Environment Agency Permitting decisions

Bespoke Permit

We have decided to grant the permit for **Swale Pharmaceuticals** operated by **GW Pharma Limited.**

The permit number is **EPR/LV3637VA**

We consider in reaching that decision we have taken into account all relevant considerations and legal requirements and that the permit will ensure that the appropriate level of environmental protection is provided.

Purpose of this document

This decision document:

- explains how the application has been determined
- provides a record of the decision-making process
- shows how all relevant factors have been taken into account
- justifies the specific conditions in the permit other than those in our generic permit template.

Unless the decision document specifies otherwise we have accepted the applicant's proposals.

Structure of this document

- Annex 1 the decision checklist and Key Issues
- Annex 2 the consultation responses

Annex 1: decision checklist

Aspect considered	Justification / Detail	Criteria met
		Yes
Receipt of submission		
Confidential information	A claim for commercial or industrial confidentiality has not been made.	✓
Consultation		
Scope of consultation	The consultation requirements were identified and implemented. The decision was taken in accordance with our guidance. The application was sent for consultation to: 1. Public Health England/Director of Public Health 2. HSE 3. Swale Borough Council Environmental Health Department	✓
Responses to consultation and web publicising	The consultation responses (Annex 2) were taken into account in the decision. *Two responses have been received.* The decision was taken in accordance with our guidance.	✓
European Directives		
Applicable Directives	All applicable European Directives have been considered in the determination of this application	✓
The site		
Extent of the site of the facility	The applicant has provided a plan which we consider is satisfactory, showing the extent of the site of the facility. A plan is included in the permit and the applicant is required to carry on the permitted activities within the site boundary. The installation boundary consists of 5 blocks within the same Kent Science Park.	✓
Site Condition Report	The applicant has provided a site condition report with this application with final version provided in request for information response dated 27/02/15,	

Aspect considered	Justification / Detail	Criteria met Yes
	which consists of the following: • Appendix B of main supplementary application document site location plan • Figure 3 air emissions and Figure 4 Land/sewer emissions • Application supplementary information Appendix F Site Condition Report document including Enviro check report, December 2000 Waterman Environmental report and Evans and Langford GIR 2012 report. The latter two reports provide ground water and soil intrusive sampling data. The applicant has decided to utilise intrusive sampling as per Appendix F reports detailed above as baseline data for the installation. The data consists of ground water and soil monitoring data. The December 2000 Waterman and Langford Report provides intrusive sampling data for four existing installation blocks, excluding new production facility building 750. The investigation includes two 60 m boreholes, 4 off 10 m boreholes m 49 probe holes and 12 hand auger evacuations. The Evans and Langford GIR 2012 report provides intrusive sampling data for new production building 750. The request for information response dated 27/02/15 provided a location plan for monitoring points for this 2012 sampling data. The request for information gave further responses regarding the lack of sampling data linked to ethanol, a key raw material utilised in the main production facility. The applicant has stated the basis for negligible environmental impact is that the main ethanol storage facility is within a bund > 110 % of tank volume capacity; in addition there is flow monitoring on filling of waste ethanol IBC systems to prevent over-filling. The applicant has stated, in request for information response dated 27/02/15, their acceptance that without intrusive sampling data, any ethanol identified in subsequent sampling would therefore be taken as indicative of pollution and would need to be fully remediated. **Overall we accept the applicant application site condition report as a representative report. The new Industrial Emissions Directive (IED) condition has been added for ground water and soil monitoring.**	
Biodiversity, Heritage, Landscape and Nature Conservation	There are ***three European*** statutory sites within the relevant screening distances from the installation. • Queendown Warren SAC • The Swale SPA and Ramsar • Medway Estuary & Marshes SPA and Ramsar <u>The environmental impacts are as follows :</u> 1. Particulate and ethanol emissions to air: H1 assessment shows process contributions from A1 main process release is insignificant. 2. No direct surface water discharges from the installation 3. Clean water emissions release to soakaways with isolation valves to prevent spillages discharging to soakaways 4. Sewer discharge is only for domestic effluent 5. Odour emissions from A1 process vent minimized via usage of Ultra Violet Ionisation odour abatement and odour management plan to ensure effective operating techniques to minimize odour levels. *Overall the installation environmental impact on these European sites is assessed as negligible.* An Appendix 11 has been sent to Natural England for information only. There are eleven other conservation consisting of 3 local wildlife sites and 8 Ancient Woodland within the relevant screening distances of the installation. The impacts on these non-conservation sites are considered negligible for	✓

