

Permit with introductory note

The Environmental Permitting (England & Wales) Regulations 2016

Concept Life Sciences Integrated Discovery & Development Services Limited

Concept Life Sciences Kilo Facility

Building 901

Discovery Park

Ramsgate Road

Sandwich

Kent

CT13 9ND

Permit number

EPR/HP3900BG

Concept Life Sciences Kilo Facility

Permit number EPR/HP3900BG

Introductory note

This introductory note does not form a part of the permit

The main features of the permit are as follows.

This permit authorises the operator to perform the following listed activity and directly associated activities at the Concept Life Sciences Kilo:

- Listed activity:
 - Section 4.5 A(1)(a) Producing pharmaceutical products
- Directly associated activities (DAA):
 - Surface water management;
 - Chiller units providing cooling using glycol/water.

The permit allows the operator to produce active pharmaceutical ingredients (API) for commercial purposes using chemical processing and batch production techniques. The maximum capacity of the Kilo Facility is 90 kg/annum as clinical API product. API production is performed under a Multi-product Protocol (MPP) using a range of reactor vessels with capacities from 50 to 140 litres. API isolation involves liquid:liquid and liquid:solid separation techniques and drying of the API products using in-process filter dryers or by transfer to vacuum tray dryer ovens. Reactions may be in aqueous or solvent media and, where appropriate, nitrogen (from a bottled pressurised gas supply) is used to inert the atmosphere within reactor vessels and associated transfer lines or receiving vessels. Process related energy requirements rely on electrical power and there are no combustion plant on the installation.

Emissions from the permitted activities include emissions of substances to air, noise, waste and uncontaminated surface water from rainwater run-off.

Emissions to air are controlled and minimised by a range of process design, process control and abatement techniques. Abatement techniques include condensation of volatile substances, filtration using high-efficiency particulate air (HEPA) filtration and aqueous scrubbing in a two column process scrubber. Potential point source emissions to air include volatile organic compounds (VOCs), inorganic reagents, particulate matter and API at levels which have been assessed as insignificant with respect to the potential impact on ecological and human health receptors. There are no significant fugitive emissions sources.

Noise emissions have been assessed and do not present a risk of significant impacts at sensitive receptors.

Wastes arising from the permitted activities and general site activities are segregated and stored on-site pending collection for off-site recovery/disposal. Storage is in defined areas with containment designed to minimise the risk of spills. Drummed process waste is sent off-site for disposal.

The site is leased from Discovery Park Management Limited who manage the surface water drainage system and operate a biological wastewater treatment plant (WWTP) under permit reference EPR/AP3438YK. There are no emissions of trade effluents to sewer or surface water from the site. Domestic wastewater arising from the site is discharged to foul sewer and treated in the Discovery Park WWTP before release to the River Stour. Uncontaminated rainwater run-off from the main building roof is segregated, collected and released to the River Stour by connection to the wider Discovery Park site drainage system. Surface water collected in roadway drains is passed by the site drainage system to an off-site catch pit (reference 287) located within the boundary of the Sandwich Pharmaceuticals Pilot Plant which is managed by Pfizer R&D UK Ltd under permit reference EPR/RP3734QE. This catch pit is not linked to the Discovery Park drainage system and collected water is tested by Pfizer R&D UK Limited before transfer by road tanker for disposal either at the Discovery Park WWTP or at another suitable facility. Surface waters falling within

bunds associated with waste and chemicals storage on the site are collected in local blind sumps and tested before transfer to the Pfizer catch pit or transfer off-site for other suitable treatment and disposal. The operator has management procedures in place to minimise the risk of contamination of surface waters and to liaise with Pfizer R&D UK Limited in the event of an incident affected the quality of surface waters collected in the Pfizer catch pit. We do not regard the above as directly associated to the site activities and the site is not part of a multi-operator installation.

Heat and power for the facility is provide by a third-party biomass energy producer on the Discovery Park site (Kent Renewable Energy Limited). If this site is down for maintenance, power may be supplied from the national grid and heat provided by third party gas powered steam generators if the biomass facility is unable to supply.

The site is located in the Discovery Park industrial area and is surrounded to the north, south and west by industrial facilities and to the east by the River Stour. There are five designated sites within 10 km of the installation: Sandwich Bay Special Area of Conservation (SAC); Thanet Coast SAC; Stodmarsh SAC; and, Thanet Coast & Sandwich Bay Special Protection Area (SPA) and Ramsar site. Sandwich Bay to Hacklinge Marshes Site of Special Scientific Interest (SSSI) is located within 2 km of the installation. There are also two non-statutory sites (National Nature Reserve and Local Wildlife Site) located within 2 km of the installation.

The operator has an environmental management system which will be developed to meet the requirements of ISO 14001:2015 during plant commissioning. The permit includes a pre-operational condition which requires the operator to review the EMS before operations commencing operations.

The status log of the permit sets out the permitting history, including any changes to the permit reference number.

Status log of the permit		
Description	Date	Comments
Application EPR/HP3900BG/A001	Duly made 27/04/20	Application for a pharmaceuticals production plant.
Response to Schedule 5 Notice dated 27/05/20.	24/06/20	Response detailing further information concerning: <ul style="list-style-type: none"> • emissions • revised environmental risk assessment (ERA) and H1 assessment • raw materials • discharge of surface water and shared infrastructure • annual production • accident prevention and management • revised multi product protocol (MPP) • containments systems and bunds
	17/07/20	Response detailing further information concerning revised ERA.
Response to Schedule 5 Notice dated 02/07/20	16/07/20	Response detailing further information concerning: <ul style="list-style-type: none"> • management of discharge of surface water and shared infrastructure • revised H1 and air emissions assessment • environmental management systems
Permit determined EPR/HP3900BG (Billing ref. HP3900BG)	14/09/20	Permit issued to Concept Life Sciences Integrated Discovery & Development Services Limited.

