301	Crude ISDN	1	No issues with stopping asap. Crude needs no agitation or heat.
CR-6301	Pure ISDN	7	No issues with stopping asap. Maintain agitation and temperature at 20.
CR-6321	Pure ISDN	8	No issues with stopping asap. Maintain agitation and temperature at 20.



### REVISION LOG

**SOP TITLE:** Nitration production shutdown system in the event of an air emissions alarm

**SOP NUMBER/CODE:** 507.003

REVISION NO.	REQUESTED BY:	REASON FOR REVISION	EFFECTIVE DATE
0	SB	To create a new SOP	

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## RECEIPT OF SOP CONFIRMATION

<b>SOP TITLE:</b> Nitration production shutdown system in the event of an air emissions alarm	<b>SOP NO:</b> 507.003	<b>REV. NO:</b> 0
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<b>NITRATES MANUFACTURING PROCEDURE</b>	<b>S O P</b>	Page 1 of 3
<b>TITLE: THE MANUAL OPERATION OF SCRUBBERS C-100 AND C-101</b>	<b>507.002</b>	<b>Effective Date:</b> _____ <b>Revision No:</b> <u>1</u> <b>Date:</b> <u>10.05.05</u> <b>Prev Rev No:</b> <u>0</u> <b>Date:</b> <u>27.04.05</u>

**1.0 PURPOSE:**

To describe the manual operation of the scrubbing system (Scrubbers C-100 and C-101) in the Nitration plant.

**2.0 PROCEDURE:**

The results of the any checks carried out in the following steps must be recorded as per Attachment I, log book.

**Start up and fill of scrubber C-100;**

- 2.1 Ensure that Fan F-100 is not running and that no vent operations are running. That is that all vent valves are closed there is no inerting, blow through or breaking of vacuum running.
- 2.2 Add 100L of process water (via the main water line on the ground floor) and 480L of IMS (Via drums) to the sump of C-100. There are manual valves at the scrubber sump for this operation. The scrubber sump is equipped with a temporary level indicator in the form of a clear PVC hose. Level indicators have been marked at 100L (mark 1), 580L (mark 2) and 680L (mark 3).
- 2.3 Record the volume added to the C-100 sump in the log book provided.
- 2.4 Open the air line to P-100 to start the pump. The air line is fed from the ground floor in Nitration. The gate valve and hand valves of the air line must be opened in order to start the pump. This circulates the scrubbing solution through the scrubber column. Re-circulate the scrubbing solution for 1 hour. Record this in the log book provided.  
  
Take a sample of the scrubbing solution from the sump drain C-100 for lab analysis, Fill out the sampling sheet (attachment III) and bring it to QC along with the sample.
- 2.5 Check that the glycol cooling inlet and outlet valves to the heat exchanger E-100 are fully open. Ensure that pump P-100 remains running at all times.

Written By:	Approved By:	Approved By:
_____	_____	_____
S. Burke Technical Adviser Nitration	TJ Coen Production Manager	Miriam McCarthy Tech Services Specialist
Date: _____	Date: _____	Date: _____

<p style="text-align: center;"><b>NITRATES MANUFACTURING PROCEDURE</b></p> <p><b>TITLE: THE MANUAL OPERATION OF SCUBBERS C-100 AND C-101</b></p>	<p style="text-align: center;"><b>S O P</b></p> <p style="text-align: center;"><b>507.002</b></p>	<p style="text-align: right;">Page 2 of 3</p> <p>Effective Date: _____</p> <p>Revision No: <u>1</u>      Date: <u>10.05.05</u></p> <p>Prev Rev No: <u>0</u>      Dated: <u>27.04.05</u></p>
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**Start up and fill of scrubber C-101;**

- 2.6 Ensure that fan F-100 is not running and that no vent operations are in running. That is that all vent valves are closed there is no inerting, blow through or breaking of vacuum running.
- 2.7 Add 500L of process water to the sump of C-101 (via the main water line on the ground floor). The scrubber sump is equipped with a temporary level indicator in the form of a clear PVC hose. Level indicators have been marked at 100L (mark 1), 500L (mark 2) and 650L (mark 3).
- 2.8 Record the volume added to the C-101 sump in the log book provided.
- 2.9 Open the air line to P-100 to start the pump. The air line is fed from the ground floor in Nitration. The gate valve and hand valves of the air line must be opened in order to start the pump. This circulates the scrubbing solution through the scrubber column. Record this in the log book provided.
- 2.10 Check that the glycol cooling inlet and outlet valves to the heat exchanger E-101 are fully open. Ensure that pump P-101 remains running at all times.

