9

ENVIRONMENT AGENCY

Permit with introductory note

Pollution Prevention and Control (England & Wales) Regulations 2000

Gaskill Road, Speke Vaccines

Novartis Vaccines and Diagnostics Limited
Gaskill Road
Speke
Liverpool
L24 9GR

Permit number

BS5401IK

Gaskill Road, Speke Vaccines
Permit Number BS5401IK

Introductory note

This introductory note does not form a part of the permit

The main features of the installation are as follows:

The installation comprises four technically connected locations on Evans Road (Site 1), Gaskill Road (Site 2), Speke Boulevard (Site 3) and Renaissance Way (Site 4) in Speke. Site 4 is currently under construction. The installation, Grid Reference SJ 4374 8388, is located approximately 10 km south-east of Liverpool and is surrounded by a variety of industrial units, a bus depot, a railway line, and residential properties.

The Operator manufactures influenza and yellow fever vaccines and this represents the principal listed activity falling under Section 4.5 A(1)(a) of the PPC Regulations. Production of seasonal and pandemic influenza vaccines is based on primary seeds obtained from external public health bodies. The process involves inoculating eggs with virus, incubation and harvesting of the allantoic fluid. Following a series of concentration and purification stages the material is stored prior to blending and filling into syringes / vials. Production of yellow fever vaccine requires the inoculation of eggs with an attenuated strain of the virus. After appropriate incubation the eggs are harvested and the virus is formulated and filtered prior to freeze drying in vials. Each product is manufactured to the strict standards specified in the product licences issued by the pharmaceutical regulatory authorities.

This Permit supersedes the earlier authorisation under the Environmental Protection Act 1990 (Reference Number AO 0768) for Sites 1, 2 & 3 and an earlier permit under the PPC Regulations (Reference Number KP3330LF) for Site 4.

A number of directly associated activities also take place including the production of high quality water, the operation of heating, ventilation and air conditioning systems (HVAC), refrigeration activities and the operation of combustion equipment to generate steam mainly used for sanitisation and sterilisation purposes.

The manufacturing processes result in emissions to air from release points associated with the operation of the combustion plant, HVAC systems, process vents and the storage of raw materials and waste products. In addition, periodic fumigation with formaldehyde or hydrogen peroxide of manufacturing areas also results in emissions to air. Emissions associated with the storage of egg waste at site 4 are vented via activated carbon odour abatement systems in order to minimise the risk of potentially odorous releases.

Process effluent sources from areas that may contain significant mercury or nonylphenol ethoxylate content are segregated for off-site treatment and disposal. Other process effluent sources are discharged to the sewer with effluent from site 4 receiving physical treatment (pH and temperature adjustment) prior to discharge. The process effluent discharge to sewer receives further treatment at Sandon Dock Wastewater Treatment Works prior to discharge into the River Mersey.

Given the nature of the process and the land use surrounding the site, the Agency does not consider that noise from the installation will give reasonable cause for annoyance.

The closest designated habitat to the installation is the Mersey Estuary (RAMSAR site, Special Protection Area & Site of Special Scientific Interest) at approximately 3km. An Agency assessment of the impact of emissions to air concluded that the installation is unlikely to have significant effect on the European habitats alone, or in combination with other plans and projects.

Activities at Sites 1, 2 & 3 are subject to a Climate Change Levy Agreement (CCLA) operated by the Chemical Industries Association (CIA). The Operator is committed to extending the agreement to include site 4 once it is fully operational.

The Operator is committed to developing a formal environmental management system.

Status Log of the permit		
Detail	**Date**	**Response Date**
Application BS5401IK	Duly made 29/03/06	
Response to request for further information.	Request dated 16/11/06	11/12/06
Permit issued	21/12/06	

Superseded or Partially Superseded Licences/Authorisations/Consents relating to this installation			
Holder	**Reference Number**	**Date of Issue**	**Fully or Partially Superseded**
Evans Medical Ltd.	AO0768 (as varied)	21/12/94	Fully superseded
Chiron Vaccines Limited	KP3330LF	06/04/06	Fully superseded

End of Introductory Note

Permit

Permit number
BS5401IK

The Environment Agency (the Agency) in exercise of its powers under Regulation 10 of the Pollution Prevention and Control (England and Wales) Regulations 2000 (SI 2000 No 1973) hereby authorises
Novartis Vaccines and Diagnostics Limited ("the operator"),

whose registered office is
Florey House
Robert Robinson Avenue
The Oxford Science Park
Oxford
Oxfordshire
OX4 4GA

company registration number **3070000**

to operate an installation at
Gaskill Road
Speke
Liverpool
L24 9GR

to the extent authorised by and subject to the conditions of this permit.

Signed	Date
	21/12/2006

M J Peacock

Authorised to sign on behalf of the Agency

Conditions

1 Management

1.1 General management

1.1.1 The activities shall be managed and operated:

(a) in accordance with a management system, which identifies and minimises risks of pollution, including those arising from operations, maintenance, accidents, incidents and non-conformances and those drawn to the attention of the operator as a result of complaints; and

(b) by sufficient persons who are competent in respect of the responsibilities to be undertaken by them in connection with the operation of the activities.

1.1.2 Records demonstrating compliance with condition 1.1.1 shall be maintained.

1.1.3 Any person having duties that are or may be affected by the matters set out in this permit shall have convenient access to a copy of it kept at or near the place where those duties are carried out.