Aspect considered	Justification / Detail	Criteria met Yes
	reasons stated above.	
Environmental Risk Assessment and operating techniques		
Environmental risk	We have reviewed the applicant's assessment of the environmental risk from the installation. The applicant's risk assessment is satisfactory after additional information received in response to the schedule 5 notice relating to H1 atmospheric emissions, odour control complete with an odour management plan plus accident management information. H1 assessment for air emissions, assessment of odour and accident management plans are provided in key issues section of this document.	✓
Operating techniques	We have reviewed the techniques used by the applicant and compared these with the relevant guidance notes. The applicant has performed a BAT review (discussed in more details in key issues section) linked to the following Environment Agency TGNs: • EPR 1.00 How to Comply • EPR 4.02 TGN for Speciality Organic Chemicals. o Section 3 of their main application supplementary report covers their proposed measures to ensure compliance with BAT requirements under following key headings Accident Management, Energy Efficiency, Raw Material efficient usage and Waste Management. o Section 4 of their main application supplementary report covers their proposed measures to ensure compliance with BAT requirements under new process risk assessment requirements including HAZOP assessments, raw material management, reaction , purification and evaporation steps plus overall plant design and process control. o Section 5 of their main application supplementary report covers their proposed measures to ensure compliance with BAT requirements under air and water emissions controls plus fugitive, odour and noise emission controls. *The proposed techniques/ emission levels for priorities for control are in line with the benchmark levels contained in the TGN's as listed above and we consider them to represent appropriate techniques for the facility.* A more detailed assessment of indicative BAT measures with specific reference to *atmospheric emissions. odour, fugitive emissions and accident management plans are included in key issues section of this document.*	✓
The permit conditions		
Odour	We consider that the activities carried out at the site have the potential to cause odour. This process is one that handles and includes emissions of aromatic compounds and as such requires an Odour Management Plan in line with our EPR 1.00 How to Comply guidance as follows: *"manufacture, use or recovery of compounds containing sulphur, ammonia, amines and amides, aromatic compounds, styrene, pyridine and esters."* **A detailed assessment of the Odour Management Plan is included in the key issues section of this document.** The standard odour condition has been included in this permit with specific condition relating to an odour management plan (see conditions 3.3.1)	✓

Aspect considered	Justification / Detail	Criteria met
		Yes
Noise	We consider that the activities carried out at the site have the potential to cause noise and/or vibration. However based on the assessment below the conclusion is that the impacts are considered negligible on the surrounding residential sensitive receptors. The main equipment will potential for noise pollution include fans, compressors, chillers and pumps linked to liquefied CO2 and N2 storage. The compressors, as one of main facilities with potential for noise/vibration are housed internally. The applicant has complied with all the indicative BAT measures for noise and vibration within our EPR 1.00 How to Comply and EPR 4.02 Speciality Organic Chemicals guidance All equipment of the installation will be subject to a preventative maintenance programme to ensure consistent performance and minimisation of noise impacts. As background information the closest sensitive receptor is approximately 315 metres from the main new production building (residences in Broadoak Road); this is to the south east of the installation boundary. The applicant has completed noise modelling ; modelling report in supporting application document appendix E complete with usage of background noise monitoring data , dated December 2012, before main production building construction was commenced. <u>The conclusions of the report are as follows:</u> The maximum predicted noise rating during normal operating conditions is 32 dB L Aeq at the closest receptor in Broadoak Road. This is 9.5 dB. below the minimum measured background noise level. Based on BS4142 criteria this is considered as a positive indication that complaints arising from noise due to the installation are unlikely. In terms of noise mitigation steps the applicant has included the following in the installation facility design; • All Air Handling Units include in duct noise attenuators. • The dust extraction system includes an in duct noise attenuator • Compressors – all housed within main production building and selected to include integral silencer packs. • Service yard compound at ground floor level has a solid 3 metre high masonry boundary wall. We accept these controls as indicative BAT measures to minimise noise impact from the installation. The standard noise condition has been considered sufficient (3.4.1).	
Raw materials	The principal raw materials to be used within the installation are botanical raw material, ethanol, carbon dioxide, nitrogen and towns water On the basis of maximum production capacity of 4 million vials of Botanical Drug Product (840 production batches per annum) the maximum raw material usage is detailed in table 1 within application duly making response. The details of raw material storage facilities with storage facility capacities for bulk tanks, Intermediate Bulk Containers and other containers is provided within main application supplementary information document Table 5.14. The indicative BAT measures utilised by the applicant for efficient usage of raw material are detailed in Table 3.8, 3.9 and 3.10 of the application supplementary information. BAT measures for raw material reception and storage are detailed in Table 4.2 of application supplementary document. We accept these measures as BAT for the installation. The standard raw materials condition applied for on-going raw material efficiency (condition 1.3.1)	✓

