ABBVIE BIOCHEMICAL AND MEDICAL DEVICES FACILITY – ASSESSMENT OF COMPLIANCE WITH CONCLUSIONS ON BEST AVAILABLE TECHNIQUES FROM THE BREF FOR THE MANUFACTURE OF FINE ORGANIC CHEMICALS, AUGUST 2006.

The full and complete BREF is available at the EIPPC Bureau website: http://eippcb.jrc.ec.europa.eu/reference/

Conclusions on BAT	Applicability Assessment (describe how the technique applies or not to your installation)	State whether it is in place or state schedule for implementation
5.1 Prevention and minimisation of environmental impact		
5.1.1 Prevention of environmental impact		
5.1.1.1 Integration of environmental, health and safety considerations into process development		
BAT is to provide an auditable trail for the integration of environmental, health and safety considerations into process development (see Section 4.1.6).	Applicable – Environmental, health and safety considerations have been incorporated into the design process of the wider facility through specific Environmental Health & Safety (EHS) design reviews, Atmosphere Explosives (ATEX) reviews, Process Hazard Analysis studies (PHAs), etc. This ensures the process is designed in accordance with the best industry standards. The new bio-chemical suite will be designed in accordance with best practice and relevant sign offs (ATEX, HAZOP, etc) will be required prior to operations.	In Place (or Ongoing). BAT as it applies to the new development will be in place following completion of construction of the suite and grant of the Industrial Emissions (IE) licence.
BAT is to develop new processes as follows: a) to improve process design to maximise the incorporation of all the input materials used into the final product; b) to use substances that possess little or no toxicity to human health and the environment. Substances should be chosen in	Applicable – Product recipes and materials management systems are designed to minimise wastes in both the new and existing facility. Process automation system (a series of smaller controllers at the equipment level) will ensure consistency of operation from batch to batch at each step in the process in both facilities.	In Place (or Ongoing). BAT as it applies to the new development will be in place following completion of

order to minimise the potential for accidents, releases, explosions and fires; c) to avoid the use of auxiliary substances; d) to minimise energy requirements in recognition of the associated environmental and economic impacts. Reactions at ambient temperatures and pressures should be preferred; e) to use renewable feedstock rather than depleting, wherever technically and economically practicable; f) to avoid unnecessary derivatisation (e.g. blocking or protection groups); g) to apply catalytic reagents, which are typically superior to stoichiometric reagents;	A limited number of toxic (R50+ and R60+) substances, used in small quantities, are required in the process however their use will be carefully controlled, and less toxic alternatives/replacements sought in future where possible. No alternative is applicable for cyto-toxic material (R60+) which is an integral ingredient for the production. No toxic substances are required in the manufacturing process in the existing facility. Only a small amount of flammable materials (e.g. Isopropyl Alcohol (IPA) for cleaning, and solvents for printing) will be used. All products are highly controlled. An ATEX report was completed for the new suite and an Explosion Prevention Document will be compiled by AbbVie and put in place for the control of the site once operational. The appropriate ATEX and other safety assessments were also carried out during the development of the existing facility. The ingredients and other raw materials proposed are relatively low risk substances presenting minimal potential for generation of accidents, releases, explosions and fires. The design of the facility including the storage areas, process buildings, pipelines and other areas is such that all potential accident risks are assessed and minimised. The majority of the substances used in the process are not suitable for substitution. In general product reactions are carried out at moderate temperatures and pressures however the exact conditions required are determined by the nature of the biological and chemical materials used in the process. Moulding occurs using temperature and pressure within moulding machines at the existing facility.	construction of the suite and grant of the IE licence.