1.2 Accidents that may cause pollution

1.2.1 The operator shall:

(a) maintain and implement an accident management plan;

(b) review and record at least every 4 years or as soon as practicable after an accident, (whichever is the earlier) whether changes to the plan should be made;

(c) make any appropriate changes to the plan identified by a review.

1.3 Energy efficiency

1.3.1 The operator shall:

(a) take appropriate measures to ensure that energy is used efficiently in the activities;

(b) review and record at least every 4 years whether there are suitable opportunities to improve the energy efficiency of the activities; and

(c) take any further appropriate measures by a review.

1.4 Efficient use of raw materials

1.4.1 The operator shall:

(a) take appropriate measures to ensure that raw materials and water are used efficiently in the activities;

(b) maintain records of raw materials and water used in the activities;

(c) review and record at least every 4 years whether there are suitable alternative materials that could reduce environmental impact or opportunities to improve the efficiency of raw material and water use; and

(d) take any appropriate further measures identified by a review.

1.5 Avoidance, recovery and disposal of wastes produced by the activities

1.5.1. The operator shall:

(a) take appropriate measures to ensure that waste produced by the activities is avoided or reduced, or where waste is produced it is recovered wherever practicable or otherwise disposed of in a manner which minimises its impact on the environment;

(b) review and record at least every 4 years whether changes to those measures should be made; and

(c) take any further appropriate measures identified by a review.

1.6 Site security

1.6.1. Site security measures shall prevent unauthorised access to the site, as far as practicable.

2. Operations

2.1 Permitted activities

2.1.1 The operator is authorised to carry out the activities specified in schedule 1 table S1.1 (the "activities").

2.2 The site

2.2.1 The activities shall not extend beyond the site, being the land shown edged in red on the site plan at schedule 2 to this permit.

2.3 Operating techniques

2.3.1 The activities shall, subject to the conditions of this permit, be operated using the techniques and in the manner described in the documentation specified in schedule 1 table S1.2, unless otherwise agreed in writing by the Agency.

2.3.2 No raw materials or fuels listed in schedule 3 table S3.1 shall be used unless they comply with the specifications set out in that table.

2.4 Off-site conditions

There are no off-site conditions under this section.

2.5 Improvement programme

2.5.1 The operator shall complete the improvements specified in schedule 1 table S1.3 by the date specified in that table unless otherwise agreed in writing by the Agency.

2.5.2 Except in the case of an improvement which consists only of a submission to the Agency, the operator shall notify the Agency within 14 days of completion of each improvement.

2.6 Pre-operational conditions

2.6.1 The activities shall not be brought into operation until the measures specified in schedule 1 table S1.4 have been completed.

2.7 Closure and decommissioning

2.7.1 The operator shall maintain and operate the activities so as to prevent or where that is not practicable, to minimise, any pollution risk on closure and decommissioning.

2.7.2 The operator shall maintain a site closure plan which demonstrates how the activities can be decommissioned to avoid any pollution risk and return the site to a satisfactory state.

2.7.3 The operator shall carry out and record a review of the site closure plan at least every 4 years.

2.7.4 The site closure plan (or relevant part thereof) shall be implemented on final cessation or decommissioning of the activities or part thereof.

2.8 Site protection and monitoring programme

2.8.1 The operator shall, within 4 months of the issue of this permit, submit a site protection and monitoring programme.

2.8.2 The operator shall implement and maintain the site protection and monitoring programme and shall carry out and record a review of it at least every 4 years.

3. Emissions and monitoring

3.1 Emissions to water, air or land

3.1.1 There shall be no point source emissions to water, air or land except from the sources and emission points listed in schedule 4 tables S4.1(a-d), S4.2 and S4.3(a-d).

3.1.2 The limits given in schedule 4 shall not be exceeded.

3.1.3 No condition applies.

3.1.4 No condition applies.

3.2 Transfers off-site

3.2.1 Records of all the wastes sent off site from the activities, for either disposal or recovery, shall be maintained.

3.3 Fugitive emissions of substances

3.3.1 Fugitive emissions of substances (excluding odour, noise and vibration) shall not cause pollution. The operator shall not be taken to have breached this condition if appropriate measures have been taken to prevent or where that is not practicable, to minimise, those emissions.

3.3.2 No condition applies.

3.3.3 No condition applies.

3.3.4 All liquids, whose emission to water or land could cause pollution, shall be provided with secondary containment, unless the operator has used other appropriate measures to prevent or where that is not practicable, to minimise, leakage and spillage from the primary container.

3.4 Odour

3.4.1 Emissions from the activities shall be free from odour at levels likely to cause annoyance outside the site, as perceived by an authorised officer of the Agency, unless the operator has used appropriate measures to prevent or where that is not practicable to minimise the odour.

3.5 Noise and vibration

3.5.1 Emissions from the activities shall be free from noise and vibration at levels likely to cause annoyance outside the site, as perceived by an authorised officer of the Agency, unless the operator has used appropriate measures to prevent or where that is not practicable to minimise the noise and vibration.

3.6 Monitoring

3.6.1 The operator shall, unless otherwise agreed in writing by the Agency, undertake the monitoring specified in the following tables in schedule 4 to this permit:

(a) point source emissions specified in tables S4.1(a-d), S4.2 and S4.3(a-d).

3.6.2 The operator shall maintain records of all monitoring required by this permit including records of the taking and analysis of samples, instrument measurements (periodic and continual), calibrations, examinations, tests and surveys and any assessment or evaluation made on the basis of such data.