Aspect considered	Justification / Detail	Criteria met Yes
Waste types	The expanded facility will generate two key waste streams; waste ethanol and Botanical Raw Material. The annual waste consumption for these two materials based on 840 batches per annum is quantified in Table 2 of duly making response. Within Tables 3.11 and 3.13 of application supplementary cover applicant BAT indicatives measures for waste management, storage and waste minimisation. Table 3.12 gives a complete list of waste streams for installation with streams sent to recovery/reuse and justification of waste sent to disposal. The applicant has committed to a periodic waste minimisation review. The spent BRM waste EWC code to be applied is confirmed in response 6 of applicant duly making response. The applicant final proposals for waste treatment/disposal will be reviewed by our compliance team.	
Pre-operational conditions	We consider that we need to impose one pre-operational condition. This is linked to a to a commissioning protocol with specific emphasis on odour emissions controls and stack monitoring to show applicant compliance with application estimates.	✓
Improvement conditions	Based on the information on the application, we consider that we need to impose improvement conditions. We have imposed 2 improvement conditions to cover: • IP 1 Commissioning Report including odour monitoring • IP2 Final OMP submission, after review of IP1 commissioning report implications.	✓
Emission limits	We have decided that emission limits should be set for the parameters listed in the permit under Tables S3.1.	✓
Monitoring	We have decided that monitoring requirements should be set as follows: • Table S3.1 listed monitoring requirements specifically for new production facility emission A1 and existing facility emission A6. The Total VOC and ethanol emissions monitoring will be a measure of on-going process control and UV abatement system performance. The atmospheric monitoring techniques are in line with our M2 guidance.	✓
Reporting	We have decided that reporting requirements should be set as per permit table S4.1, linked to submission of atmospheric monitoring data.	✓
Environment Management System	There is no known reason to consider that the applicant will not have the management systems to enable it to comply with the permit conditions. The decision was taken in accordance with RGN 5 on Applicant Competence. The applicant has confirmed they will be operating an in-house EMS based on ISO14001. A management organisation chart is presented in Appendix B Figure 8 of application supplementary information.	✓
Relevant Convictions	The National Enforcement Database has been checked to ensure that all relevant convictions have been declared. No relevant convictions were found.	✓

Key issues of the decision.

1. Process introduction

The installation is located at the southern edge of Kent Science Park, which lies to the south of Broadoak Road 1.5 km to the south east of the village of Tunstall and approximately 3.3 km to the south of Sittingbourne.

The installation consists of a pharmaceutical production process. The relevant scheduled activity under the Environmental Permitting Regulations is as follows:

"Section 4.5 A (1) (a) Producing pharmaceutical products using a chemical or biological process."

The main scheduled activity includes pharmaceutical manufacturing process with ethanol raw material storage, usage of Cleaning in Place facilities, Ultra Violet ionisation atmospheric odour abatement and air compressor facilities.

The directly associated activities are as follows:

- Waste handling and storage
- Use of bulk CO2 and N2
- Compressed air.

The key raw materials to be utilised within the installation are Botanical Raw Material (BRM), ethanol, liquid carbon dioxide and nitrogen.

There will be six emission points to air and two soakaways linked to the installation.

The applicant has submitted plans to minimise environmental impacts from the installation including an Odour Management Plan and Accident Management Plan. The installation emission point A1, the main process emission point, is complete with ionisation technology odour abatement. Two pre-operational conditions and an improvement plan are included to ensure effective commissioning of the odour abatement system and updating of the Odour Management Plan to reflect this commissioning.

The installation boundary consists of 5 blocks within the common Kent Science Park. The applicant has confirmed these are all integral parts of the installation and the split of activities across the five blocks and various buildings is as follows:

- Main new production building 750.
- Back up existing production building 740.
- Raw Material Storage area building 750,760, 820 and 840.
- Finished Goods Storage areas buildings 830, 840,740 and 750.
- Milling production in buildings 740 and 820.

The movement of materials between sites is by specialist vehicles and not on main highways. As such we accept that the installation boundary is in compliance with our Regulatory Guidance RGN No.2.

The maximum annual production capacity for the installation is 4 million vials equivalent of Botanical Drug Product. This equates to 840 batches of production with 66 kg of Botanical Raw Material per batch

Process description in more details

Key process details are as follows:

- The Botanical Raw Material (BRM) material is delivered and stored prior to milling.
- Milling: The BRM is milled through one of two small mills, in an enclosed room, to a particle size of 1mm.
- Decarboxylation (CO2 evolved from the BRM): Milled BRM is loaded into the Decarboxylation vessel. Air is evacuated from the vessel and replaced by nitrogen. The milled BRM is then heated (to 115 C) and cooled (to 60 C) which facilitates the decarboxylation process. Heating is via usage of an electrical jacket.
- Extraction: The decarboxylated BRM is then loaded into a Supercritical Fluid Extraction System which extracts the BRM by means of liquid CO2. The crude extract is a brown semi-solid solid going forward for further processing. The spent BRM is collected for waste disposal.
- Winterisation: Ethanol is added at this stage of the process in order to improve the properties of the extract for further processing. Once the ethanol has been added the mixture it is agitated to ensure effective mixing. The Botanical Drug Substance (BDS) extract is then cooled and stored until required in order to precipitate any waxes.
- Filtration: The winterised extract is passed through a filter to remove any remaining solids plus any waxes.
- Evaporation: The filtered BDS is passed through an Evaporator to remove the ethanol. The ethanol waste is then collected and transferred for disposal. The concentrated crude product is collected into a product vessel and discharged into a container for transport to intermediate storage.