Other Part A installation permits relating to this installation		
Operator	Permit number	Date of issue
Discovery Park Management Limited	EPR/AP3438YK	07/11/06
WasteCare Limited	EPR/TP3200PR	07/11/06
Kent Renewable Energy Limited	EPR/LP3034RD	16/06/16
Pfizer R&D UK Limited	EPR/RP3734QE	07/11/06

End of introductory note

Permit

The Environmental Permitting (England and Wales) Regulations 2016

Permit number

EPR/HP3900BG

The Environment Agency hereby authorises, under regulation 13 of the Environmental Permitting (England and Wales) Regulations 2016

Concept Life Sciences Integrated Discovery & Development Services Limited (“the operator”),

whose registered office is/whose principal office is

Heritage House

Church Road

Egham

TW20 9QD

company registration number 02345676

to operate an installation at

Concept Life Sciences Kilo Facility

Building 901

Discovery Park

Ramsgate Road

Sandwich

Kent

CT13 9ND

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

Name	Date
Claire Roberts	14/09/2020

Authorised on behalf of the Environment Agency

Conditions

1 Management

1.1 General management

- 1.1.1 The operator shall manage and operate the activities:
- (a) in accordance with a written management system that identifies and minimises risks of pollution, including those arising from operations, maintenance, accidents, incidents, non-conformances, closure and those drawn to the attention of the operator as a result of complaints; and
 - (b) using sufficient competent persons and resources.
- 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 Energy efficiency

- 1.2.1 The operator shall:
- (a) take appropriate measures to ensure that energy is used efficiently in the activities;
 - (b) review and record at least every four years whether there are suitable opportunities to improve the energy efficiency of the activities; and
 - (c) take any further appropriate measures identified by a review.

1.3 Efficient use of raw materials

- 1.3.1 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 four 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 further appropriate measures identified by a review.

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

- 1.4.1 The operator shall take appropriate measures to ensure that:
- (a) the waste hierarchy referred to in Article 4 of the Waste Framework Directive is applied to the generation of waste by the activities; and
 - (b) any waste generated by the activities is treated in accordance with the waste hierarchy referred to in Article 4 of the Waste Framework Directive; and
 - (c) where disposal is necessary, this is undertaken in a manner which minimises its impact on the environment.
- 1.4.2 The operator shall review and record at least every four years whether changes to those measures should be made and take any further appropriate measures identified by a review.

1.5 Multi product protocol

- 1.5.1 Where the operator proposes to make a change under a multi product protocol that is not otherwise the subject of an application for approval under the Regulations or this permit:
- (a) the Environment Agency shall be notified of the proposed change;
 - (b) the notification shall contain a description of the change including: an assessment of its environmental impact; any relevant supporting assessments and drawings; and the proposed implementation date;
 - (c) the change shall not be implemented unless approved in writing by the Environment Agency;
 - (d) as from any approved implementation date, the operator shall operate in accordance with the changed multi product protocol in place of the previously approved version.

1.6 Climate change

- 1.6.1 The operator shall review and if appropriate update, at least every 4 years, the climate change adaptation risk assessment submitted with the permit application, and shall update the written management system as appropriate.

2 Operations

2.1 Permitted activities

- 2.1.1 The operator is only 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 green on the site plan at schedule 7 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 Environment Agency.
- 2.3.2 If notified by the Environment Agency that the activities are giving rise to pollution, the operator shall submit to the Environment Agency for approval within the period specified, a revision of any plan or other documentation ("plan") specified in schedule 1, table S1.2 or otherwise required under this permit which identifies and minimises the risks of pollution relevant to that plan, and shall implement the approved revised plan in place of the original from the date of approval, unless otherwise agreed in writing by the Environment Agency.
- 2.3.3 Any raw materials or fuels listed in schedule 2 table S2.1 shall conform to the specifications set out in that table.
- 2.3.4 The operator shall ensure that where waste produced by the activities is sent to a relevant waste operation, that operation is provided with the following information, prior to the receipt of the waste:
- (a) the nature of the process producing the waste;
 - (b) the composition of the waste;
 - (c) the handling requirements of the waste;
 - (d) the hazardous property associated with the waste, if applicable; and

(e) the waste code of the waste.

2.3.5 The operator shall ensure that where waste produced by the activities is sent to a landfill site, it meets the waste acceptance criteria for that landfill.

2.4 Improvement programme

2.4.1 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 Environment Agency.

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

2.5 Pre-operational conditions

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

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 3 tables S3.1, S3.2 and S3.3.

3.1.2 The limits given in schedule 3 shall not be exceeded.

3.1.3 Total annual emissions from the emission point(s) set out in schedule 3 tables S3.1, S3.2 and S3.3 of a substance listed in schedule 3 table S3.4 shall not exceed the relevant limit in table S3.4.

3.1.4 Periodic monitoring shall be carried out at least once every 5 years for groundwater and 10 years for soil, unless such monitoring is based on a systematic appraisal of the risk of contamination.

3.2 Emissions of substances not controlled by emission limits

3.2.1 Emissions of substances not controlled by emission limits (excluding odour) shall not cause pollution. The operator shall not be taken to have breached this condition if appropriate measures, including, but not limited to, those specified in any approved emissions management plan, have been taken to prevent or where that is not practicable, to minimise, those emissions.