3,6.3 Monitoring equipment, techniques, personnel and organisations employed for the emissions monitoring programme specified in condition 3.6.1 shall have either MCERTS certification or MCERTS accreditation (as appropriate) unless otherwise agreed in writing by the Agency.

3.6.4 Permanent means of access shall be provided to enable sampling/monitoring to be carried out in relation to the emission points specified in schedule 4 tables S4.1(a-d), S4.2 and S4.3(a-d) unless otherwise specified in that schedule.

4. Information

4.1 Records

4.1.1 All records required to be made by this permit shall:

(a) be legible;

(b) be made as soon as reasonably practicable;

(c) if amended, be amended in such a way that the original and any subsequent amendments remain legible, or are capable of retrieval; and

(d) be retained, unless otherwise agreed in writing by the Agency, for at least 6 years from the date when the records were made, or in the case of the following records until permit surrender:

(i) the site protection and monitoring programme.

4.1.2 Any records required to be made by this permit shall be supplied to the Agency within 14 days where the records have been requested in writing by the Agency.

4.1.3 All records required to be held by this permit shall be held on the site and shall be available for inspection by the Agency at any reasonable time.

4.2 Reporting

4.2.1 A report or reports on the performance of the activities over the previous year shall be submitted to the Agency by 31 January (or other date agreed in writing by the Agency) each year. The report(s) shall include as a minimum:

(a) a review of the results of the monitoring and assessment carried out in accordance with this permit against the relevant assumptions, parameters and results in the assessment of the impact of the emissions submitted with the application;

(b) where the operator's management system encompasses annual improvement targets, a summary report of the previous year's progress against such targets;

(c) the annual production /treatment data set out in schedule 5 table S5.2;

(d) the performance parameters set out in schedule 5 table S5.3 using the forms specified in table S5.4 of that schedule; and

(e) details of any contamination or decontamination of the site which has occurred.

4.2.2 Within 28 days of the end of the reporting period the operator shall, unless otherwise agreed in writing by the Agency, submit reports of the monitoring and assessment carried out in accordance with the conditions of this permit, as follows:

(a) in respect of the parameters and emission points specified in schedule 5 table S5.1;

(b) for the reporting periods specified in schedule 5 table S5.1 and using the forms specified in schedule 5 table S5.4 ; and

(c) giving the information from such results and assessments as may be required by the forms specified in those tables.

4.2.3 No condition applies.

4.2.4 The operator shall, unless notice under this condition has been served within the preceding 4 years, submit to the Agency, within 6 months of receipt of a written notice, a report assessing whether there are other appropriate measures that could be taken to prevent, or where that is not practicable, to minimise pollution.

4.2.5 All reports and notifications required by the permit shall be sent to the Agency using the contact details supplied in writing by the Agency

4.2.6 The results of reviews and any changes made to the site protection and monitoring programme shall be reported to the Agency, within 1 month of the review or change.

4.3 Notifications

4.3.1 The Agency shall be notified without delay following the detection of:

(a) any malfunction, breakdown or failure of equipment or techniques, accident, or fugitive emission which has caused, is causing or may cause significant pollution;

(b) the breach of a limit specified in the permit;

(c) any significant adverse environmental effects.

4.3.2 Any information provided under condition 4.3.1 shall be confirmed by sending the information listed in schedule 6 to this permit within the time period specified in that schedule.

4.3.3 Prior written notification shall be given to the Agency of the following events and in the specified timescales:

(a) as soon as practicable prior to the permanent cessation of any of the activities;

(b) cessation of operation of part or all of the activities for a period likely to exceed 1 year; and

(c) resumption of the operation of part or all of the activities after a cessation notified under (b) above.

4.3.4 The Agency shall be given at least 14 days notice before implementation of any part of the site closure plan.

4.3.5 Where the Agency has requested in writing that it shall be notified when the operator is to undertake monitoring and/or spot sampling, the operator shall inform the Agency when the relevant monitoring is to take place. The operator shall provide this information to the Agency at least 14 days before the date the monitoring is to be undertaken.

4.3.6 No condition applies.

4.3.7 No condition applies.

4.3.8 No condition applies.

4.3.9 The Agency shall be notified within 14 days of the occurrence of the following matters, except where such disclosure is prohibited by Stock Exchange rules:

(a) any change in the operator's trading name, registered name or registered office address;

(b) any change to particulars of the operator's ultimate holding company (including details of an ultimate holding company where an operator has become a subsidiary); and

(c) any steps taken with a view to the operator going into administration, entering into a company voluntary arrangement or being wound up.

Climate Change Agreement

4.3.10 Where the operator has entered into a climate change agreement with the Government, the Agency shall be notified within one month of:

(a) a decision by the Secretary of State not to re-certify the agreement;

(b) a decision by either the operator or the Secretary of State to terminate the agreement; and

(c) any subsequent decision by the Secretary of State to re-certify such an agreement.