- Botanical Drug Production (BDP): The crude BDP is mixed with excipients, filtered and filled into vials. The finished product in a vial is then put into secondary packaging.

There are six sources of releases to air (excluding emergency events which would only release in the event of an incident);

- A1 – Exhaust from the Heating Ventilation and Air Conditioning system (HVAC1) for main production facility including ethanol, carbon dioxide, BRM particulate and odorous emissions from decarboxylation process vents. This emission point includes particulate filtration and Ultra Violet oxidation odour abatement.
- A2 - HVAC 2 emission.
- A3 – HVAC 3 emission.
- A4 – Ethanol Storage vent from lev system.
- A5 – Waste Solvent vent from lev system.
- A6 – Existing research and development existing process building with ethanol, particulate and carbon dioxide emissions.

Water from the town's water supply is only used for cooling water and hot water at 80 C is used for heating of the extraction skid. This is a closed system.

The site only discharges domestic effluent form toilets and showers to sewer; there is no scheduled activity discharge to sewer from this installation.

2. Environmental Assessment

Below is a summary of the environmental assessment:

Atmospheric.

Overall there are 6 emission points for this installation to atmosphere. The process emissions are linked to A1 and A6 as detailed below.

The changes linked to this variation are summarised as follows:

Emission point ref.	Source	Total Flow m3/hr	Effective Stack Height in metres	Parameters
A1.	Building 750 new production building	5,200	0	Ethanol and Particulates
A6.	Building 740 existing back up production building	810	0	Ethanol and Particulates

The applicant has carried out first a H1 assessment on this basis.

BAT measures for particulate emission control.

In addition to the panel filter utilised for current A6 particulate emissions control, the new A1 emission has a primary bag filter upstream of the panel filter with > 99 % particulate emissions particulate control at 0.4 microns.

H1 ASSESSMENT FOR ATMOSPHERIC EMISSIONS

Stage 1: Screen Out Insignificant Emissions

Once short-term and long-term PCs have been calculated, in this application via dispersion modelling, they are compared with Environmental Quality Standards (EQS) referred to as "benchmarks" in the H1 Guidance.

Where an EU EQS exists, the relevant standard is the EU EQS. Where an EU EQS does not exist, our guidance sets out a National EQS (also referred to as Environmental Assessment Level - EAL) which has been derived to provide a similar level of protection to Human Health and the Environment as the EU EQS levels.

PCs are considered **Insignificant** if:

- The **long-term** process contribution is less than **1%** of the relevant EQS; and
- The **short-term** process contribution is less than **10%** of the relevant EQS.

- The **long term** 1% process contribution insignificance threshold is based on the judgements that: It is unlikely that an emission at this level will make a significant contribution to air quality;
- The threshold provides a substantial safety margin to protect health and the environment.

- The **short term** 10% process contribution insignificance threshold is based on the judgements that: spatial and temporal conditions mean that short term process contributions are transient and limited in comparison with long term process contributions;
- The proposed threshold provides a substantial safety margin to protect health and the environment.

Stage 2: Decide Whether Detailed Modelling is needed
Where an emission cannot be screened out as insignificant as a PC through applying the first stage of our H1 Guidance, it does not mean it will necessarily be significant.

In these circumstances, the H1 Guidance justifies the need for detailed modelling of emissions, long-term, short-term or both, taking into account the state of the environment before the Installation operates, where:
- local receptors may be sensitive to emissions;
- released substances fall under an Air Quality Management Plan;
- the long term Predicted Environmental Concentration (PEC) exceeds 70% of the appropriate long term standard, (where the PEC is equal to the sum of the background concentration in the absence of the Installation and the process contribution);
- the short term Process Contribution exceeds 20% of the headroom, (where the headroom is the appropriate short term standard minus twice the long term background concentration).

H1 assessments:

The following table summarises the results

Pollutant	EQS / EAL Long Term (µg/m^3)	EQS / EAL Short Term (µg/m^3)	LT Process Contribution (PC) (µg/m^3)	PC LT as % of EQS / EAL	PC < 1 % of the EQS/EAL	ST Process Contribution (PC) (µg/m^3)	PC ST as % of EQS / EAL	PCST < 10 % of the EQS/EAL
Particles PM_{10}	40.00	50	0.0675	0.017	No	2.18	4.35	No
Particles $PM_{2.5}$	25	-	0.0675	0.27	No	**-**	-	-
Ethanol	19,200	-	7.7	0.04	No	**-**	-	-

Note 1 In absence of a relevant standard for ethanol in current H1annex F guidance, the 2003 version of H1 annex F) has a long EAL of 19,200 µg/m3.