**Start up of Vent Fan F-100.**

**Note: The Nitration building vent headers need to be maintained at between -5mbar and -10 mbarg.**

- 2.11 Ensure that the vent fan F-100 is not running.
- 2.12 Fully open the dispersion air line valve.
- 2.13 Start the vent fan F-100 from the computer in the control room, with the dispersion air line valve fully open.

<p align="center"><b>NITRATES MANUFACTURING PROCEDURE</b></p>	<p align="center"><b>S O P</b></p>	<p align="right">Page 3 of 3</p>
<p><b>TITLE: THE MANUAL OPERATION OF SCUBBERS C-100 AND C-101</b></p>	<p align="center"><b>507.002</b></p>	<p><b>Effective Date:</b> _____  <b>Revision No:</b> <u>1</u>      <b>Date:</b> <u>10.05.05</u>  <b>Prev Rev No:</b> <u>0</u>      <b>Dated:</b> <u>27.04.05</u></p>

**Operation during production and monitoring of the scrubber solutions;**

2.14 Take a sample of the scrubbing solutions for analysis once the mass flow % equals 40.

The result of this test will determine if the scrubbing solutions require changing. Fill out the sampling sheet (attachment III) and bring it to QC along with the sample.

2.15 If indicated by the site co-ordinator to change the scrubbing solutions carry out steps 2.1 to 2.13.

2.16 When sampling the scrubbing solutions also check that the Nitration building vent headers are between -5mbar and -10 mbarg.

**Note: This scrubbing system will be emptied and cleaned at least once a year.**

2.17 When sampling the scrubbing solutions also check the sight glass at the bottom of the stack for liquid. If it contains liquid call the Site Co-ordinator, who will advise on how it should be emptied.

2.18 If C-100 reaches 650L drain the contents to drums.

**3.0 DOCUMENTATION:**

Attachment I - Record of checks during manual operation of the scrubbing system- **logbook**

Attachment II - Record of sampling of the scrubbing system- **logbook**

Attachment III - Example of QC sampling sheet for scrubbing solutions

<b>NITRATES MANUFACTURING ATTACHMENT I</b>	<b>SOP</b>	<b>Page 1 of 1</b>	
<b>Title:</b> (Logbook) Record of checks during manual operation of the scrubbing system "Example Only".	507.002	<b>Effective Date:</b>	
		<b>Revision No:</b> <u>1</u>	<b>Date:</b> <u>10.05.05</u>
		<b>Prev Rev No:</b> <u>0</u>	<b>Dated:</b> <u>27.04.05</u>

Fill out this log in conjunction with the steps 2.1 to 2.13 of the SOP 507.002. Read the questions and tick or provide values where required.

<b>Checks during filling and start up</b>	Date	
	Time	
	Sign	
	<b>Start up and fill of Scrubber C-100</b>	
	Fan F-100 is not running	
	No vent operations are running	
	Record the volume of process/mains water added to the C-100 sump	
	Record the volume of IMS added to the C-100 sump	
	Record the start time of re-circulation of scrubbing solution	
	Record the finish time of re-circulation of scrubbing solution	
	Record the total recirculation time:	
	Scrubber solution sampled	
	Cooling fully opened	
	<b>Start up and fill of Scrubber C-101</b>	
	Fan F-100 is not running	
	No vent operations are running	
	Record the volume of process water added to the C-101 sump	
	Cooling fully opened	
	<b>Start up of Vent Fan F-100</b>	
	Fan F-100 is not running	
	No vent operations are running	
	Dispersion air line valve fully opened	
	Vent fan started from the control room	







### REVISION LOG

SOP TITLE: THE MANUAL OPERATION OF SCUBBERS C-100 AND C-101		SOP NUMBER/CODE: 5007.002	
REVISION NO.	REQUESTED BY:	REASON FOR REVISION	EFFECTIVE DATE
0	SB	To create a new SOP	02.04.05
1	SB	Update for new levels, IMS, and fan settings.	