4.4 Interpretation

4.4.1 In this permit the expressions listed in schedule 7 shall have the meaning given in that schedule.

Schedule 1 - Operations

Table S1.1 activities		
Activity listed in Schedule 1 of the PPC Regulations	**Description of specified activity**	**Limits of specified activity**
Section 4.5 Part A(1)(a) – Producing pharmaceutical products using a chemical or biological process.	The manufacture of seasonal/pandemic influenza and yellow fever vaccines.	From the receipt of raw materials to the manufacture, storage and despatch of finished product (including the cleaning and fumigation of process plant, and the storage and handling of waste/wastewater arising from the process).
Section 5.3 Part A(1)(c)(ii) – Disposal of non-hazardous waste in a facility with a capacity of more than 50 tonnes per day by physico-chemical treatment, not being treatment specified in any paragraph other than paragraph D9 in Annex IIA to Council Directive 75/442/EEC, which results in final compounds or mixtures which are discarded by means of any of the operations numbered D1 to D12 in that Annex.	Treatment of process effluent from Site 4.	Physical treatment (pH and temperature control) prior to discharge into the public sewer.
Directly Associated Activity		
Steam Supply	Operation of the following combustion plant for heating, sanitisation and sterilisation purposes: • Site 1 - 1.4MW & 2.1MW gas-fired boilers; • Site 2 - two 5.0MW fuel oil-fired boilers; • Site 3 – 1.4MW gas-fired boiler; and • Site 4 - two 5.4MW gas-fired boilers.	From the receipt, handling and combustion of fuel to steam generation (including the storage of heavy fuel oil).
Heating Ventilation & Cooling	Maintenance of workplace environment and air quality.	Operation of Heating Ventilation & Cooling (HVAC) systems
Refrigeration	The operation of Blast Chillers.	The cooling of eggs following incubation.
Water Purification.	The production of Purified Water (PW) and Water for Injection (WFI).	Water purification using softeners, reverse osmosis, electro-deionisation and distillation techniques.

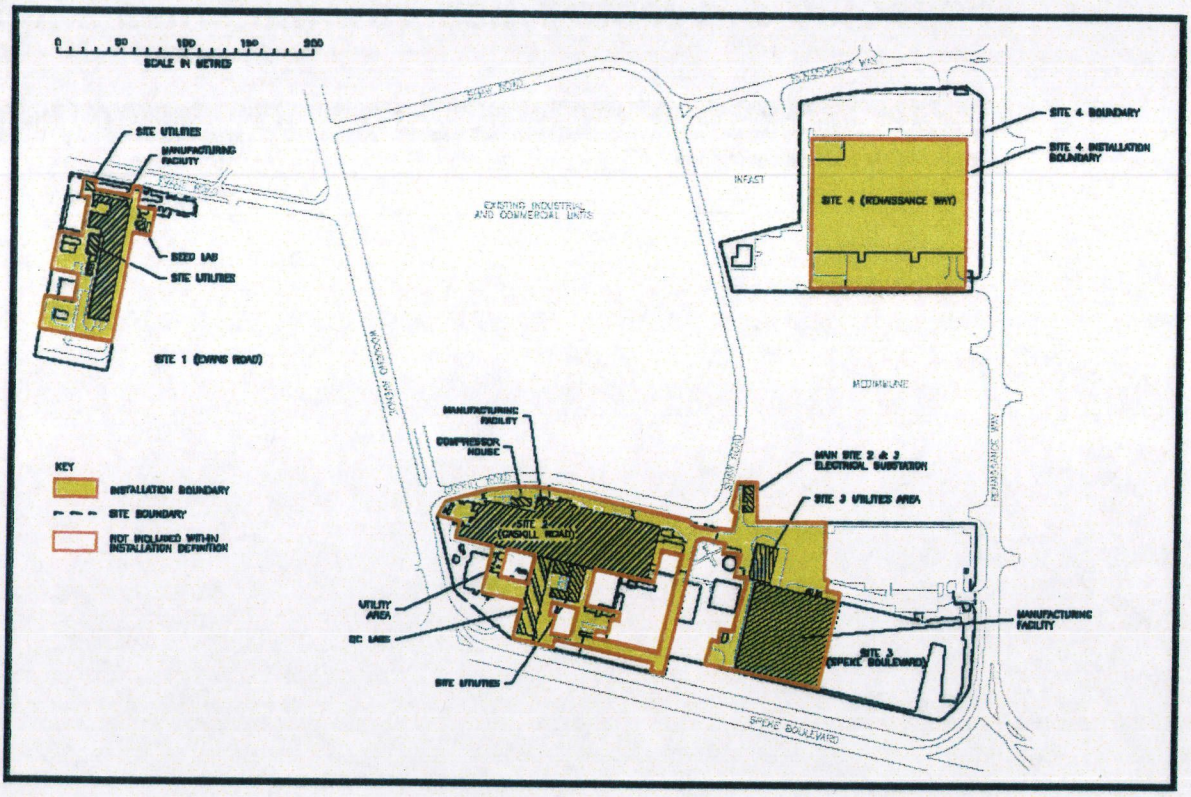
Table S1.2 Operating techniques		
Description	**Parts**	**Date Received**
Application	The response to section 2.1 and 2.2 in the Application.	29/03/06
Response to request for additional information.	a) Revised drainage plan (Figure 6) and references to effluent discharge locations (Table 1); b) Details of boiler specification and operation (Table 3); c) Revised installation layout plan (Figure 3); and d) Revised H1 assessment.	11/12/06