Conclusions:
*All the parameters **do** screen out at stage 1 for all of the relevant* AQS's. The environmental impacts for these parameters from the installation are assessed as **insignificant**

3 Odour

Risk Assessment

The operations within the installation that will have the greatest potential to give rise to odour are:
- Botanical Raw Material (BRM) Milling
- Botanical Raw Material Drying
- Ethanol Storage
- Waste Ethanol /Waste Solvent Handling
- Cleaning and maintenance activities

The applicant has provided a H1 basic risk assessment for odour within Appendix C of their supporting information.

There are residential properties between *200 and 400 metres* from the installation boundary. Relative to the main production building there are a number of buildings including glass houses, offices, light industrial and commercial units.

The process emissions from the installation, with the potential for odour, are primarily linked to terpenes from BRM Drying/Decarboxylation phase. These are linked to emissions from A1 and A6 emission points.

The Odour Management Plan discussed below provides a more detailed risk assessment for normal and abnormal scenarios complete with contingency plan for corrective measures.

BAT assessment

The applicant has carried out a BAT assessment for the optimum odour abatement for process emissions from main A1 new process discharge.
As background the applicant has an existing UV ionisation system on existing pilot plant emission A6. Odour monitoring data detailed below from A6, has informed the BAT assessment.

Key performance criteria

- Provide effective abatement to cover the range of emissions during the batch cycle of BRM based pharmaceutical process (including terpenes abatement plus provide allowance for moisture and particulate emission levels)
- Appropriate abatement for high temperature gas stream during decarboxylation phase
- Process Integration – chosen abatement needs to be able to be integrated with process control.
- Storage room Integration - chosen abatement needs to be able to provide effective abatement for air volume from process (5,200 m3/hour).

The applicant has utilised the following guidance, within their application supplementary information review, in assessing possible BAT measures for final selection:

- EPR 4.02 Speciality Chemicals Guidance
- Manufacture of Organic Fine Chemicals BREF 2006
- Best Available Techniques in Common Waste Water and Waste Gas Treatment / Management Systems in the Chemical Sector February 2003

The BAT option assessment for Odour assessment is provided in appendix D of the application supporting information.

The abatement options the applicant has initially assessed are as follows:

1. **Bio-filtration;** bio-filters are not practical for **hot** gas applications and also tend to be favoured for higher volumetric flows than exist here**.** Suitable for low concentrations of pollutants. Not suitable for large fluctuations in the gas stream composition, with negative impact on filter media.
2. **Bio-scrubbing / bio-trickling;** Well suited to low concentrations of pollutants easily soluble in water. However a disadvantage of these systems is the fluctuations on process emission concentrations lead to significant variation on abatement efficiency performance.
3. **Thermal systems;** a regenerative thermal oxidiser has a theoretically high odour abatement efficiency (>95% odour abatement efficiency). A regenerative unit also required some time to reach optimum operating conditions and is not suitable for regular start up/shutdown scenarios. Such systems can treat air flows of required level. These systems can deal with process fluctuations but would require additional fuel where the VOC concentration is below the auto-ignition temperature.

   Catalytic oxidation systems are more sensitive to process fluctuations, due to lower operating temperatures, than regenerative thermal oxidisers

   Such systems involve a significantly high capital cost.

4. **Flaring;** Such systems can be flexible to handle gas flow variations and can be utilised to abate intermittent or fluctuating waste gas streams.

5. **Ionisation systems;** effective odour control can be achieved by subjecting the gas stream for in situ ionisation. The ozone can be generated either by a corona discharge mechanism (e.g. plasma technology) or by Ultraviolet (UV) irradiation. There are no moving parts in the system.
   Typical odour abatement efficiency levels are 80-95%
   The UV system can handle discontinuous operations, as almost instantaneous to start up and shut down.

Overall conclusion
After above review, only the abatement systems able to cope with fluctuating streams were carried forward to a more detailed options appraisal i.e. thermal oxidation/catalytic oxidation, flaring and UV Photolysis.

Technology Costs
Table 2.4 of the applicant's BAT assessment showed thermal oxidation, catalytic oxidation and flaring have significant higher capital costs and operating costs than UV Photolysis.

Detailed Assessment Criteria:
Each of the technologies has been assessed against the above parameters and assigned a value for 1 for best and 4 for worst, with the technology that performs the best having the lowest overall score.

Parameter	Thermal Oxidiser	Catalytic Oxidiser	Flaring	UV Photolysis
Air Emissions /Odour	2	3	1	3
Energy Use	4	3	2	1
Resource Consumption	3	4	2	1
Global Warming Potential	4	2	3	1
Waste Generation	3	4	1	2
Water Use	3	3	1	1
Accident Risk	3	4	2	1
Noise Risk	2	2	4	1
Operational Complexity	3	4	2	1
Total	**27**	**29**	**18**	**12**

Each of the systems detailed above are capable of achieving in excess of 90 % destruction efficiencies for VOC's and odour. UV Photolysis abatement is lower than flaring but overall ranks as the most effective abatement system after a review of all the above criteria.