	The process is aqueous based and as such water is a major component of the production process. The volume of water required in production is restricted by Good Management Practice (GMP) requirements; however, water usage has been reduced across the facility where practical. In the fixed system section in the new facility, water is reduced by utilising low water usage cleaning processes. Water will be sourced from Irish Water. Plastic resin and colouring are the only inputs for the moulding process in the existing facility. The process in each facility has been designed to efficiently use all inputs and minimise waste generation. AbbVie will strive to source from renewable sources where economically practical in future. No un-necessary derivatisation. Process at the new facility primarily involves bio-chemical reactions so limited opportunity to use catalytic reagents (in comparison to a typical chemicals or other facility). There is no opportunity to use catalytic reagents in the existing facility either.	
5.1.1.2 Process safety and prevention of runaway reactions		
5.1.1.2.1 Safety assessment		
BAT is to carry out a structured safety assessment for normal operation and to take into account effects due to deviations of the chemical process and deviations in the operation of the plant. In order to ensure that a process can be controlled adequately, BAT is to apply one or a combination of the following techniques (without ranking): a) organisational measures b) concepts involving control engineering techniques	Applicable – A full programme of PHA studies to cover all process steps including waste treatment has been completed. ATEX and all other relevant safety studies have been included in the design scope. Staff will be fully trained in site procedures including all Standard Operating Procedures (SOPs) and emergency response and safety procedures.	In Place (or Ongoing). BAT as it applies to the new development will be in place following completion of construction of the suite and grant of the IE licence.

c) reaction stoppers (e.g. neutralisation, quenching) d) emergency cooling e) pressure resistant construction f) pressure relief	Control and instrumentation are provided for each process step and evaluated through HAZOP and other reviews where required. There is no exothermic reaction that would require emergency cooling. Pressure rated vessels and pipework are provided where required as specified by AbbVie Engineering Standards. Relief devices have been provided where risks of over-pressure have been identified from the PHA reviews	
5.1.2 Minimisation of environmental impact		
5.1.2.1 Plant design		
BAT is to design new plants in such a way that emissions are minimised by applying techniques including the following: a) using closed and sealed equipment b) closing the production building and ventilating it mechanically c) using inert gas blanketing for process equipment where VOCs are handled d) connecting reactors to one or more condensers for solvent recovery e) connecting condensers to the recovery/abatement system f) using gravity flow instead of pumps (pumps can be an important source of fugitive emissions) g) enabling the segregation and selective treatment of waste water streams h) enabling a high degree of automation by application of a modern process control system in order to ensure a stable and efficient operation.	Applicable – The measures listed have been incorporated into the design of the new suite where applicable. The facility is a GMP process and will be fully enclosed and all equipment sealed in accordance with good engineering practice and relevant GMP standards. The building is ventilated by mechanical systems with air change rates designed to suit the requirements of each specific area within the building. Nitrogen blanketing is not required, as the limited Volatile Organic Compounds (VOCs) used (typically alcohols) are water-diluted. Only small amounts of solvent will be used in the bio-chemical pharma production process. These will be used up by the process and as such solvent recovery is not possible. In the existing facility, solvents are used in printing only which is non-recoverable (evaporates entirely after printing).	In Place (or Ongoing). BAT as it applies to the new development will be in place following completion of construction of the suite and grant of the IE licence.

	Gravity flow systems are used in the process drainage systems, but pumped systems are also required generally in the process to enable process automation systems and ensure maximum efficiency. The process has been designed to segregate low strength wastewater from high high strength waste water and route directly to sewer. Therefore, there will be 3 principal waste water streams – high high strength wastewater (tankered offsite), treated low strength waste water (discharging to foul sewer) and surface water (going to storm drain). The various process control systems will ensure a stable and efficient operation i.e. maximum efficiency and control of the process.	
5.1.2.2 Ground protection and water retention options		
BAT is to design, build, operate and maintain facilities, where substances (usually liquids) which represent a potential risk of contamination of ground and groundwater are handled, in such a way that spill potential is minimised. Facilities have to be sealed, stable and sufficiently resistant against possible mechanical, thermal or chemical stress	Applicable – The facility has been designed to operate as a high containment facility. Chemical storage is limited to bunded tanks, drums stores and designated process areas. Handling and transfer of fuel and chemicals will be carefully controlled. The volume of chemicals stored and the containment measures planned will minimise the risk of release of solid/liquid material spillages to the water environment. All process materials, product and chemicals will be delivered to the site in tamper proof and/or lockable containers or tankers, which are approved for transport use. Storage of hazardous materials on site will be in bunded containers or compartments. All holding/ storage and chemical tanks will be bunded and will be located on a bunded concrete	In Place (or Ongoing). BAT as it applies to the new development will be in place following completion of construction of the suite and grant of the IE licence.