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<b>BPC MANUFACTURING PROCEDURE</b>	<b>SOP</b>	Page 1 of 7	
<b>Title: Operation of Scrubbers 1 and 3 in the BPC Building</b>	<b>208.200</b>	<b>Effective Date:</b>	
		<b>Revision No:</b> <u>4</u>	<b>Date:</b> <u>06.05.05</u>
		<b>Prev Rev No:</b> <u>3</u>	<b>Dated:</b> <u>24.10.01</u>

**1.0 PURPOSE:**

To describe the correct method to operate the vent scrubbers in the BPC plant in Schwarz Pharma, Shannon.

**2.0 RESPONSIBILITY**

It is the responsibility of the production manager to ensure all personnel operating scrubber 1 and 3 in the BPC building are adequately trained in the operation of scrubbers 1 and 3.

**3.0 APPROVAL**

This SOP and any changes must be approved by the Q.A. Manager.

**4.0 SCOPE**

To provide guidelines to personnel who operate and monitor the vent scrubbers in the BPC building.

**5.0 PROCEDURE**

The operation of Scrubbers 1 and 3 is described in this section.

**5.1 Operation of Scrubber 1:**

Scrubber 1 is designed to neutralise acidic or basic vapours and gases which may be released from the process vessels, and scrub any water miscible solvent vapour which may have passed scrubber 3. It is also used to scrub the exhaust gas vented via the Local Extract Ventilation (LEV or "snuffler") system. It is the final treatment of these streams before emission to atmosphere.

Written By:	Approved By:	Approved By:	Approved By:	Approved By:
S Mowat BPC Supervisor.	T.J. Coen Production Manager	Miriam McCarthy Technical Specialist	Dermot Hanrahan Env & Safety Manager	Dorothea Diewald QA/Validation Specialist
Date: _____	Date: _____	Date: _____	Date: _____	Date: _____

<p><b>BPC MANUFACTURING PROCEDURE</b></p> <p><b>Title: Operation of Scrubbers 1 and 3 in the BPC Building</b></p>	<p><b>SOP</b></p> <p><b>208.200</b></p>	<p><b>Page 2 of 7</b></p> <p><b>Effective Date:</b> _____</p> <p><b>Revision No:</b> <u>4</u>      <b>Date:</b> <u>06.05.05</u></p> <p><b>Prev Rev No:</b> <u>3</u>      <b>Dated:</b> <u>24.10.01</u></p>
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**5.2 Monitoring of Scrubber 1:**

- 5.2.1 The operation of Scrubber 1 must be monitored four times every day, i.e. at 4:00, 10:00 16:00 and 22:00.
- 5.2.2 On each occasion the Checklist Log must be completed, as per Attachment 1.
- 5.2.3 Check that the Fan, Circulation Pump, and Chiller are operating normally.
- 5.2.4 Inspect the scrubber for leaks. If a leak is found stop the scrubber (ref. 5.4) and contact maintenance to have it repaired immediately.
- 5.2.5 Verify that the flow rate of the scrubber solution is above 60% at the flow indicator
- 5.2.6 Check that falling liquid is visible in the sight glass of the scrubber
- 5.2.7 Manually check two LEV points within the BPC to ensure that there is suction. At least one of these points should be in the vicinity of R25-R28 or R19-R20 to ensure that there is suction in the most remote parts of the system.
- 5.2.8 Take a sample of the solution via the sample valve on the circulation line. Complete the sampling attachment (Attachment II) and submit the sample to QC as per SOP 004.021.
- 5.2.9 If the scrubber composition is out of specification refer to SOP 201.014

**5.3 Changing the Scrubber Solution**

- 5.3.1 The Scrubber Solution must be drained fully and recharged when required by any of the following:
  - 1) A specific process requirement, as instructed in the BMI. If two processes require different scrubbing solutions in Scrubber 1 refer to SOP 201.013 for scrubber solution selection.
  - 2) If the routine sampling shows the solution composition is out of specification
  - 3) By default, the solution is to be changed on Monday morning.
- 5.3.2 Every time the scrubber is recharged, an entry must be made in the Scrubber Startup Checklist (Ref Attachment 3).
- 5.3.3 Before changing the scrubber solution refer to Attachment IV to check that proposed solution is compatible with processes that are ongoing in BPC.
- 5.3.4 Follow instructions in sections 5.6.1 – 5.6.1 to change the solution in Scrubber 1.

**Note:** PPE must be worn during sampling, draining and filling of scrubber. Ensure that a respirator fitted with A2B2E2K2P3 and gloves are worn.