Table S1.3 Improvement programme requirements		
Reference	**Requirement**	**Date**
IP1	The Operator shall carry out a noise assessment for Sites 3 and 4 of the Permitted Installation in accordance with the requirements of BS4142: 1997 – Method for Rating Industrial Noise affecting mixed Residential and Industrial Areas. The assessment shall consider the background noise climate and the impact of operations during daytime and night-time periods. A report summarising the outcome of the assessment, including a timetable for the implementation of any improvements identified, shall be submitted to the Agency.	Within 6 months of the commencement, at Site 4, of activities covered by the description in Section 4.5 A(1)(a) in Schedule 1 of the PPC Regulations (unless otherwise agreed in writing with the Agency).
IP2	The Operator shall, having regard to Agency Guidance Note IPPC H4 Odour Part 2 – Assessment and Control, verify the effectiveness of the measures in place at Site 4 to minimise potentially odorous emissions from the Permitted Installation. A written summary of the assessment shall be submitted to the Agency, which shall include, but not be limited to, the following: • the handling and storage of egg waste and bulk liquid waste; • the maximum storage period for egg waste and bulk liquid waste; • the optimisation and monitoring of the activated carbon odour abatement systems; • interpretation of the results of the monitoring for hydrogen sulphide from emission points A24, A25, A26 & A27, detailed in improvement condition 3; and • a timetable for the implementation of any improvements identified.	Within 6 months of the commencement, at Site 4, of activities covered by the description in Section 4.5 A(1)(a) in Schedule 1 of the PPC Regulations (unless otherwise agreed in writing with the Agency).
IP3	The Operator shall, having regard to Agency Guidance Note M2: Monitoring of Stack Emissions to Air, undertake monitoring to verify the estimated emissions to air, of the following substances: • β-propiolactone from emission points A20, A29 & A30; • Mercury and its compounds from emission point A20; • Hydrogen sulphide from emission points A24, A25, A26 & A27; and • Oxides of nitrogen from emission point A23. The emissions of β-propiolactone and mercury and its compounds shall be monitored during periods corresponding with maximum β-propiolactone and Thiomersal consumption. A report summarising the monitoring, including details of the methodology used and interpretation of the results, shall be submitted to the Agency.	Within 6 months of the commencement, at Site 4, of activities covered by the description in Section 4.5 A(1)(a) in Schedule 1 of the PPC Regulations (unless otherwise agreed in writing with the Agency).
IP4	The Operator shall, having regard to Agency Guidance Note H1, undertake an exercise to assess the combined impact of the emissions to air from combustion plant at the installation. A report summarising the exercise shall be submitted to the Agency, which shall include, but not be limited to, the following: • details of, and justification for, the methodology used; • assessment of the combined impact of emissions from Sites 1 to 4; • assessment of the combined impact of emissions from Sites 3 and 4 (assuming the transfer of activities from Sites 1 & 2); and • a timetable for the implementation of any improvements identified.	30/09/07
IP5	A report shall be submitted to the Agency detailing the emissions of nonylphenol ethoxylates to sewer from the Installation. The report shall include the following: • characterisation of the emissions; • an assessment of their impact; and • a timetable for the implementation of any measures identified to minimise their release.	30/09/07
IP6	A written procedure shall be submitted to the Agency detailing the measures to be used so that monitoring equipment, personnel and organisations employed for the emissions monitoring programme shall have either MCERTS certification or accreditation in accordance with condition 3.6.3 where this is appropriate. The notification requirements of condition 2.5.2 shall be deemed to have been complied with on submission of the procedure.	31/12/07

Table S1.3 Improvement programme requirements		
Reference	**Requirement**	**Date**
IP7	A fugitive emission management plan shall be submitted to the Agency, detailing the measures to be used to control fugitives emissions to surface water, sewer and groundwater which shall be in accordance with Section 2.2.5 of Agency Guidance Note IPPC S4.02. The plan shall be implemented by the operator from the date of approval in writing by the Agency	31/12/07
IP8	The Operator shall, having regard to Section 2.4 of Agency Guidance Note IPPC S4.02, carry out a waste minimisation audit and water use audit of the Installation. A report summarising the audits, including details of the methodology used and a timetable for the implementation of any improvements identified, shall be submitted to the Agency.	31/12/08 (unless otherwise agreed in writing with the Agency).
IP9	The Operator shall develop and implement a formal Environmental Management System, having regard to Section 2.3 of Agency Guidance Note IPPC S4.02.	31/12/07

Table S1.4 Pre-operational measures	
Reference	**Pre-operational measures**
1	The fitting of oil droplet abatement systems on the centrifuge exhausts in zone 2 of Site 4.
2	The fitting of a recirculating liquid ring vacuum pump or dry vacuum pump (or an alternative vacuum system agreed with the Agency) to be used for harvesting activities in zone 1 of Site 4.
3	Inclusion of any additional noise attenuation measures for Site 4, required to meet BAT, identified during the detailed design stage.

Schedule 2 - Site plan



Schedule 3 - Waste types, raw materials and fuels

Table S3.1 Raw materials and fuels

Raw materials and fuel description	Specification
Heavy Fuel Oil	less than 1% Sulphur (w/w)

Schedule 4 – Emissions and monitoring

Table S4.1a (Site 1) Point source emissions to air – emission limits and monitoring requirements						
Emission point ref. & location (as detailed on Figure 5, received 29/03/06)	**Parameter**	**Source**	**Limit (including unit)**	**Reference period**	**Monitoring frequency**	**Monitoring standard or method[1]**
A1, A12, A13	No parameters set	Inoculation, Incubation & Harvest suites	No limit set	-	-	-
A2	No parameters set	Intermediate Bulk Fluid following inactivation with β-propiolactone.	No limit set	-	-	-
A3, A4	Oxides of Nitrogen (expressed as NO_2) (mg/m³)	Boiler 1, Boiler 2	No limit set	Hourly average	As requested by the Agency	ISO 10849

Note 1: Permanent sampling access not required.