	hard stand. The design of all bunds will conform to standard bunding specifications - BS8007:1987. There is no existing external bunding onsite, only self-bunded chemstores for solvents and hydrocarbons stored in rear yard.	
BAT is to enable leakages to be quickly and reliably recognised	Applicable – Preventative maintenance of all process tank installations, bunds, pipelines etc will be carried out by AbbVie personnel. Integrity testing will be carried out every 3 years as per IE licence. All exterior bunds will have leak detection (level detection) to monitor losses or rainwater build-up should either occur.	BAT as it applies to the new development will be in place following completion of construction of the suite and grant of the IE licence.
BAT is to provide sufficient retention volumes to safely retain spills and leaking substances in order to enable treatment or disposal	Applicable - All bunds have been designed to BS8007 "Code of Practice for design of concrete structures for retaining aqueous liquids" i.e. 110% of the capacity of the largest tank or drum within the bunded area or 25% of the total volume of substances stored within the bund (whichever is the larger). The tanker standing area is bunded and any leakage in this area will flow back into the waste tank bunded area.	BAT as it applies to the new development will be in place following completion of construction of the suite and grant of the IE licence.
BAT is to provide sufficient retention volume to safely retain firefighting water and contaminated surface water	Applicable – Firewater from the bio-chemical production suite will be contained in the combined wastewater bund as per the firewater risk assessment.	BAT as it applies to the new development will be in place following completion of construction of the suite and grant of the IE licence.
BAT is to apply all the following techniques: a) carrying out loading and unloading only in designated areas protected against leakage run-off	Applicable – All techniques will be in place at the facility. Loading/unloading will be carried out in designated areas with impermeable surfaces in the event of a spill. The diesel tank for	In Place (or Ongoing). BAT as it applies to the new development will be

b) storing and collecting materials awaiting disposal in designated areas protected against leakage run-off c) fitting all pump sumps or other treatment plant chambers from which spillage might occur with high liquid level alarms or regularly supervising pump sumps by personnel instead d) establishing programmes for testing and inspecting tanks and pipelines including flanges and valves e) providing spill control equipment, such as containment booms and suitable absorbent material f) testing and demonstrating the integrity of bunds g) equipping tanks with overfill prevention.	the emergency generators will be a double lined belly tank with leak detection. Any spill during delivery would be on the hardstand and would be captured by the hydrocarbon interceptor. A waste management SOP will provide for segregation of hazardous wastes, flammable wastes (e.g. lab solvents) and general wastes. Bund and pipeline testing using a hydraulic test to be undertaken at least every 3 years and included in the annual environmental report for the site. Use of flanges is minimised. Pipework is generally constructed with welded joints. A programme of preventative maintenance procedures in combination with regular visual inspections will identify potential issues and ensure they are remedied as required. Spill kits to be provided at suitable locations prior to commencement of operations Wastewater bulk tanks will be bunded – the bunds are chemical resistant and are equipped with level detection. In the event of a spillage, the spillage would be pumped to the appropriate storage tank and tested. High high strength waste will be collected in a bunded sunken bulk storage tank and will be highly controlled through facility SOPs.	in place following completion of construction of the suite and grant of the IE licence.

5.1.2.3 Minimisation of VOC emissions		
5.1.2.3.1 Enclosure of sources		
BAT is to contain and enclose sources and to close any openings in order to minimise uncontrolled emissions.	Applicable - Solvents used in cleaning (IPA), used as 70% IPA in pre-wetted wipes and 99.7% and 70% IPA in spray bottles, will be used for cleaning and sterilising production surfaces after use. IPA will be stored internally in sealed wipes packaging in the Warehouse until used. Di-methyl alcohol (DMA) and di-methyl sulfoxide (DMSO) will be used for dilution of the toxin for Monoclonal Antibody (MAB) conjugation in small quantities (6-12L). 100% DMA will be delivered to site in sealed 5L, 15L or 25L bottles and will be stored within the designated flammables area of the Warehouse. DMA will be pumped directly to the conjugation suite using a peristaltic pump and single use tubing. Glacial acetic acid required in small quantities as part of the buffer solution formulation will be stored in sealed containers (1L bottles) in the Warehouse prior to use. These will be dispensed directly into the buffer solution within an air-controlled environment. Within the existing processes, the anticipated solvent usage will include solvents used in printing onto medical devices. Solvents used in printing are stored in sealed containers in locked cabinets until use. The volumes used are not significant and there are no significant fugitive emissions requiring abatement.	In Place (or Ongoing). BAT as it applies to the new development will be in place following completion of construction of the suite and grant of the IE licence.
5.1.2.3.2 Drying in closed circuits		
BAT is to carry out drying by using closed circuits, including condensers for solvent recovery.	Not Applicable – No drying/solvent recovery required for new suite or the existing facility.	N/A