3.2.2 The operator shall:

(a) if notified by the Environment Agency that the activities are giving rise to pollution, submit to the Environment Agency for approval within the period specified, an emissions management plan which identifies and minimises the risks of pollution from emissions of substances not controlled by emission limits;

(b) implement the approved emissions management plan, from the date of approval, unless otherwise agreed in writing by the Environment Agency.

3.2.3 All liquids in containers, 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.

3.3 Odour

3.3.1 Emissions from the activities shall be free from odour at levels likely to cause pollution outside the site, as perceived by an authorised officer of the Environment Agency, unless the operator has used

appropriate measures, including, but not limited to, those specified in any approved odour management plan, to prevent or where that is not practicable to minimise the odour.

3.3.2 The operator shall:

- (a) if notified by the Environment Agency that the activities are giving rise to pollution outside the site due to odour, submit to the Environment Agency for approval within the period specified, an odour management plan which identifies and minimises the risks of pollution from odour;
- (b) implement the approved odour management plan, from the date of approval, unless otherwise agreed in writing by the Environment Agency.

3.4 Noise and vibration

3.4.1 Emissions from the activities shall be free from noise and vibration at levels likely to cause pollution outside the site, as perceived by an authorised officer of the Environment Agency, unless the operator has used appropriate measures, including, but not limited to, those specified in any approved noise and vibration management plan to prevent or where that is not practicable to minimise the noise and vibration.

3.4.2 The operator shall:

- (a) if notified by the Environment Agency that the activities are giving rise to pollution outside the site due to noise and vibration, submit to the Environment Agency for approval within the period specified, a noise and vibration management plan which identifies and minimises the risks of pollution from noise and vibration;
- (b) implement the approved noise and vibration management plan, from the date of approval, unless otherwise agreed in writing by the Environment Agency.

3.5 Monitoring

3.5.1 The operator shall, unless otherwise agreed in writing by the Environment Agency, undertake the monitoring specified in the following tables in schedule 3 to this permit:

- (a) point source emissions specified in tables S3.1, S3.2 and S3.3;
- (b) process monitoring specified in table S3.5

3.5.2 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.

3.5.3 Monitoring equipment, techniques, personnel and organisations employed for the emissions monitoring programme and the environmental or other monitoring specified in condition 3.5.1 shall have either MCERTS certification or MCERTS accreditation (as appropriate), where available, unless otherwise agreed in writing by the Environment Agency.

3.5.4 Permanent means of access shall be provided to enable sampling/monitoring to be carried out in relation to the emission points specified in schedule 3 tables S3.1, S3.2 and S3.3 unless otherwise agreed in writing by the Environment Agency.

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 Environment 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) off-site environmental effects; and
 - (ii) matters which affect the condition of the land and groundwater.

4.1.2 The operator shall keep on site all records, plans and the management system required to be maintained by this permit, unless otherwise agreed in writing by the Environment Agency.

4.2 Reporting

4.2.1 The operator shall send all reports and notifications required by the permit to the Environment Agency using the contact details supplied in writing by the Environment Agency.

4.2.2 A report or reports on the performance of the activities over the previous year shall be submitted to the Environment Agency by 31 January (or other date agreed in writing by the Environment 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 the permit including an interpretive review of that data;
- (b) the annual production /treatment data set out in schedule 4 table S4.2; and
- (c) the performance parameters set out in schedule 4 table S4.3 using the forms specified in table S4.4 of that schedule.

4.2.3 Within 28 days of the end of the reporting period the operator shall, unless otherwise agreed in writing by the Environment 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 4 table S4.1;
- (b) for the reporting periods specified in schedule 4 table S4.1 and using the forms specified in schedule 4 table S4.4; and
- (c) giving the information from such results and assessments as may be required by the forms specified in those tables.

4.2.4 The operator shall, unless notice under this condition has been served within the preceding four years, submit to the Environment Agency, within six 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.

4.3 Notifications

4.3.1 In the event:

- (a) that the operation of the activities gives rise to an incident or accident which significantly affects or may significantly affect the environment, the operator must immediately—
 - (i) inform the Environment Agency,
 - (ii) take the measures necessary to limit the environmental consequences of such an incident or accident, and
 - (iii) take the measures necessary to prevent further possible incidents or accidents;
- (b) of a breach of any permit condition the operator must immediately—
 - (i) inform the Environment Agency, and