Table S4.1b (Site 2) Point source emissions to air – emission limits and monitoring requirements						
Emission point ref. & location (as detailed on Figure 5, received 29/03/06)	**Parameter**	**Source**	**Limit (including unit)**	**Reference period**	**Monitoring frequency**	**Monitoring standard or method[1]**
A5, A14, A15, A16, A17, A18	No parameters set	Centrifugation suite, Formulation suite, Media suite, Zone YA Yellow Fever, Technical Development Lab & Centrifugation suite (extension).	No limit set	-	-	-
A6	No parameters set	Centrifugation suite zone YB	No limit set	-	-	-
A7, A8	Oxides of Nitrogen (expressed as NO_2) (mg/m³)	Boiler 1, Boiler 2	No limit set	Hourly average	As requested by the Agency	ISO 10849
A7, A8	Sulphur Dioxide (expressed as SO_2) (mg/m³)	Boiler 1, Boiler 2	No limit set	Hourly average	As requested by the Agency	BS EN 14791

Note 1: Permanent sampling access not required.

Table S4.1c (Site 3) Point source emissions to air – emission limits and monitoring requirements						
Emission point ref. & location (as detailed on Figure 5, received 29/03/06)	**Parameter**	**Source**	**Limit (including unit)**	**Reference period**	**Monitoring frequency**	**Monitoring standard or method[1]**
A9	No parameters set	VPL suite	No limit set	-	-	-
A10	No parameters set	RSL suite	No limit set	-	-	-
A11	Oxides of Nitrogen (expressed as NO_2) (mg/m^3)	Boiler 1	No limit set	Hourly average	As requested by the Agency	ISO 10849

Note 1: Permanent sampling access not required.

Table S4.1d (Site 4) Point source emissions to air – emission limits and monitoring requirements						
Emission point ref. & location	**Parameter**	**Source**	**Limit (including unit)**	**Reference period**	**Monitoring frequency**	**Monitoring standard or method[1]**
A19, A28 (Points A1 & A10 on Figure 3, received 03/11/05)	No parameters set	zone 1, zone 2 (including vacuum system exhaust)	No limit set	-	-	-
A20, A30 (Points A2 & A12 on Figure 3, received 03/11/05)	No parameters set	β-propiolactone vent headers: zone 1, 2.	No limit set	-	-	-
A21 (Point A3 on Figure 3, received 03/11/05)	No parameters set	Brine tank	No limit set	-	-	-
A22 (Point A4 on Figure 3, received 03/11/05)	No parameters set	Hotwell stack	No limit set	-	-	-
A23 (Point A5 on Figure 3, received 03/11/05)	Oxides of Nitrogen (expressed as NO_2)	Boiler 1, 2	150 mg/m^3	Hourly average	As requested by the Agency	ISO 10849
A24, A25 (Points A6 & A7 on Figure 3, received 03/11/05)	No parameters set	Bulk waste tanks (TK417004 & TK417005)	No limit set	-	-	-
A26, A27 (Points A8 & A9 on Figure 3, received 03/11/05)	No parameters set	Egg waste tanks (TK397002 & TK397003)	No limit set	-	-	-
A29, A31, A32, A34, A35 (Points A11, A13, A14, A15 & A16 on Figure 3, received 03/11/05)	No parameters set	Zone 1, 3[2], 4, 5, 6[2] Heating Ventilation and Cooling (HVAC) systems.	No limit set	-	-	-

Note 1: Permanent sampling access not required.
Note 2: Written agreement from the Agency is required prior to use of this emission point.

Table S4.2 Point Source emissions to water (other than sewer) – emission limits and monitoring requirements						
Emission point ref. & location	**Parameter**	**Source**	**Limit (incl. unit)**	**Reference period**	**Monitoring frequency**	**Monitoring standard or method**
-						

Table S4.3a (Site 1) Point source emissions to sewer, effluent treatment plant or other transfers off-site– emission limits and monitoring requirements						
Emission point ref. & location	**Parameter**	**Source**	**Limit (incl. Unit)**	**Reference period**	**Monitoring frequency**	**Monitoring standard or method**
S1 (Point W5 on Figure 6, received 11/12/06) to Evans Road sewer.	Total Mercury	Process Effluent from the Harvest suite.	10µg/l	Weekly flow proportional composite sample[1].	Weekly	Cold vapour atomic absorption technique.
S1 (Point W5 on Figure 6, received 11/12/06) to Evans Road sewer.	Total Mercury (µg/l)	Process Effluent from the Harvest suite.	No limit set	Spot sample	Monthly	UKAS accredited
W1–W4 (Points W1-W4 on Figure 6, received 11/12/06) to sewer.	No parameters set	Surface water	No limit set	-	-	Permanent sampling access not required

Note 1: A daily composite sample shall be used until installation, no later than 30/04/07, of a weekly flow proportional sampling device.