5.1.2.3.3 Equipment cleaning using solvents In Place		
BAT is to keep equipment closed for rinsing and cleaning with solvents.	Applicable – Cleaning of the main process areas will be done using IPA impregnated wipes in air-locked production rooms. Spent IPA wipes will be stored in sealed flammable waste containers for disposal.	In Place (or Ongoing). BAT as it applies to the new development will be in place following completion of construction of the suite and grant of the IE licence.
5.1.2.3.4 Recirculation of process vents		
BAT is to use recirculation of process vapours where purity requirements allow this.	Not applicable – new process in water-based process. Solvents only used for surface cleaning and sterilisation or in very small quantities in solution prep. Volatiles are generally supplied to site in small volume bottles therefore no balancing required. 100% DMA and DMSO will be stored in 5L, 15L or 25L bottles (for conjugation) and will be stored within the designated flammables area of the Warehouse. At the existing facility, volatiles are generally supplied in small volume containers (1L containers) and will be stored in a designated solvent storage area.	N/A
5.1.2.4 Minimisation of exhaust gas volume flows and loads		
5.1.2.4.1 Closure of openings		
BAT is to close any unnecessary openings in order to prevent air being sucked to the gas collection system via the process equipment.	Not Applicable – no exhaust gas collection from the process. Minor emissions from the process only (e.g. process vents, autoclave vents, lyo vents)	N/A
5.1.2.4.2 Testing the airtightness of process equipment		
BAT is to ensure the airtightness of process equipment, especially of vessels	Not Applicable – no exhaust gases produced from production. Fixed vessels are typically pressure tested as part of their cleaning-in-place cycle to validate their air-tightness.	N/A

5.1.2.4.3 Inertisation		
BAT is to apply shock inertisation instead of continuous inertisation	Not Applicable – no requirement for inertisation	N/A
5.1.2.4.4 Minimisation of exhaust gas volume flows from distillations		
BAT is to minimise the exhaust gas volume flows from distillations by optimising the layout of the condenser.	Not Applicable – no distillation	N/A
5.1.2.4.5 Liquid additions into vessels		
BAT is to carry out liquid addition to vessels as bottom feed or with dip-leg, unless reaction chemistry and/or safety considerations make it impractical. In such cases, the addition of liquid as top feed with a pipe directed to the wall reduces splashing and hence, the organic load in the displaced gas. If both solids and an organic liquid are added to a vessel, BAT is to use solids as a blanket in circumstances where the density difference promotes the reduction of the organic load in the displaced gas, unless reaction chemistry and/or safety considerations make it impractical.	Not Applicable - Process liquids are non-volatile and therefore no need for special addition processes. Solids generally added via closed addition system to vessels already pre-charged with liquid (mostly Water for Injection). Closed design of system minimises displacement of gas.	N/A
5.1.2.4.6 Minimisation of peak emission concentrations		
BAT is to minimise the accumulation of peak loads and flows and related emission concentration peaks by, e.g. a) optimisation of the production matrix; b) application of smoothing filters.	Not Applicable – no exhaust gas abatement system required	N/A