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#### 5.4 Shut down of Scrubber 1:

- 5.4.1 To be performed when required for maintenance or change of scrubbing solution.
- 5.4.2 Inform the Site Co-ordinator and other BPC operators that the scrubber is to be shut down to enable processes to be safely held, if necessary, before scrubber shut down.
- 5.4.3 When it is safe to do so, shut down the fan and pump on both Scrubber 1 and Scrubber 3 (controls located inside the BPC building, on the ground floor). Stop the circulation of chilled glycol to the scrubber heat exchanger. Display "Do not start" signs at the Scrubber controls, signed and dated appropriately.
- 5.4.4 Ensure valve on water supply line is closed (located on the ground floor of BPC)

#### 5.5 Drain Scrubber 1:

- 5.5.1 Open valve on fixed line to effluent and drain the contents.
- 5.5.2 Open the manhole cover on the scrubber sump and wash the sump using a hose until it is clean and free of residue. Attach a pump and hoses to the effluent drain to allow the sump to be drained fully. Pump the remaining contents of the sump to effluent.  
**Note:** Refer to note for wearing of PPE.
- 5.5.3 Replace the manhole cover securely and charge approximately 300 L of water to the sump. Start circulation pump 1 or 2 and circulate this through the scrubber for 15 minutes. Stop the circulation pump, and drain the contents of the sump to effluent.

#### 5.6 Fill Scrubber 1:

- 5.6.1 Refer to the appropriate BMI for instructions regarding the type and quantity of materials to charge to the scrubber. When handling these materials, take the precautions specified in the relevant Chemical Handling Cards.
- 5.6.2 Ensure the fixed line to the drain is closed.
- 5.6.3 Add approximately 400L of water to the sump.
- 5.6.4 Add quantity of 30% Caustic Soda or 50% Sulphuric Acid as directed by the relevant BMI. Use the fixed fill-line provided for pumping in these materials.  
**Note:** Clean up any spills immediately
- 5.6.5 Top up the sump to 1200L using water. Ensure that water supply has been stopped fully, in order to avoid overflow.

**Note:** PPE must be worn during sampling, draining and filling of scrubber. Ensure that a respirator fitted with A2B2E2K2P3 and gloves are worn.

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- 5.6.6 Start the circulation pump. Confirm the flow rate is reading greater than 60% on the flow indicator on the circulation line. Check that the Scrubber 1 chiller is on and that the chilled glycol is circulating via Scrubber 1 heat exchanger.
- 5.6.7 Start the fan and reset the pump and fan alarms on the main alarm panel.
- 5.6.8 Remove the "Do not start" signs from Scrubber 1 and 3 operating controls and start the fan and pump on Scrubber 3.
- 5.6.9 Allow the scrubbing solution to circulate for 30 mins. Take a sample of the solution via the sample valve on the circulation line. Complete the sampling attachment (Attachment II) and submit the sample to QC as per SOP 004.021. Refer to note for wearing of PPE.
- 5.6.10 Complete the entry in the Scrubber Changing Checklist, as detailed in Attachment 3
- 5.7 Scrubber 1 Alarms:**  
Refer to note for wearing of PPE.
- 5.7.1 Scrubber 1 is fitted with flow switches so that if the fan or feed pump fails the alarm will sound on the main alarm panel. The alarm will also sound for the duration of cleaning i.e. while fan and pump are switched off.
- 5.7.2 If alarm sounds check main panel. (Refer to Attachment V).
- 5.7.3 If the light for main scrubber fan or pump is on check that fan or pump are not turned off in BPC building.
- 5.7.4 If the fan or pump light are on and the alarm does not reset then contact Maintenance. Inform the Site Co-ordinator and the other BPC personnel that the scrubber is unavailable and processes should not proceed if they must vent to either the general or specific process vents. Stop Scrubber 3 until the fault is rectified.
- 5.7.5 If scrubber light on main panel is on then check second panel, which is situated in Electrical Room. (Refer to Attachment V).
- 5.7.6 If the water level low alarm is indicated then top up with water.
- 5.7.7 If the second panel reads fan fails – fan should reset itself, if not call an electrician.
- 5.7.8 If pump 1 fails it should reset itself, if not switch to pump 2. If pump 2 fails and doesn't reset switch to pump 1. If neither pump starts call an electrician.
- 5.7.9 While the alarms can be silenced on the panel, they will not reset until the problem has been rectified.