- (ii) take the measures necessary to ensure that compliance is restored within the shortest possible time;
 - (c) of a breach of permit condition which poses an immediate danger to human health or threatens to cause an immediate significant adverse effect on the environment, the operator must immediately suspend the operation of the activities or the relevant part of it until compliance with the permit conditions has been restored.
- 4.3.2 Any information provided under condition 4.3.1 (a)(i), or 4.3.1 (b)(i) where the information relates to the breach of a limit specified in the permit, shall be confirmed by sending the information listed in schedule 5 to this permit within the time period specified in that schedule.
- 4.3.3 Where the Environment 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 Environment Agency when the relevant monitoring and/or spot sampling is to take place. The operator shall provide this information to the Environment Agency at least 14 days before the date the monitoring is to be undertaken.
- 4.3.4 The Environment Agency shall be notified within 14 days of the occurrence of the following matters, except where such disclosure is prohibited by Stock Exchange rules:
 - Where the operator is a registered company:
 - (a) any change in the operator's trading name, registered name or registered office address; and
 - (b) any steps taken with a view to the operator going into administration, entering into a company voluntary arrangement or being wound up.
 - Where the operator is a corporate body other than a registered company:
 - (a) any change in the operator's name or address; and
 - (b) any steps taken with a view to the dissolution of the operator.
 - In any other case:
 - (a) the death of any of the named operators (where the operator consists of more than one named individual);
 - (b) any change in the operator's name(s) or address(es); and
 - (c) any steps taken with a view to the operator, or any one of them, going into bankruptcy, entering into a composition or arrangement with creditors, or, in the case of them being in a partnership, dissolving the partnership.
- 4.3.5 Where the operator proposes to make a change in the nature or functioning, or an extension of the activities, which may have consequences for the environment and the change is not otherwise the subject of an application for approval under the Regulations or this permit:
 - (a) the Environment Agency shall be notified at least 14 days before making the change; and
 - (b) the notification shall contain a description of the proposed change in operation.
- 4.3.6 The Environment Agency shall be given at least 14 days' notice before implementation of any part of the site closure plan.
- 4.3.7 Where the operator has entered into a climate change agreement with the Government, the Environment 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 6 shall have the meaning given in that schedule.

4.4.2 In this permit references to reports and notifications mean written reports and notifications, except where reference is made to notification being made “immediately”, in which case it may be provided by telephone.

Schedule 1 – Operations

Table S1.1 activities			
Activity reference	Activity listed in Schedule 1 of the EP Regulations	Description of specified activity	Limits of specified activity
AR1	Section S4.5 A(1)(a) Producing pharmaceutical products	Production of active pharmaceutical ingredients (API) for commercial purposes using chemical processing and batch production techniques under a Multi-product Protocol (MPP).	<p>Production of API includes final products and non-isolated chemical intermediates.</p> <p>Production limited to up to six reactor vessels with a maximum single vessel capacity 140 litres.</p> <p>Maximum production capacity 90 kg/annum as clinical API product. Under normal operations emissions released to air are appropriately abated using one, or a combination of, the following techniques: HEPA filtration, low temperature condensation and aqueous scrubbing.</p> <p>Receipt of raw materials to despatch of finished product.</p> <p>Storage of process related wastes generated pending removal from site for recovery.</p> <p>Maximum storage of solvents, included waste solvents, on site at any one time 9,750 litres.</p>
Directly Associated Activity			
Activity reference	Description of activities for waste operations	Limits of activities	
AR2	Surface water management	From collection of surface waters within bunded chemicals and waste storage areas to transfer off-site for disposal.	
AR3	Operation of chiller units	Operation of refrigeration units providing cooling using glycol/water heat transfer fluid.	

Table S1.2 Operating techniques		
Description	Parts	Date Received
Application	Sections 3.0, 4.0, 6.0 of the application document provided in response to section 3a – technical standards, Part B3 of the application.	Duly Made 27/04/20
Response to Schedule 5 Notice dated 27/05/20	Responses to: question 7 detailing surface water management and effluent collection techniques; question 8 detailing the maximum production capacity of the facility as 90 kg of final API product; questions 9 and 10 excluding processing using hydrogen gas and providing the Multi-product protocol (MPP); question 11 confirming compliance of containment arrangements with CIRIA C736 requirements; and, questions 12 and 13 confirming emissions sources and providing a revised process vents process & instrument diagram DPL-901-007-002-000-00037_r01.	24/06/20
Response to Schedule 5 Notice dated 27/05/20	Response to question 5 limiting the raw materials inventory and storage arrangements associated with the MPP.	16/07/20
Response to Schedule 5 Notice dated 02/07/20	Responses to: question 1 detailing techniques to prevent overflow of the reactor vessel catch pot; and, question 2 detailing techniques to manage surface water collected in chemical and waste storage bunds. Description of the Environmental Management System (EMS) for the facility.	16/07/20
Response to Schedule 5 Notice dated 27/05/20	Response to: question 14 providing an updated Environmental Risk Assessment which: details maximum operating hours (3,120 per annum); risk management techniques; and, the risk assessment methodology and the envelope of assessed emissions for the MPP.	17/07/20

Table S1.3 Improvement programme requirements		
Reference	Requirement	Date
IC1	<p>The operator shall submit a report to the Environment Agency for technical assessment and approval.</p> <p>The report shall justify any reductions in the monitoring frequencies specified in table S3.1 for parameters in the discharge to air. Justification for any reduction in monitoring frequency for a specific parameter shall be based on:</p> <ul style="list-style-type: none"> evidence of the effectiveness of the techniques to minimise and abate emissions from the reactor vessels, filtration and drying equipment to such a level as to present no risk of exceedance of the emission limit values (ELVs) or mass emission limits set in the permit; and/or, evidence that the emissions levels are sufficiently stable; and/or, evidence that monitoring of a process control parameter may be used to reliably replace monitoring of that parameter in the emission to air. <p>Any such justifications shall be made with reference to the standards for BAT set out in the sector guidance note EPR 4.02 and /or any other relevant guidance notified to the operator and confirmed in writing by the Environment Agency.</p>	15 months from start of operations

Table S1.3 Improvement programme requirements		
Reference	Requirement	Date
	<p>If appropriate, the report shall include proposals for the revised monitoring frequencies for specific parameters.</p> <p>The notification requirements of condition 2.4.2 will be deemed to have been complied with on submission of the plan.</p> <p>Once approved in writing and from the date stipulated by the Environment Agency, the operator may adopt the revised monitoring frequencies, subject to such amendments or additions as notified by the Environment Agency.</p>	