5.1.2.5 Minimisation of volume and load of waste water streams		
5.1.2.5.1 Mother liquors with high salt content		
BAT is to avoid mother liquors with high salt content or to enable the work-up of mother liquors by the application of alternative separation techniques, e.g. a) membrane processes b) solvent-based processes c) reactive extraction d) or to omit intermediate isolation.	Applicable - Process completed at the facility is subject to process recipe requirements and GMP regulations however high salt content will be minimised where practicable. Wastewaters from both the new and the existing facility will not contain solvents and all high high strength wastewater in the new facility will be stored in the high high strength wastewater tank and tankered offsite.	In Place (or Ongoing). BAT as it applies to the new development will be in place following completion of construction of the suite and grant of the IE licence.
5.1.2.5.2 Counter-current product washing		
BAT is to apply counter-current product washing where the production scale justifies the introduction of the technique.	Not applicable – very small production scale so not justified.	N/A
5.1.2.5.3 Water-free vacuum generation		
BAT is to apply water-free vacuum generation.	Applicable – Water free vacuum pumps used in new production suite. Autoclaves use closed loop water seal (i.e. full recirculation)	BAT as it applies to the new development will be in place following completion of construction of the suite and grant of the IE licence.
5.1.2.5.4 Determination of the completion of reactions		
For batch processes, BAT is to establish clear procedures for the determination of the desired end point of the reaction.	Applicable – vessel contents are sampled and analysed continuously to determine end-point of bio-chemical reaction (new suite);	BAT as it applies to the new development will be in place following completion of construction of the

		suite and grant of the IE licence.
5.1.2.5.5 Indirect cooling		
BAT is to apply indirect cooling.	Applicable –20% Propylene glycol will be used in the jackets of the temperature control units.	BAT as it applies to the new development will be in place following completion of construction of the suite and grant of the IE licence.
5.1.2.5.6 Cleaning		
BAT is to apply a pre-rinsing step prior to rinsing/cleaning of equipment to minimise organic loads in wash-waters.	Applicable – pre-rinsing with water in place prior to CIP for new production suite.	BAT as it applies to the new development will be in place following completion of construction of the suite and grant of the IE licence.
5.1.2.6 Minimisation of energy consumption		
BAT is to assess the options and to optimise the energy consumption.	Applicable – AbbVie have an Energy Management System which incorporates the relative policies and operating and monitoring procedures required under BAT. Energy efficient design was applied in the design of the new facility and further details are provided in Section 9 of the IE licence application. Building automation and metering will be in place. All equipment is to be used as required only. AbbVie also maintain an EHS & Energy Sustainability Long Range Plan which sets out targets for energy efficiency and persons responsible for monitoring and measuring those targets and	In Place (or Ongoing). BAT as it applies to the new development will be in place following completion of construction of the suite and grant of the IE licence.

	documenting successes. This document includes short term and long-term targets. AbbVie has established Environmental Health & Safety (EHS) management requirements that conform to the ISO14001, ISO 50001, ISO 55001 and OHSAS18001 management system standards.	
5.2 Management and treatment of waste streams		
5.2.1 Mass balances and process waste stream analysis		
5.2.1.1.1 Mass balances		
BAT is to establish mass balances for VOCs (including CHCs), TOC or COD, AOX or EOX and heavy metals on a yearly basis	Applicable – to be completed annually and provided in AER for wastewater (Chemical Oxygen Demand (COD)/ Biochemical Oxygen Demand (BOD) only).	BAT as it applies to the new development will be in place following completion of construction of the suite and grant of the IE licence.
5.2.1.1.2 Waste stream analysis		
BAT is to carry out a detailed waste stream analysis in order to identify the origin of the waste stream and a basic data set to enable management and suitable treatment of exhaust gases, waste water streams and solid residues.	Applicable –All wastes will be tracked and emissions to sewer will be tracked and tested annually. A mass balance will be completed annually as part of the Annual Environmental Report (AER).	In Place (or Ongoing). BAT as it applies to the new development will be in place following completion of construction of the suite and grant of the IE licence.