UV photolysis systems are extremely reactive in that they can instantly be started up and shutdown. They are linked to both a VOC and ozone monitor, in air stream upstream of abatement, which enables them to optimize odour usage and pollutant abatement efficiency. The applicant is familiar with the operation of these systems, as one is in operation on existing pilot plant facility. The UV photolysis system is a more bespoke application for a range of flows and VOC conditions and best suited for relatively low flow rates as here.

The system needs particulate filtration to protect UV lamps; this is in place with bag filtration and panel filtration in place upstream of UV system.

Odour monitoring data assessment
The final part of BAT assessment and final option selection is the provision of actual odour unit (ou/m3) data from the existing pilot plant process with equivalent UV photolysis abatement
Results

		Average	***Peak***
Unabated Odour Concentration	*OU/m^3*	*Run 1 – 5005* *Run 3 -3663*	*Run 1 – 690 to 19091* *Run 3 – 1328 to 9385*
Abated Emission Stack Odour Concentration	*OU/m^3*	*Below 100.*	

Interpretation
The results show elevated odour levels within unabated emission sample. The abated emissions are below the threshold level of detection for odour panel BS EN 13725 odour unit analysis procedure i.e. < 100 ou/m3. The levels are likely to be in the range of 60 to 100 ou/m3.
As such it is considered that the UV abatement system is effective in providing abatement of this odour stream.

Conclusion
In review of all the above factors within the BAT options assessment the BAT selected option for the odour abatement is UV Photolysis

Odour Management Plan.

The applicant supplied an Odour Management Plan (OMP) linked to new installation with specific emphasis on new production building and pharmaceutical production process. The final version of the OMP was submitted 07/04/15, after multiple versions and comments by ourselves.

The centre of the installation is at National Grid Reference TQ 90010 60370. Overall the Botanical Raw Material has a distinctive smell and this process is one that handles and includes emissions of aromatic compounds and as such requires an Odour Management Plan in line with our EPR 1.00 How to Comply guidance as follows:
"manufacture, use or recovery of compounds containing sulphur, ammonia, amines and amides, aromatic compounds, styrene, pyridine and esters."

OMP content
The applicant OMP covers all the key components required under our H4 Odour Guidance.

The OMP covers

- Site location and introduction. This includes the installation boundary site plan plus description of surrounding area plus an overview of main installation activities and ancillary activities with a summary of raw materials and wastes.
- Risk assessment – review of potential odour sources (table 3 of OMP), pathways and receptors. This includes a list of local sensitive receptors as per table 4 of the OMP and Figure 2 site plan with receptor locations. Table 3 covers risk assessment and a summary of control measures for normal operating and cleaning scenarios. Table 1 gives a full list of Point Source Emissions to Air (A1 to A6) and Table 2 gives a list of main Fugitive Emissions to Air.
- Odour control measures including an overview, measures to prevent odour releases, critical process controls specifically for decarboxylation process, odour abatement systems and local ventilation controls linked to ethanol and waste solvent storage. In addition management controls are detailed including operating procedures, material acceptance procedures, EMS procedures and Accident Management Plan details.
- Odour monitoring; this covers process control monitoring, odour abatement system monitoring, ventilation system monitoring and odour site tours. The applicant has provided a summary of their commissioning monitoring for providing evidence for the effectiveness of process and abatement controls.
- Contingency plans. Table 9 provides a detailed risk assessment of all abnormal operating scenarios with potential for elevated odour pollution. The table provides corrective measures and timeframes for completion
- Complaint procedures.
- OMP review and change control procedures to ensure OMP updated when key changes made.

Further OMP appendices cover

- Appendix A – Installation Layout Plan
- Appendix B – H1 Odour Risk Assessment
- Appendix C – Odour Reporting Form
- Appendix D: Odour Compliant Form
- Appendix E : Ventilation Pressure Cascades.

OMP review
The main potential for odorous emissions is from the decarboxylation phase with the release of mainly terpenes, at the end of each batch during the decarboxylation and evaporation phases as well as the potential for ethanol from the end of each evaporation phase.
The main process controls to prevent the release of odours is that the majority of the odorous compounds will be extracted from the Botanical Raw Material as part of the production process. In addition the process is carried out in enclosed vessels which are only vented at the end of each batch. The timeframe linked to terpenes emissions is approximately no more than 2 hours per batch. The A1 and A6 process emissions pass through UV photo oxidation abatement systems. In addition the process is highly automated to ensure that the process is kept within set point parameters to ensure consistent product quality. The EMS includes procedures for the investigation for any non-conformances and releases.
The applicant is to commence with 2 batches per week and gradually ramp up to 2 batches per day. The applicant will utilise initial 12 months commissioning period at lower production rate to optimise process and abatement control and minimise odorous emissions.