Table S1.4 Pre-operational measures	
Reference	Pre-operational measures
1	<p>At least 2 weeks before operation the operator shall submit a report to the Environment Agency for technical assessment and approval.</p> <p>The report shall validate the key assumptions made in developing the envelope of assessed emissions for the MPP regarding in particular the concentration and rates of emissions to air from emission point references A1 and A4, and confirming the validity of the H1 emissions screening assessment submitted with the application. The report shall be based on monitoring data and other observations collated during commissioning for relevant parameters: volatile organic compounds (VOCs), inorganic compounds and particulate matter. If appropriate, the report should include an improvement plan, with timescales for deliveries of these improvements.</p> <p>Once approved in writing and from the date stipulated by the Environment Agency, the improvement plan shall be delivered in accordance with the agreed timescales, subject to such amendments or additions as notified by the Environment Agency.</p>
2	<p>At least 2 weeks before operation the operator shall submit a report to the Environment Agency for technical assessment and approval.</p> <p>The report shall include a review of the environmental management system (EMS), including the policies and procedures, against the permit conditions. The report must describe how the commitments made in sections 2 and 6 of the Application Support Document have been met. If appropriate, the report should include an improvement plan, with timescales for deliveries of these improvements.</p> <p>Once approved in writing and from the date stipulated by the Environment Agency, the improvement plan shall be delivered in accordance with the agreed timescales, subject to such amendments or additions as notified by the Environment Agency.</p>
3	<p>By a date agreed with the Environment Agency, prior to the commencement of commissioning of the installation for production purposes, the operator shall provide a written commissioning plan (including timescales for completion and milestone for reporting progress) for approval by the Environment Agency. The commissioning plan shall include the expected emissions to the environment during the different stages of commissioning, the expected durations of commissioning activities and the measures to be taken to protect the environment and report to the Environment Agency in the event that actual emissions exceed expected emissions. Commissioning shall be carried out in accordance with the commissioning plan as approved by the Environment Agency.</p> <p>No production shall commence at the installation unless the Environment Agency has given prior written permission under this condition.</p>

Table S1.4 Pre-operational measures	
Reference	Pre-operational measures
4	<p>By a date agreed with the Environment Agency, prior to the commencement of commissioning of the installation for production purposes, the operator shall provide a report for approval by the Environment Agency. The report shall include a description the methodology to be applied in determining the monitoring frequency for the measurement of the abatement scrubber fluid pH and oxidant concentration. The methodology must take into account the potential impact of all the reactor vessels being linked to the scrubber on the condition of the scrubbing liquor. Commissioning shall be carried out in accordance with the commissioning plan as approved by the Environment Agency.</p> <p>No production shall commence at the installation unless the Environment Agency has given prior written permission under this condition.</p>

Schedule 2 – Waste types, raw materials and fuels

Table S2.1 Raw materials and fuels	
Raw materials and fuel description	Specification
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Schedule 3 – Emissions and monitoring

Emission point ref. & location	Source	Parameter	Limit (including unit)	Reference period	Monitoring frequency	Monitoring standard or method
A1 [Point EP1 on site plan in Schedule 7]	Process scrubber abatement system	Volumetric Flow Rate (actual)	0.029 m ³ /s	Daily Mean	Six monthly [Note 1]	[Note 2]
		Ammonia	10 mg/m ³	Hourly average	Six monthly [Note 1]	[Note 2]
		Hypochlorite (as chlorine)	10 mg/m ³	Hourly average	Six monthly [Note 1]	[Note 2]
		Hydrazine	0.6 mg/m ³	Hourly average	Six monthly [Note 1]	[Note 2]
		Hydrogen bromide	5 mg/m ³	Hourly average	Six monthly [Note 1]	[Note 2]
		Hydrogen chloride	10 mg/m ³	Hourly average	Six monthly [Note 1]	[Note 2]
		Oxides of Nitrogen (NO and NO ₂ expressed as NO ₂)	50 mg/m ³	Hourly average	Six monthly [Note 1]	[Note 2]
		Phosphoryl chloride	48 mg/m ³	Hourly average	Six monthly [Note 1]	[Note 2]
		Sulphur dioxide	51 mg/m ³	Hourly average	Six monthly [Note 1]	[Note 2]
		Thionyl chloride	5 mg/m ³	Hourly average	Six monthly [Note 1]	[Note 2]
		Acetyl chloride	10.4 mg/m ³	Hourly average	Six monthly [Note 1]	[Note 2]
		Benzyl chloroformate	0.6 mg/m ³	Hourly average	Six monthly [Note 1]	[Note 2]
		BOC anhydride(di-tert-butyl dicarbonate)	10.5 mg/m ³	Hourly average	Six monthly [Note 1]	[Note 2]
		n-Butyl lithium	0.6 mg/m ³	Hourly average	Six monthly [Note 1]	[Note 2]
		n-Hexane	2,483 mg/m ³	Hourly average	Six monthly [Note 1]	[Note 2]
		Iodomethane	0.6 mg/m ³	Hourly average	Six monthly [Note 1]	[Note 2]
		Methanol	120.0 mg/m ³	Hourly average	Six monthly [Note 1]	[Note 2]
Methyl chloroformate	378 mg/m ³	Hourly average	Six monthly [Note 1]	[Note 2]		
Pyridine	7.4 mg/m ³	Hourly average	Six monthly [Note 1]	[Note 2]		