5.2.1.1.3 Assessment of waste water streams		
BAT is to assess at least the parameters given in Table 5.1 for waste water streams, unless the parameter can be seen as irrelevant from a scientific point of view.	Applicable – Wastewater discharged from the site into the foul sewer will be monitored for pH, flow and temperature with a continuous monitoring system. Other parameters to be monitored in accordance with the IE licence for the facility.	In Place (or Ongoing). BAT as it applies to the new development will be in place following completion of construction of the suite and grant of the IE licence.
5.2.1.1.4 Monitoring of emissions to air		
For emissions to air, BAT is to monitor the emission profile which reflects the operational mode of the production process. In the case of a non-oxidative abatement/recovery system, BAT is to apply a continuous monitoring system (e.g. FID), where exhaust gases from various processes are treated in a central recovery/abatement system. BAT is to individually monitor substances with ecotoxicological potential if such substances are released.	Not applicable – no major process emissions to air (boiler emissions only).	N/A
5.2.1.1.5 Assessment of individual volume flows		
BAT is to assess individual exhaust gas volume flows from process equipment to recovery/abatement systems.	Not applicable – No exhaust gas abatement required	N/A
5.2.2 Re-use of solvents		
BAT is to re-use solvents as far as purity requirements (e.g. requirements according to cGMP) allow, by: a) using the solvent from previous batches of a production campaign for future batches as far as purity requirements allow b) collecting spent solvents for on-site or off-site purification and re-use	Applicable - The process will be predominantly water based and uses a small amount of solvent. Spent solvents from laboratory and production area cleaning will be collected and sent for disposal/recovery with specialist contractors.	In Place (or Ongoing). BAT as it applies to the new development will be in place following completion of construction of the

c) collecting spent solvents for on-site or off-site utilisation of the calorific value	Solvents are used as required in the existing facility. Spent solvents from the production area cleaning are collected and sent for disposal/recovery with specialist contractors.	suite and grant of the IE licence.
5.2.3 Treatment of exhaust gases		
5.2.3.1 Selection of VOC recovery/abatement techniques and achievable emission levels		
5.2.3.1.1 Selection of VOC and recovery abatement techniques		
BAT is to select VOC recovery and abatement techniques according to the flow scheme in Figure 5.1 of the BREF document.	Not applicable – No exhaust gas abatement required	N/A
5.2.3.1.2 Non-oxidative VOC recovery and abatement techniques		
BAT is to reduce emissions to the levels given in Table 5.2 of the BREF document where non-oxidative VOC recovery or abatement techniques are applied	Not applicable – No exhaust gas abatement required	N/A
5.2.3.1.3 VOC abatement by thermal oxidation/incineration and catalytic oxidation		
BAT is to reduce VOC emissions to the levels given in Table 5.3 where thermal oxidation/incineration or catalytic oxidation are applied.	Not applicable – No exhaust gas abatement required	N/A
5.2.3.2 Recovery/abatement of NOX		
5.2.3.2.1 NOX from thermal oxidation/incineration or catalytic oxidation		
For thermal oxidation/incineration or catalytic oxidation, BAT is to achieve the NOX emission levels given in Table 5.5 of the BREF document and, where necessary, to apply a DeNOX system (e.g. SCR or SNCR) or two stage combustion to achieve such levels.	Not applicable – No exhaust gas abatement required	N/A

5.2.3.2.2 NOX from chemical processes		
For exhaust gases from chemical production processes, BAT is to achieve the NOX emission levels given in Table 5.5 and, where necessary to apply treatment techniques such as scrubbing or scrubber cascades with scrubber media such as H2O and/or H2O2 to achieve such levels.	Not applicable – No exhaust gas abatement required	N/A
5.2.3.3 Recovery/abatement of HCl, Cl2 and HBr/Br2		
BAT is to achieve HCl emission levels of 0.2 – 7.5 mg/m3 or 0.001 – 0.08 kg/hour and, where necessary, to apply of one or more scrubbers using scrubbing media such as H2O or NaOH in order to achieve such levels.	Not applicable – No exhaust gas abatement required	N/A
BAT is to achieve Cl2 emission levels of 0.1 – 1 mg/m3 and, where necessary, to apply techniques such as absorption of the excess chlorine and/or scrubbing with scrubbing media such as NaHSO3 in order to achieve such levels.	Not applicable – No exhaust gas abatement required	N/A
BAT is to achieve HBr emission levels <1mg / m³ and, where necessary, to apply scrubbing with scrubbing media such as H2O or NaOH in order to achieve such levels.	Not applicable – No exhaust gas abatement required	N/A
5.2.3.4 NH3 emission levels		
5.2.3.4.1 Removal of NH3 from exhaust gases		
BAT is to achieve NH3 emission levels of 0.1 – 10 mg/m3 or 0.001 – 0.1 kg/hour and, where necessary, to apply scrubbing with scrubbing media such as H2O or acid in order to achieve such levels (see Section 4.3.5.20).	Not applicable – No exhaust gas abatement required	N/A
5.2.3.4.2 NH3 slip from DeNOX		
BAT is to achieve NH3 slip levels from SCR or SNCR of<2mg/m3 or <0.02kg/hour	Not applicable – No exhaust gas abatement required	N/A