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**Note:** PPE must be worn during sampling, draining and filling of scrubber. Ensure that a respirator fitted with A2B2E2K2P3 and gloves are worn.

5.7.10 When the problem has been rectified restart the operation of Scrubbers 1 and 3 and inform the Site Co-ordinator and other BPC personnel that the process vents are available again.

5.7.11 Fill in Scrubber 1 logbook as per attachment VI.

### **5.8 Operation of Scrubber 3:**

The purpose of Scrubber 3 is to remove solvent vapours from exhaust gas vented from reactors via the specific process vent. Its exhaust is subsequently vented to Scrubber 1.

#### **5.9 Monitoring of Scrubber 3:**

- 5.9.1 The operation of Scrubber 3 must be monitored four times every day, i.e. at 4:00, 10:00 16:00 and 22:00.
- 5.9.2 On each occasion the Checklist Log must be completed, as per Attachment 1.
- 5.9.3 Check that the Fan, Circulation Pump, and Heat exchanger are operating normally.
- 5.9.4 Inspect the scrubber for leaks. If a leak is found stop the scrubber (ref. 5.11) and contact maintenance to have it repaired immediately.
- 5.9.5 Verify that the flow rate of the scrubber solution is above 60% at the flow indicator
- 5.9.6 Check that falling liquid is visible in the sight glass of the scrubber
- 5.9.7 Manually check two LEV points within the BPC to ensure that there is suction. At least one of these points should be in the vicinity of R25-R28 or R19-R20 to ensure that there is suction in the most remote parts of the system.
- 5.9.8 Take a sample of the solution via the sample valve on the circulation line. Complete the sampling attachment (Attachment 2) and submit the sample to QC as per SOP 004.021. Refer to note for wearing of PPE.
- 5.9.9 If the scrubber composition is out of specification refer to SOP 201.014

#### **5.10 Changing the Solution in Scrubber 3**

Refer to not for wearing of PPE

- 5.10.1 The Scrubber Solution must be drained fully and recharged when the QC Result confirms the scrubber composition is out of specification, as per SOP 201.014.

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5.10.2 Every time the scrubber is recharged, an entry must be made in the Scrubber Startup Checklist (Ref Attachment III).

**Note:** PPE must be worn during sampling, draining and filling of scrubber. Ensure that a respirator fitted with A2B2E2K2P3 and gloves are worn.

5.10.3 Follow instructions in sections 5.10 to change the solution in Scrubber 3.

5.10.4 Fill in Scrubber 3 logbook attachment VII.

### 5.11 Shut down of Scrubber 3:

5.11.1 To be performed when required for maintenance or change of scrubbing solution.

5.11.2 Inform the Site Co-ordinator and other BPC operators that the scrubber is to be shut down to enable processes to be safely held, if necessary, before scrubber shut down.

5.11.3 When it is safe to do so, shut down the fan and pump on Scrubber 3 (controls located inside the BPC building, on the ground floor). Display "Do not start" signs at the Scrubber controls, signed and dated appropriately.

### 5.12 Drain Scrubber 3:

Refer to note for wearing of PPE.

5.12.1 Set up pump and pump to drums, via dip leg on fill / drain nozzle.

5.12.2 Pump material to waste drums

5.12.3 Open the small charge port and, using a hose, remove any residue from the sump walls. Pump any remaining liquid to waste drums. Use a face visor and heavy gauntlets for this operation.

5.12.4 Charge approximately 300 L of water to the sump. Start circulation pump and circulate this through the scrubber for approximately 15 minutes. Stop the circulation pump, and drain the contents of the sump to effluent

5.12.5 Dismantle the pump and hose, close charge line and charge port.

5.12.6 Remove waste drums and using the fixed line in the BPC building pump the waste solution to Tank 14.

### 5.13 Fill Scrubber 3:

Refer to note for wearing of PPE.

5.13.1 Ensure the fixed line to the drain is closed.

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5.13.2 Set up a pump and hose to the fill point. Add 400L/316kg of IMS from drums to the sump.

5.13.3 Add approximately 100L of process water

**Note:** PPE must be worn during sampling, draining and filling of scrubber. Ensure that a respirator fitted with A2B2E2K2P3 and gloves are worn.