Table S3.1 Point source emissions to air – emission limits and monitoring requirements						
Emission point ref. & location	Source	Parameter	Limit (including unit)	Reference period	Monitoring frequency	Monitoring standard or method
		Toluene	327 mg/m ³	Hourly average	Six monthly [Note 1]	[Note 2]
		Trifluoroacetic acid	8.4 mg/m ³	Hourly average	Six monthly [Note 1]	[Note 2]
		VOC total Class A (acetonitrile, dichloromethane, 1,4 dioxane, dimethyl formamide, n-heptane, methyl chloroform, m-xylene)	100 g/hr or 20 mg/m ³	Hourly average	Six monthly [Note 1]	[Note 2]
		VOC Total Class B (expressed as carbon): acetone, borane tetrahydrofuran, diethyl ether, diethyl ketone, di-i-propyl ether, dimethyl sulphoxide, ethanol, ethyl acetate, methylethyl ketone, methylpropyl ketone, methyl-t-butyl ether, propan-1-ol, propan-2-ol and tetrahydrofuran)	2 kg/hr or 5 TPA (expressed as carbon) whichever is lower and 75 mg/m ³ when the mass emission rates are exceeded	Hourly average	Six monthly [Note 1]	[Note 2]
A2 [Point EP2 on site plan in Schedule 7]	Emergency vent – reaction vessel bursting disc release tank	No parameters set	No limit set	--	--	
A3 [Point EP3 on site plan in schedule 7]	Fume hoods and HVAC System	No parameters set	No limit set	--	--	
A4 [Point EP4 on site plan in schedule 7]	Oven Tray Dryer Vacuum Pump Vent	Particulate matter	0.3 µg/m ³	-	-	
<p>Note 1: when in use and unless otherwise agreed in writing with the Environment Agency in line with IC1.</p> <p>Note 2: in accordance with our online guidance on 'Monitoring stack emissions: techniques and standards for periodic monitoring' 18 December 2019, available from this link (active July 2020).</p>						

Table S3.2 Point Source emissions to water (other than sewer) and land – emission limits and monitoring requirements

Emission point ref. & location	Source	Parameter	Limit (incl. unit)	Reference Period	Monitoring frequency	Monitoring standard or method
W1 on site plan in schedule 7 emission to Discovery Park surface water drainage system	Clean roof water from Building 901	No parameters set	No limit set			

Table S3.3 Point source emissions to sewer, effluent treatment plant or other transfers off-site– emission limits and monitoring requirements

Emission point ref. & location	Source	Parameter	Limit (incl. Unit)	Reference period	Monitoring frequency	Monitoring standard or method
S1 on site plan in schedule 7 emission to catch pit 287 [Note 1]	Uncontaminated surface water collected in site drainage system	No parameters set	No limit set			

Note 1: This is the release point to the off-site drainage linked to catch pit 287 which is located within the boundary of the Sandwich Pharmaceuticals Pilot Plant managed by Pfizer R&D UK Ltd under permit reference EPR/RP3734QE.

Table S3.4 Annual limits

Substance	Medium	Limit (including unit)
--	--	--

Table S3.5 Process monitoring requirements

Emission point reference or source or description of point of measurement	Parameter	Monitoring frequency	Monitoring standard or method	Other specifications
Process scrubber liquor outlet	pH	[Note 1]	Not applicable	When effective abatement relies on pH of the scrubber liquor.
Process scrubber liquor outlet	Oxidant (hypochlorite or hydrogen peroxide)	[Note 1]	Not applicable	When effective abatement relies on oxidation of parameters.
Heat transfer fluid monitoring point.	Heat transfer fluid temperature	Continuous	Not applicable	When in use

Note 1: Frequency as determined under the Multi-product Protocol as described in the report of pre-operational measure 4.

Schedule 4 – Reporting

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

Table S4.1 Reporting of monitoring data			
Parameter	Emission or monitoring point/reference	Reporting period	Period begins
Emissions to air Parameters as required by condition 3.5.1.	A1, A4	Every 12 months	1 January

Table S4.2: Annual production/treatment	
Parameter	Units
API, clinical grade product	kg

Table S4.3 Performance parameters		
Parameter	Frequency of assessment	Units
Water usage	Annually	tonnes
Energy usage	Annually	MWh
Total raw material used	Annually	tonnes
Total solvent consumption [Note 1]	Annually	tonnes

Note 1: Solvent consumption as defined in Article 57 of the Industrial Emissions Directive.

Table S4.4 Reporting forms		
Media/parameter	Reporting format	Date of form
Air	Form air 1 or other form as agreed in writing by the Environment Agency	14/09/20
Water usage	Form water usage 1 or other form as agreed in writing by the Environment Agency	14/09/20
Energy usage	Form energy 1 or other form as agreed in writing by the Environment Agency	14/09/20
Other performance indicators	Form performance 1 or other form as agreed in writing by the Environment Agency	14/09/20

Schedule 5 – 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 EP Regulations.

Part A

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

(a) Notification requirements for any malfunction, breakdown or failure of equipment or techniques, accident, or emission of a substance not controlled by an emission limit 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	

(b) Notification requirements for the breach of a limit	
To be notified within 24 hours of detection unless otherwise specified below	
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 facility in the preceding 24 months.	

Name*	
Post	
Signature	
Date	

* authorised to sign on behalf of the operator

Schedule 6 – Interpretation

“accident” means an accident that may result in pollution.

“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 5 to the EP Regulations.

“authorised officer” means any person authorised by the Environment 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.

“EP Regulations” means The Environmental Permitting (England and Wales) Regulations SI 2016 No.1154 and words and expressions used in this permit which are also used in the Regulations have the same meanings as in those Regulations.