5.2.3.5 Removal of SOx from exhaust gases		
BAT is to achieve SOx emission levels of 1 – 15 mg/m3 or 0.001 – 0.1 kg/hour and, where necessary, to apply scrubbing with scrubbing media such as H2O or NaOH in order to achieve such levels.	Not applicable – No exhaust gas abatement required	N/A
5.2.3.6 Removal of particulates from exhaust gases		
BAT is to achieve particulate emission levels of 0.05 – 5 mg/m3 or 0.001 – 0.1 kg/hour and, where necessary, to apply techniques such as bag filters, fabric filters, cyclones, scrubbing, or wet electrostatic precipitation (WESP) in order to achieve such levels (see Section 4.3.5.22).	Not applicable – No exhaust gas abatement required	N/A
5.2.3.7 Removal of free cyanides from exhaust gases		
BAT is to remove free cyanides from exhaust gases, and to achieve a waste gas emission level of 1 mg/m3 or 3 g/hour as HCN (see Section 4.3.6.2).	Not applicable – No exhaust gas abatement required	N/A
5.2.4 Management and treatment of waste water streams		
5.2.4.1 Typical waste water streams for segregation, pre-treatment or disposal		
5.2.4.1.1 Mother liquors from halogenation and sulphochlorination		
BAT is to segregate and pre-treat or dispose of mother liquors from halogenations and sulphochlorinations (see Sections 4.3.2.5, 4.3.2.10).	Not applicable - No halogenation reactions in the process	N/A
5.2.4.1.2 Waste water streams containing biologically active substances		
BAT is to pre-treat waste water streams containing biologically active substances at levels which could pose a risk either to a subsequent waste water treatment or to the receiving environment after discharge (see Sections 4.3.2.6, 4.3.7.5, 4.3.7.9, 4.3.8.13 and 4.3.8.18).	Applicable – High high strength wastewater containing cyto-toxic material will be collected in a controlled double contained polypropylene pipe system including a bunded storage tank which will be emptied and tankered offsite for incineration.	BAT as it applies to the new development will be in place following completion of construction of the suite and grant of the IE licence.

5.2.4.1.3 Spent acids from sulphonations or nitrations		
BAT is to segregate and collect separately spent acids, e.g. from sulphonations or nitrations for on-site or off-site recovery or to apply BAT given in 5.2.4.2 (see Sections 4.3.2.6, 4.3.2.8).	Not applicable – No sulphonations or nitrations as part of site processes. Acids are used in wastewater treatment for pH adjustment and are thus consumed.	N/A
5.2.4.2 Treatment of waste water streams with relevant refractory organic load		
5.2.4.2.1 Relevant refractory organic loading		
For the purposes of pre-treatment, BAT is to classify organic loading as follows: Refractory organic loading is not relevant if the waste water stream shows a bio eliminability of greater than about 80 – 90 % (see Sections 4.3.7.6, 4.3.7.7, 4.3.7.8). In cases with lower bio eliminability, the refractory organic loading is not relevant if it is lower than the range of about 7.5 – 40 kg TOC per batch or per day (see Sections 4.3.7.10, 4.3.7.12 and 4.3.7.13).	Not applicable – no significant refractory organic loads	N/A.
5.2.4.2.2 Segregation and pre-treatment		
BAT is to segregate and pre-treat waste water streams containing relevant refractory organic loadings according to the criteria given in Section 5.2.4.2.1.	Not applicable – no significant refractory organic loads	N/A.
5.2.4.2.3 Overall COD elimination		
For the segregated waste water streams carrying a relevant refractory organic load according to Section 5.2.4.2.1, BAT is to achieve overall COD elimination rates for the combination of pre-treatment and biological treatment of >95 % (see Section 4.3.8.9).	Not applicable – no significant refractory organic loads	N/A.
5.2.4.3 Removal of solvents from waste water streams		
BAT is to recover solvents from waste water streams for on-site or off-site reuse, using techniques such as stripping, distillation/rectification, extraction or combinations of such	Applicable – limited solvent usage and therefore solvent only present in very low concentrations in aqueous residues (i.e. IPA	N/A