Table S4.3b (Site 2) Point source emissions to sewer, effluent treatment plant or other transfers off-site– emission limits and monitoring requirements						
Emission point ref. & location	**Parameter**	**Source**	**Limit (incl. Unit)**	**Reference period**	**Monitoring frequency**	**Monitoring standard or method**
S2 (Point W6 on Figure 6, received 11/12/06) to Gaskill Road sewer.	Total Mercury	Process Effluent & Surface Water run-off.	10µg/l	Weekly flow proportional composite sample[1].	Weekly	Cold vapour atomic absorption technique.
S2 (Point W6 on Figure 6, received 11/12/06) to Gaskill Road sewer.	Total Mercury (µg/l)	Process Effluent & Surface Water run-off.	No limit set	Spot sample	Monthly	UKAS accredited
S3 (Point W7 on Figure 6, received 11/12/06) to Speke Boulevard sewer.	Total Mercury	Process Effluent & Surface Water run-off.	10µg/l	Weekly flow proportional composite sample[1].	Weekly	Cold vapour atomic absorption technique.
S3 (Point W7 on Figure 6, received 11/12/06) to Speke Boulevard sewer.	Total Mercury (µg/l)	Process Effluent & Surface Water run-off.	No limit set	Spot sample	Monthly	UKAS accredited
S3 (Point W7 on Figure 6, received 11/12/06) to Speke Boulevard sewer.	Nonylphenol ethoxylate (µg/l)	Process Effluent & Surface Water run-off.	No limit set	Weekly flow proportional composite sample[1].	Monthly	UKAS accredited
S4 (Point W8 on Figure 6, received 11/12/06) to Speke Boulevard sewer.	Total Mercury	Process Effluent & Surface Water run-off.	10µg/l	Weekly flow proportional composite sample[1].	Weekly	Cold vapour atomic absorption technique.
S4 (Point W8 on Figure 6, received 11/12/06) to Speke Boulevard sewer.	Total Mercury (µg/l)	Process Effluent & Surface Water run-off.	No limit set	Spot sample	Monthly	UKAS accredited
S4 (Point W8 on Figure 6, received 11/12/06) to Speke Boulevard sewer.	Nonylphenol ethoxylate (µg/l)	Process Effluent & Surface Water run-off.	No limit set	Weekly flow proportional composite sample[1].	Monthly	UKAS accredited

Note 1: A daily composite sample shall be used until installation, no later than 30/04/07, of a weekly flow proportional sampling device.

Table S4.3c (Site 3) Point source emissions to sewer, effluent treatment plant or other transfers off-site– emission limits and monitoring requirements						
Emission point ref. & location	**Parameter**	**Source**	**Limit (incl. Unit)**	**Reference period**	**Monitoring frequency**	**Monitoring standard or method**
S5 (Point W9 on Figure 6, received 11/12/06) to Speke Boulevard sewer	Total Mercury	Process Effluent via bulk storage tanks	10µg/l	Weekly flow proportional composite sample[1].	Weekly	Cold vapour atomic absorption technique.
S5 (Point W9 on Figure 6, received 11/12/06) to Speke Boulevard sewer	Total Mercury (µg/l)	Process Effluent via bulk storage tanks	No limit set	Spot sample	Monthly	UKAS accredited
S5 (Point W9 on Figure 6, received 11/12/06) to Speke Boulevard sewer	Nonylphenol ethoxylate (µg/l)	Process Effluent via bulk storage tanks	No limit set	Weekly flow proportional composite sample[1].	Monthly	UKAS accredited
W5, W6 (Points S1 & S2 on Figure 6, received 11/12/06) to Speke Boulevard sewer	No parameters set	Surface water	No limit set	-	-	Permanent sampling access not required

Note 1: A daily composite sample shall be used until installation, no later than 30/04/07, of a weekly flow proportional sampling device.

Table S4.3d (Site 4) Point source emissions to sewer, effluent treatment plant or other transfers off-site– emission limits and monitoring requirements						
Emission point ref. & location	**Parameter**	**Source**	**Limit (incl. Unit)**	**Reference period**	**Monitoring frequency[3]**	**Monitoring standard or method**
S6 (Point S1 on Figure 4, received 03/11/05) to Shaw Road sewer	No parameters set	Process Effluent[1] from S7 & Surface Water run-off[2].	No limit set	-	-	-
S7 (Point S2 on Figure 4, received 03/11/05)	Total Mercury	The discharge of process effluent[1] from sump 2.	10µg/l	Weekly flow proportional composite sample.	Weekly	Cold vapour atomic absorption technique.
S7 (Point S2 on Figure 4, received 03/11/05)	Total Mercury (µg/l)	The discharge of process effluent[1] from sump 2.	No limit set		Monthly	UKAS accredited
S7 (Point S2 on Figure 4, received 03/11/05)	Nonylphenol ethoxylate (µg/l)	The discharge of process effluent[1] from sump 2.	No limit set	Weekly flow proportional composite sample.	Monthly	UKAS accredited

Note 1: Excluding segregated sources of effluent potentially contaminated with mercury and nonylphenol ethoxylate and process effluent from zones 4 & 5.
Note 2: Discharge via on oil interceptor.
Note 3: Monitoring shall apply following commencement of activities detailed in Section 4.5 A(1)(a) in Schedule 1 of the PPC Regulations.

Schedule 5 - Reporting

Parameters, for which reports shall be made, in accordance with conditions of this permit, are listed below.

Table S5.1 Reporting of monitoring data

Parameter	Emission or monitoring point/reference	Reporting period	Period begins
Emissions to air Parameters as required by condition 3.6.1.	A3, A4, A7, A8, A11 & A23	Every 12 months	01/01/07
Emissions to sewer Parameters as required by condition 3.6.1	S1, S2, S3, S4, S5 & S7.	Monthly	01/01/07

Table S5.2: Annual production/treatment

Parameter	Units
-	

Table S5.3 Performance parameters

Parameter	Frequency of assessment	Units
Water usage	Annually	m^3
Energy usage	Annually	MWh
Emissions of Formaldehyde	Annually	kg
Emissions of Oxides of Nitrogen (expressed as NO_2)[1]	Annually	kg
Emissions of Sulphur Dioxide (expressed as SO_2)[1]	Annually	kg
Nonylphenol ethoxylate content of the discharges to sewer from the installation.	Annually	kg
Mercury content of contaminated liquid waste leaving installation (excluding discharge to sewer).	Annually	kg
Mercury content of the discharges to sewer from the installation.	Annually	g

Note 1: Emissions of sulphur dioxide and oxides of nitrogen shall be calculated from the annual consumption of natural gas and fuel oil in the combustion plant and individual emission factors agreed with the Agency.