Odour Controls
A summary of odour controls in place are as follows as outlined in section **4** of the OMP.
Prevention

The risk assessment has led to key measures to prevent or minimise odour releases e.g. contained process vessels, sealed IBC's for solvent /waste storage and prevention of overfilling of IBC's by usage of high level alarms

Process Controls

The BRM milling is undertaken in a room in an enclosed building with no extraction or ventilation from this room.

The critical decarboxylation and BRM heating to 115 C, has set point temperature and vessel pressure controls. The decarboxylation step, as all process steps, is controlled by a central Process Control System. The decarboxylation process is controlled via the use of a product temperature transmitter and there is a high temperature trip and process shutdown to minimise risk of elevated odour levels.

Critical process controls linked to temperature, pressure and flow measurement and control are detailed in OMP table 5.
The process has a built in cleaning in place procedure for critical process vessels to prevent built up of BRM and minimise risk of elevated odour levels.

Overall the process equipment is designed to minimise risk of fugitive emission releases with vessel pressure control and monitoring at each stage.

Interlocks

The process is fitted with the following interlocks relevant to odour control

- *Decarboxylation vessel door interlock – to ensure vessel closed prior to processing and hence prevention of accidental release of BRM into room.*
- *Pressure transmitters interlocked to thermal control unit on decarboxylation vessel. Therefore if elevated pressures detected in decarboxylation vessel, heat input to vessel jacket isolated.*
- *UV abatement system interlocked with VOC sensors in upstream ducting to ensure UV lamps operational at all times well VOC levels above monitoring system limit of detection.*
- *Ethanol and waste solvent IBC local exhaust ventilation (lev) systems interlocked with in duct VOC sensors to ensure lev on when process operational.*

The facility abatement controls full details are provided in OMP section 4.2.4. Table 7 of OMP confirms all checks done before batch start up to ensure process and abatement controls are functioning effectively.

Ventilation

General Ventilation

The new production building will be complete with a general ventilation system, as outlined in section 4.2.5 of the OMP. The system design has a pressure balance for each room to both ensure product quality and ensure air flow of any fugitive emissions to the extract duct. The ventilation system is computer controlled with high and low pressure drop alarms across the particulate filters.

Local Exhaust Ventilation (Lev)

Lev systems are included for ethanol and waste solvent storage areas as fugitive emission controls. There is a low flow indicator to alert to lev failures. The lev system is interlocked with VOC sensors to ensure operation when process operates. The details of lev systems are provided in Table 2 of OMP.

Abatement System

The new production facility has a UV Photolysis odour abatement system in the A1 emission, as discussed above in BAT assessment.
The UV lamp arrays (5 lamps per array) are only to be energised during processing periods, these will activate when a signal is received from VOC sensors. This signal is managed by the central Process Control System

The OMP confirms the lamps have a guaranteed operational life of at least 17,000 hours.
The abatement system is to be subject to a preventative maintenance regime, in line with abatement system supplier's guidance. In addition to this the abatement will be subject to a weekly maintenance plant room tour and inspection.

The lamp output is utilised as critical factor to assess abatement effectiveness and when lamps need to be changed. The particulate abatement upstream of UV system ensures particulate removal and optimum UV performance for odour abatement.

In the case of a UV lamp failure, the process goes into a hold state where the plant supervisor decides remedial actions.

Monitoring

Section 5 of the OMP provides detail of facility monitoring linked to odour control.

This monitoring includes:

- Routine Inspection and Site Tours sniff monitoring at site boundary. Weekly site tours and maintenance checks will be carried out and results recorded in line with OMP Appendix C reporting form
- Process monitoring – critical process monitoring linked to odour control are provided in Table 7 of OMP and include BRM raw material weight measurements and process mass balances, ethanol process mass balances, pressure bursting disc detection on Decarboxylation Vessel, Pressure and Temperature monitoring on Decarboxylation Vessel and Local exhaust ventilation fan systems status
- Complaints Monitoring – a compliant procedure is in place and actions recorded in line with OMP appendix D form. Additional site tours will be carried out to ensure source of odour determined and relevant action plans implemented
- Abatement system monitoring – The UV lamp output is monitored by the Process Control System and an alarm activates to alerts to the need to change lamps.
- Stack Monitoring – A1 and A6 Total VOC monitoring will be completed to ensure on-going effectiveness of abatement system performance in addition to commissioning monitoring discussed below

Contingency Plans

All potential abnormal scenarios will be investigated in accordance with EMS reporting and investigation of environmental incident and complaint procedure.

Continuous monitoring of critical process parameters is designed to be able to promptly action corrective measures. Spare parts for critical equipment are maintained on site including a full set of UV lamps.

Table 9 of the OMP lists each potential abnormal operating scenarios, control measures in place to minimise odour risk and remedial actions with timescales to complete.

The critical process steps with risk of elevated odour pollution include the Decarboxylation and Evaporation process steps, spillage of Ethanol, Cleaning in Place step and failure of UV abatement system.