5.13.4 Start the circulation pump. Confirm the flow rate is reading greater than 60% on the flow indicator on the circulation line. Check that the cooling water is on to the Scrubber 3 heat exchanger.

5.13.5 Start the fan and reset the pump and fan alarms on the main alarm panel.

5.13.6 Remove the "Do not start" signs from Scrubber 3 operating controls and start the fan and pump on Scrubber 3.

5.13.7 Allow the scrubbing solution to circulate for 30 mins. Take a sample of the solution via the sample valve on the circulation line. Complete the sampling attachment (Attachment 2) and submit the sample to QC as per SOP 004.021.

5.13.8 Complete the entry in the Scrubber Changing Checklist, as detailed in Attachment III.

## 6.0 DOCUMENTATION:

Attachment I Logbook of Record of checking and sampling of the scrubbing system.

Attachment II QC sampling sheet for scrubbing solutions.

Attachment III Checklist for changing of scrubbing solutions.

Attachment IV Compatible Chart.

Attachment V Alarm sounds panel

Attachment VI Scrubber 1 logbook.

Attachment VII Scrubber Operating Procedures.







<b>BPC MANUFACTURING ATTACHMENT III</b>	<b>SOP</b>	<b>Page 1 of 1</b>
<b>Title: Checklist for changing of scrubbing Solutions</b>	<b>208.200</b>	<b>Effective Date:</b> _____
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Fill out this log in conjunction with the steps 5.1.2 – 5.1.5 (Scrubber 1) and or steps 5.2.2 – 5.2.5 (Scrubber 3) of the SOP 208.200. Read the questions and tick or provide values where required.

Checks during filling and start up	Date	
	<b>Time</b>	
	Sign	
	<b>Start up and fill of Scrubber 1</b>	
	No vent operations are running	
	Ensure Scrubber Fan and pump are not running	
	Sump has been drained and cleaned as per SOP 208.200	
	Record scrubbing liquor type: caustic or sulphuric acid	
	Record the volume of caustic / sulphuric acid added to the Scrubber 1 sump	
	Record the volume of water added to the Scrubber 1 sump	
	Record the start time of re-circulation of scrubbing solution	
	Record the finish time of re-circulation of scrubbing solution	
	Record the total recirculation time:	
	Scrubber solution sampled	
	Cooling fully opened, fan restarted	
	<b>Start up and fill of Scrubber 3</b>	
	No operations are running which vent to the Specific Process Vent	
	Ensure Scrubber Fan and pump are not running	
	Sump has been drained and cleaned as per SOP 208.200	
	Record the volume of IMS added to the Scrubber 3 sump	
	Record the volume of process water added to the sump	
	Record the start time of re-circulation of scrubbing solution	
	Record the finish time of re-circulation of scrubbing solution	
	Record the total recirculation time:	
	Scrubber solution sampled	
	Cooling fully opened, fan restarted	
	<b>Inform Site Co-ordinator that the scrubbers are live</b>	

<b>BPC MANUFACTURING ATTACHMENT IV</b>	<b>SOP</b>	<b>Page 1 of 1</b>
<b>Title: Scrubber 1 Process Compatibility Chart</b>	<b>208.200</b>	<b>Effective Date:</b> _____
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### COMPATIBLE SCRUBBING

	Valproic Acid Hydrolysis	Valproic Acid HCl	Benzbromarone	Desipramine Carbamate	CR Bases	Nifedipine Crude	Nifedipine Rex.	Pin Cr
Valproic Acid Hydrolysis	Y*	N	N	N	Y	Y	N	
Valproic Acid HCl	N	Y*	N	N	N	N	Y	
Benzbromarone	N	N	Y	N	N	N	Y	
Desipramine Carbamate	N	N	N	Y*	N	N	N	
CR Bases	Y*	N	N	N	Y	Y	N	
Nifedipine Crude	Y*	N	N	N	Y	Y	N	
Nifedipine Rex	N	Y*	N	N	N	N	Y	
Xylazine	N	Y	N	N	Y			
Pindolol	Y*	N	N	N	Y	Y	N	

\*Y IS A PROVISIONAL YES, BECAUSE THE SCRUBBER MAY NOT BE ABLE TO DEAL WITH THE VOLUME OF GASES FROM TWO LARGE BATCHES.