Table S5.4 Reporting forms

Media/parameter	Reporting format	Date of form
Annual Trends Report	Form T1 or other form as agreed in writing by the Agency	01/12/06
Emissions to Air and Sewer	Form S1 or other form as agreed in writing by the Agency	01/12/06

Schedule 6 - Notification

These pages outline the information that the operator must provide.

Units of measurement used in information supplied under Part A and B requirements shall be appropriate to the circumstances of the emission. Where appropriate, a comparison should be made of actual emissions and authorised emission limits.

If any information is considered commercially confidential, it should be separated from non-confidential information, supplied on a separate sheet and accompanied by an application for commercial confidentiality under the provisions of the PPC Regulations.

Part A

Permit Number	
Name of operator	
Location of Installation	
Time and date of the detection	

(a) Notification requirements for any malfunction, breakdown or failure of equipment or techniques, accident, or fugitive emission which has caused, is causing or may cause significant pollution	
To be notified within 24 hours of detection	
Date and time of the event	
Reference or description of the location of the event	
Description of where any release into the environment took place	
Substances(s) potentially released	
Best estimate of the quantity or rate of release of substances	
Measures taken, or intended to be taken, to stop any emission	
Description of the failure or accident.	

(b) Notification requirements for the breach of a limit	
To be notified within 24 hours of detection unless otherwise specified below	
Emission point reference/ source	
Parameter(s)	
Limit	
Measured value and uncertainty	
Date and time of monitoring	
Measures taken, or intended to be taken, to stop the emission	

Time periods for notification following detection of a breach of a limit	
Parameter	**Notification period**

(c) Notification requirements for the detection of any significant adverse environmental effect	
To be notified within 24 hours of detection	
Description of where the effect on the environment was detected	
Substances(s) detected	
Concentrations of substances detected	
Date of monitoring/sampling	

Part B - to be submitted as soon as practicable

Any more accurate information on the matters for notification under Part A.	
Measures taken, or intended to be taken, to prevent a recurrence of the incident	
Measures taken, or intended to be taken, to rectify, limit or prevent any pollution of the environment which has been or may be caused by the emission	
The dates of any unauthorised emissions from the installation in the preceding 24 months.	

Name*	
Post	
Signature	
Date	

* authorised to sign on behalf of Novartis Vaccines and Diagnostics Limited

Schedule 7 - Interpretation

"*accident*" means an accident that may result in pollution.
"*annually*" means once every year.

"*application*" means the application for this permit, together with any additional information supplied by the operator as part of the application and any response to a notice served under Schedule 4 to the PPC Regulations.

"authorised officer" means any person authorised by the Agency under section 108(1) of The Environment Act 1995 to exercise, in accordance with the terms of any such authorisation, any power specified in section 108(4) of that Act.

"BAT" means best available techniques means the most effective and advanced stage of development of activities and their methods of operation which indicates the practical suitability of particular techniques to prevent and where that is not practicable to reduce emissions and the impact on the environment as a whole. For these purposes: "available techniques" means "those techniques which have been developed on a scale which allows implementation in the relevant industrial sector, under economically and technically viable conditions, taking into consideration the cost and advantages, whether or not the techniques are used or produced inside the United Kingdom, as long as they are reasonably accessible to the operator"; "best" means "in relation to techniques, the most effective in achieving a high general level of protection of the environment as a whole" and "techniques" "includes both the technology used and the way in which the installation is designed, built, maintained, operated and decommissioned." . In addition, Schedule 2 of the PPC Regulations has effect in relation to the determination of BAT.

"emissions to land", includes emissions to groundwater.

"fugitive emission" means an emission to air, water or land from the activities which is not controlled by an emission limit.

"groundwater" means all water, which is below the surface of the ground in the saturation zone and in direct contact with the ground or subsoil.

"*land protection guidance*", means Agency guidance "H7 - Guidance on the protection of land under the PPC Regime: application site report and site protection monitoring programme".

"MCERTS" means the Environment Agency's Monitoring Certification Scheme.

"notify/notified without delay" means that a telephone call can be used, whereas all other reports and notifications must be supplied in writing, either electronically or on paper.

"PPC Regulations" means the Pollution, Prevention and Control (England and Wales) Regulations SI 2000 No.1973 and words and expressions used in this permit which are also used in the Regulations have the same meanings as in those Regulations.

"*quarter*" means a calendar year quarter commencing on 1 January, 1 April, 1 July or 1 October.

"*site protection and monitoring programme*" means a document which meets the requirements for site protection and monitoring programmes described in the Land Protection Guidance.

"year" means calendar year ending 31 December.

Where a minimum limit is set for any emission parameter, for example pH, reference to exceeding the limit shall mean that the parameter shall not be less than that limit.

Unless otherwise stated, any references in this permit to concentrations of substances in emissions into air means:

(a) in relation to emissions from combustion processes, the concentration in dry air at a temperature of 273K, at a pressure of 101.3 kPa and with an oxygen content of 3% dry for liquid and gaseous fuels, 6% dry for solid fuels; and/or

(b) in relation to emissions from non-combustion sources, the concentration at a temperature of 273K and at a pressure of 101.3 kPa, with no correction for water vapour content

END OF PERMIT