“emissions of substances not controlled by emission limits” means emissions of substances to air, water or land from the activities, either from the emission points specified in schedule 3 or from other localised or diffuse sources, which are 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.

“Hazardous property” has the meaning in Annex III of the Waste Framework Directive.

“Industrial Emissions Directive” means DIRECTIVE 2010/75/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 24 November 2010 on industrial emissions.

“MCERTS” means the Environment Agency’s Monitoring Certification Scheme.

“Multi-product Protocol” (MPP) - means a procedure written by an operator and approved by the Environment Agency, which is referenced in the operational techniques table of this permit. It describes the operator’s management process which can be used to request changes, within the limits in that document only, to the original permit without the need for a formal permit variation application.

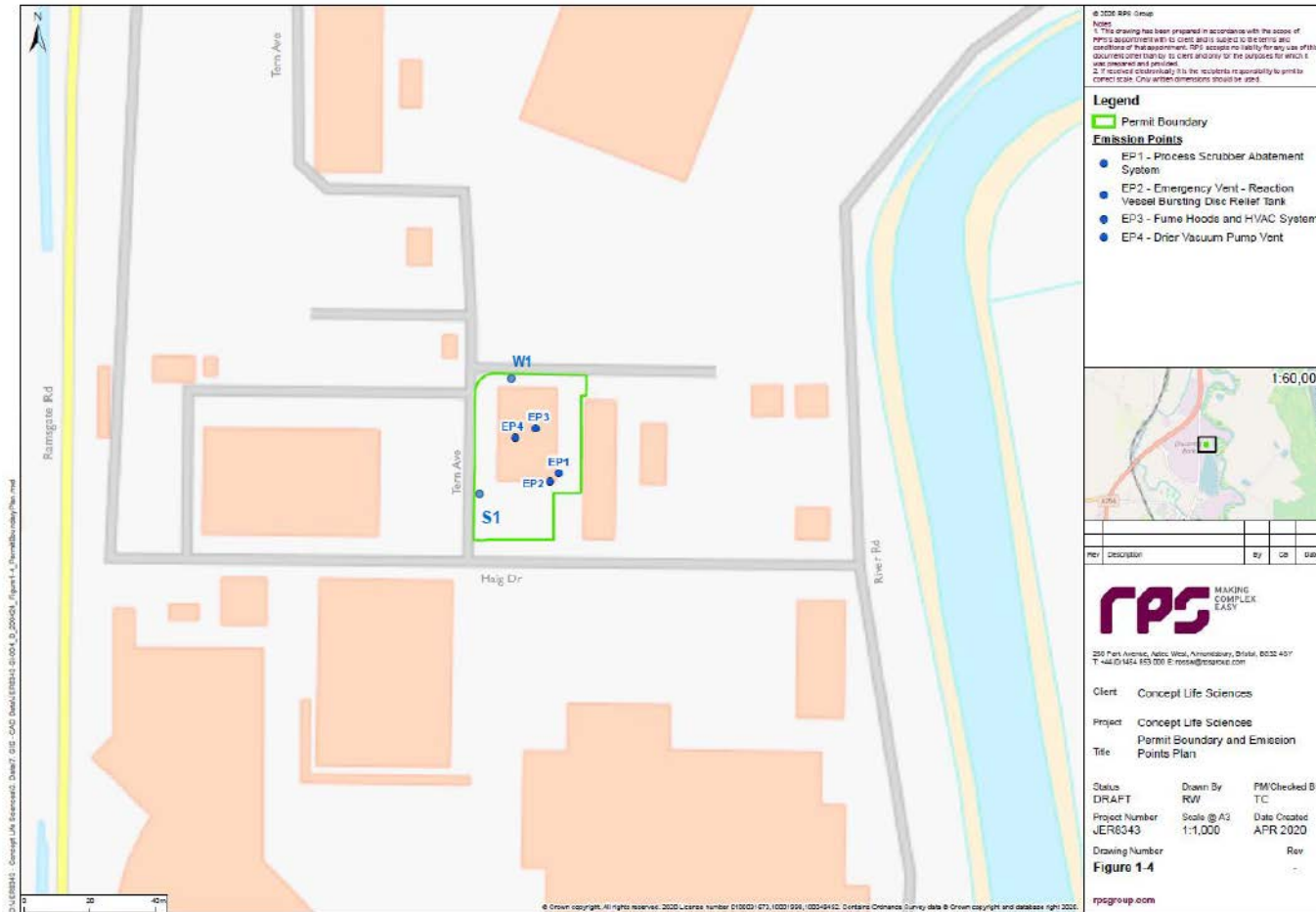
“year” means calendar year ending 31 December.

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:

- 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
- 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.