**SULPHURIC ACID SCRUB**

Cr Bases

Valproic Acid Hydrolysis

Pindolol Crude

Valproic Acid HCl

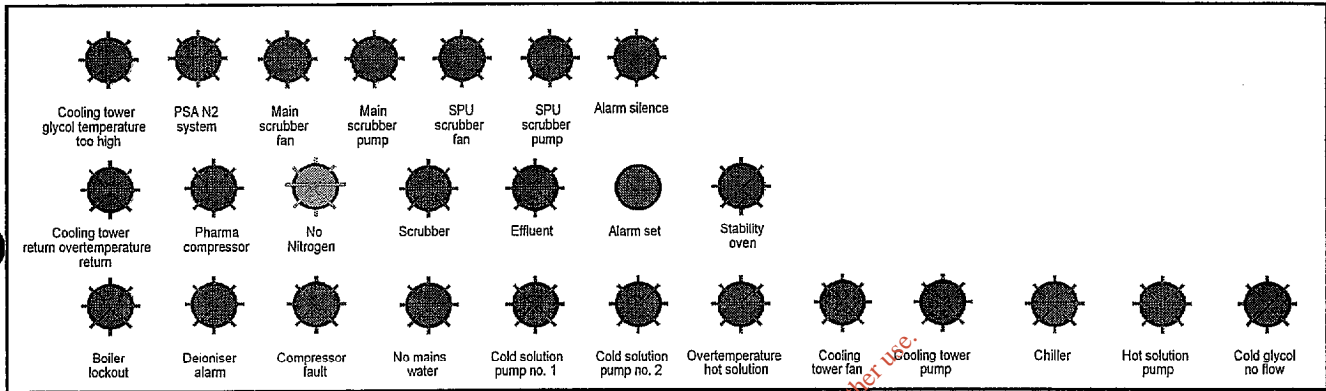
**CAUSTIC SCRUB**

Nifedipene Pure

**METHANOL/WATER/KOH**

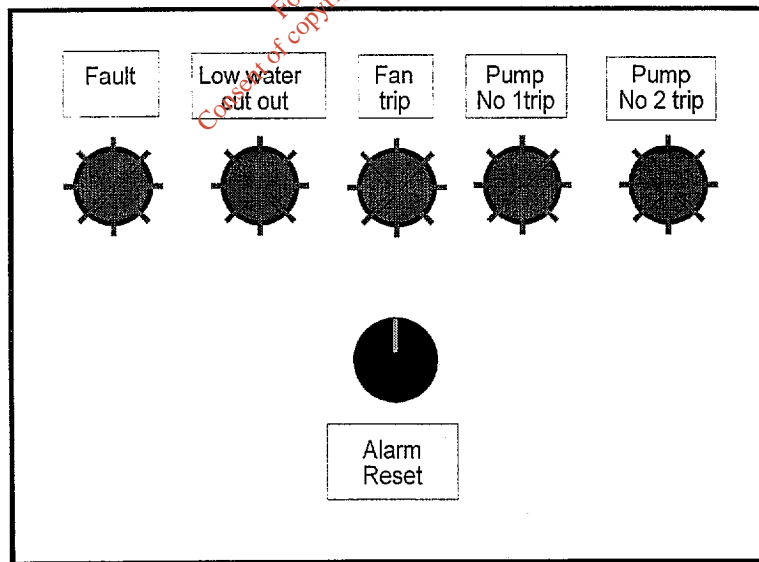
Desipramine Carbamate

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<b>Title: Scrubber Operating Procedure Alarm Sounds Panel Attachment V</b>	<b>208.200</b>	<b>Effective Date:</b> _____ <b>Revision No:</b> <u>4</u> <b>Date:</b> <u>06.05.05</u> <b>Prev Rev No:</b> <u>3</u> <b>Dated:</b> <u>24.10.01</u>



Main Production alarm panel.

Scrubber 1 alarm panel (located in electrical room).



4.0 PURP







## RECEIPT OF SOP CONFIRMATION

<b>SOP TITLE:</b> Operation of Scrubbers 1 and 3 in the BPC Building.	<b>SOP NO:</b> 208.200	<b>REV. NO:</b> 4
<p>I acknowledge receipt of the above SOP.</p> <p><i><u>For All Copies Except O.A Master Copy:</u></i></p> <p>I have destroyed (returned in the case of Master BMP's and CPs) the superseded revision of the SOP.</p>		
<b>Signed:</b>	<b>Department:</b>	<b>Date:</b>

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