Below are some of highest risk scenarios linked to odour pollution and remedial actions

- Overpressure of Decarboxylation Vessel: The vessel pressure transmitter will trip heat input to vessel heating jacket minimising odorous emissions generation. Equipment inspection would be initiated to ensure corrective actions implanted. Fugitive room emissions would be abated as general ventilation system passes via A1 UV photolysis abatement system.
- Overheating of Decarboxylation Vessel contents: The vessel temperature transmitter linked to Process Control System would target to return Vessel temperature to 115 C set point and otherwise process should go to shutdown mode. The heating jacket as well as vessel temperature has a high temperature alarm and if jacket high temperature exceeded electrical input to jacket cut off. UV abatement system would minimise risk of odour pollution.
- UV abatement system failure. Detailed standard operating procedure for operation of the UV abatement system will be in place. The abatement system is interlocked with VOC sensors to ensure abatement functioning when process operating. The UV system is over-specified with 5 lamps in place, when supplier design is for a minimum of 4 lamps to be functioning for effective abatement. Power output on UV lamps will ensure lamp change at end of relevant batch. With odorous emissions occurring over approximately only 2 hours of 8 hour process batch time and lamp life specified as 17,000 hours chance of unexpected lamp failure is low.

  Table 9 of OMP confirms that no batch will be commenced without UV abatement system functioning correctly.

- *Commissioning Monitoring*
  The applicant will carry out odour stack monitoring to quantity actual final stack odour unit levels during first 12 month commissioning phase. The applicant will complete following parameter monitoring for A1 emission over at least three separate process batches:

  - Odour unit concentration sampling for odour panel analysis
  - Total VOC monitoring
  - Speciated VOC monitoring.

The applicant will be required to submit a detailed commissioning protocol as part of a permit pre-operational condition and improvement program IP1 will require submission of the resultant commissioning report to ensure effective process and abatement controls is achieved in practice.

Further IP2 will ensure the applicant provides a final OMP with long term frequencies of qualitative and quantitative odour monitoring

Conclusion
After our review of the OMP, plus our comments to the applicant to create a final version dated 07/04/15, **we approve the OMP** based on information available at permit variation determination.

The OMP will be updated as part of improvement condition IP2 to cover commissioning experience to optimise operating procedures and confirm final odour monitoring frequency after review of commissioning odour stack monitoring data. At this time we will review the updated OMP and confirm our final approval of the OMP.

4. Fugitive Emissions

A risk assessment was submitted with the application supplementary document including a BAT measures review. This is covered in section 5.3 of main application supplementary document.
In addition with Appendix C of the supplementary application information a H1 annex A) assessment has been completed for all fugitive emissions risks for installation activities. This covers air and water potential emissions plus control measures in place to minimise risk.

Conclusion
The standard fugitive emissions permit conditions have been included in this permit (conditions 3.2.1 and 3.2.2).
Fugitive management controls has been accepted as satisfactory after additional information received.
The Environment Agency considers that the fugitive emissions controls are satisfactory.

5. Accident Management Plan (AMP)

The applicant has provided a summary AMP in their application supporting information Appendix C. In addition section 3 of main application supporting document provides a review of measures to be implanted for accident management control and provide evidence of compliance with BAT requirements as outlined in our "How to comply with your environmental permit." Guidance and EPR 4.02 Speciality Organic Chemicals Guidance.

Within their schedule 5 response they have also clarified the AMP includes the following key procedures

- GE HS 008 Procedure for Dealing with a Spillage in the Production Area
- GE HS 016 Managing Spillages
- GE PR 008 Emergency Shutdown and Re-start Procedure for Production Department Areas and Equipment
- GL HS001 Reporting of Accidents or Near Misses

The final AMP will be in place as part of applicant EMS prior to commencement of commissioning of facility with raw materials.

Conclusion
The standard Accident Management permit conditions have been included in this permit (conditions 1.1.1, 1.1.2 and 1.1.3).
Accident management controls has been accepted as satisfactory after additional information received.
The Environment Agency considers that the fugitive emissions controls are satisfactory.

Annex 2: Consultation

Summary of responses to consultation and the way in which we have taken these into account in the determination process.

Two responses were received as follows:

1. Response received from Public Health England dated 29/12/14
Brief summary of issues raised: Odour, VOC and particulate emissions raised as potential concerns.
Summary of actions taken or show how this has been covered – linked to issues raised above Our response is based on applicant implementation of an Odour Management Plan (OMP) and our review and partial approval of this OMP. We are satisfied that this will control odour. The UV abatement on A1 emission will minimise VOC emissions to atmosphere and H1 assessment has concluded environmental impacts are insignificant. **Equally particulate filtration on A1 emission** will minimise particulate emissions to atmosphere and H1 assessment has concluded environmental impacts are insignificant.

2. Response received from Swale Borough Council 03/12/14
Brief summary of issues raised: Odour emission concerns raised.
Summary of actions taken or show how this has been covered – linked to issues raised above Usage of OMP as discussed above in response 1 is concluded as sufficient to minimise risk of odour emissions from the installation.