Schedule 7 – Site plan



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END OF PERMIT

Permit number
EPR/HP3900BG

Reporting Forms

Permit Number: HP3900BG **Operator:** Concept Life Sciences Integrated Discovery & Development Service Limited
Facility: Concept Life Sciences Kilo Facility **Form Number:** Air1 / 14/09/20

Reporting of emissions to air for the period from DD/MM/YYYY to DD/MM/YYYY

Emission Point	Substance / Parameter	Emission Limit Value	Reference Period	Result ^[1]	Test Method ^[2]	Sample Date and Times ^[3]	Uncertainty ^[4]
A1	Volumetric Flow Rate (actual)	0.029 m ³ /s	Daily Mean		Note 1		
A1	Ammonia	10 mg/m ³	Hourly average		Note 1		
	Hypochlorite (as chlorine)	10 mg/m ³	Hourly average		Note 1		
	Hydrazine	0.6 mg/m ³	Hourly average		Note 1		
	Hydrogen bromide	5 mg/m ³	Hourly average		Note 1		
	Hydrogen chloride	10 mg/m ³	Hourly average		Note 1		
	Oxides of Nitrogen (NO and NO ₂ expressed as NO ₂)	50 mg/m ³	Hourly average				
Phosphoryl chloride	48 mg/m ³	Hourly average		Note 1			
Sulphur dioxide	51 mg/m ³	Hourly average					

Emission Point	Substance / Parameter	Emission Limit Value	Reference Period	Result ^[1]	Test Method ^[2]	Sample Date and Times ^[3]	Uncertainty ^[4]
	Thionyl chloride	5 mg/m ³	Hourly average		Note 1		
	Acetyl chloride	10.4 mg/m ³	Hourly average		Note 1		
	Benzyl chloroformate	0.6 mg/m ³	Hourly average				
	BOC anhydride (di-tert-butyl dicarbonate)	10.5 mg/m ³	Hourly average		Note 1		
	n-Butyl lithium	0.6 mg/m ³	Hourly average		Note 1		
	n-Hexane	2,483 mg/m ³	Hourly average		Note 1		
	Iodomethane	0.6 mg/m ³	Hourly average		Note 1		
	Methanol	120.0 mg/m ³	Hourly average		Note 1		
	Methyl chloroformate	378 mg/m ³	Hourly average		Note 1		
	Pyridine	7.4 mg/m ³	Hourly average		Note 1		
	Toluene	327 mg/m ³	Hourly average		Note 1		
	Trifluoroacetic acid	8.4 mg/m ³	Hourly average		Note 1		

Emission Point	Substance / Parameter	Emission Limit Value	Reference Period	Result ^[1]	Test Method ^[2]	Sample Date and Times ^[3]	Uncertainty ^[4]
	VOC total Class A (acetonitrile, dichloromethane, 1,4 dioxane, dimethyl formamide, n-heptane, methyl chloroform, m-xylene)	100 g/hr or 20 mg/m ³	Hourly average		Note 1		
	VOC Total Class B (expressed as carbon): acetone, borane tetrahydrofuran, diethyl ether, diethyl ketone, di-i-propyl ether, dimethyl sulphoxide, ethanol, ethyl acetate, methylethyl ketone, methylpropyl ketone, methyl-t-butyl ether, propan-1-ol, propan-2-ol and tetrahydrofuran)	2 kg/hr or 5 TPA (expressed as carbon) whichever is lower and 75 mg/m ³ when the mass emission rates are exceeded	Hourly average		Note 1		

Emission Point	Substance / Parameter	Emission Limit Value	Reference Period	Result ^[1]	Test Method ^[2]	Sample Date and Times ^[3]	Uncertainty ^[4]
A4	Oven Tray Dryer Vacuum Pump Vent	Particulate matter	0.3 µg/m ³		-		

Note 1 - Monitoring stack emissions: techniques and standards for periodic monitoring' 18 December 2019, available from [this link](#) (active July 2020).

1. The result given is the maximum value (or the minimum value in the case of a limit that is expressed as a minimum) obtained during the reporting period, expressed in the same terms as the emission limit value. Where the emission limit value is expressed as a range, the result is given as the 'minimum – maximum' measured values.
2. Where an internationally recognised standard test method is used the reference number is given. Where another method that has been formally agreed with the Environment Agency is used, then the appropriate identifier is given. In other cases the principal technique is stated, for example gas chromatography.
3. For non-continuous measurements the date and time of the sample that produced the result is given. For continuous measurements the percentage of the process operating time covered by the result is given.
4. The uncertainty associated with the quoted result at the 95% confidence interval, unless otherwise stated.

Signed

Date.....

(Authorised to sign as representative of Operator)

Permit Number: HP3900BG **Operator:** Concept Life Sciences Integrated Discovery & Development Service Limited
Facility: Concept Life Sciences Kilo Facility **Form Number:** WaterUsage1 / 14/09/20

Reporting of Water Usage for the year YYYY

Water Source	Usage (m ³ /year)	Specific Usage (m ³ /unit output)
Mains water		
TOTAL WATER USAGE		

Operator's comments:

Signed

Date.....

(authorised to sign as representative of Operator)

Permit Number: HP3900BG **Operator:** Concept Life Sciences Integrated Discovery & Development Service Limited
Facility: Concept Life Sciences Kilo Facility **Form Number:** Energy1 / 14/09/20

Reporting of Energy Usage for the year YYYY

Energy Source	Energy Usage		Specific Usage (MWh/unit output)
	Quantity	Primary Energy (MWh)	
Electricity *	MWh		
Steam	MWh equivalent		
TOTAL	-		

* Conversion factor for delivered electricity to primary energy = 2.4

Operator's comments:

Signed

Date.....

(Authorised to sign as representative of Operator)

Permit Number: HP3900BG **Operator:** Concept Life Sciences Integrated Discovery & Development Service Limited

Facility: Concept Life Sciences Kilo Facility **Form Number:** Performance1 / 14/09/20

Reporting of other performance indicators for the period DD/MM/YYYY to DD/MM/YYYY

Parameter	Units
Total raw material used	tonnes
Total solvent consumption [Note 1]	tonnes
Note1: Solvent consumption as defined in Article 57 of the Industrial Emissions Directive.	

Operator's comments:

Signed

Date.....

(Authorised to sign as representative of Operator)