techniques, where the costs for biological treatment and purchase of fresh solvents are higher than the costs for recovery and purification (see Section 4.3.7.18). BAT is to recover solvents from waste water streams in order to use the calorific value if the energy balance shows that overall natural fuel can be substituted (see Section 4.3.5.7).	from equipment and facility cleaning) in both the new and existing facility. No recovery feasible.	
5.2.4.4 Removal of halogenated compounds from waste water streams		
5.2.4.4.1 Removal of purgeable chlorinated hydrocarbons		
BAT is to remove purgeable CHCs from waste water streams, e.g. by stripping, rectification or extraction and to achieve sum concentrations.	Not applicable - no CHC in the process.	N/A.
5.2.4.4.2 Pre-treatment of waste water streams containing AOX		
BAT is to pre-treat waste water streams with significant AOX loads and to achieve the AOX levels given in Table 5.6 in the inlet to the on-site biological WWTP or in the inlet to the municipal sewerage system (see Section 4.3.7.14).	Not applicable - no AOX in the process.	N/A
5.2.4.5 Pre-treatment of waste water streams containing heavy metals		
BAT is to pre-treat waste water streams containing significant levels of heavy metals or heavy metal compounds from processes where they are used deliberately and to achieve the heavy metal concentrations given in Table 5.7 in the inlet to the on-site biological WWTP or in the inlet to the municipal sewerage system (see Section 4.3.7.22).	Not applicable - no heavy metals used/generated in the process.	N/A
5.2.4.6 Destruction of free cyanides		
BAT is to recondition waste water streams containing free cyanides in order to substitute raw materials where technically possible (see Section 4.3.6.2). BAT is to: a) pre-treat waste water streams containing significant loads of cyanides and to achieve a cyanide level of 1 mg/l or lower in the treated waste water stream (see Section 4.3.6.2) or to b) enable safe degradation in a biological WWTP (see Section 4.3.6.2).	Not applicable – no cyanides in the process.	N/A

5.2.4.7 Biological waste water treatment		
After the application of BAT given in Sections 5.2.4.1, 5.2.4.2, 5.2.4.3, 5.2.4.4 and 5.2.4.5 (management and treatment of waste water streams), BAT is to treat effluents containing a relevant organic load, such as waste water streams from production processes, rinsing and cleaning water, in a biological WWTP (see Sections 4.3.8.6 and 4.3.8.10).	Applicable – Wastewater will be treated by biological treatment in the local authority wastewater treatment plant (WWTP) which is considered sufficient to treat the wastewater to BAT. The local authority WWTP has a higher BOD and is more equipped to deal with Nitrogen and Phosphorus removal.	In Place (or Ongoing). BAT as it applies to the new development will be in place following completion of construction of the suite and grant of the IE licence.
5.2.4.7.1 On-site and joint treatment		
BAT is to ensure that the elimination in a joint waste water treatment is overall not poorer than in the case of on-site treatment. This is realised by regular degradability/bio eliminability testing (see Section 4.3.8.5).	Applicable – An assessment on the equivalent level of treatment provided by the offsite WWTP is provided in Attachment 7.3.2. Irish Water have confirmed that the WWTP have sufficient capacity to treat the wastewater stream and its components as outlined in Attachment 7.3.1.	In Place (or Ongoing). BAT as it applies to the new development will be in place following completion of construction of the suite and grant of the IE licence.
5.2.4.7.2 Elimination rates and emission levels		
BAT is to take full advantage of the biological degradation potential of the total effluent and to achieve BOD elimination rates above 99 % and yearly average BOD emission levels of 1 – 18 mg/l. The levels relate to the effluent after biological treatment without dilution, e.g. by mixing with cooling water (see Section 4.3.8.11). BAT is to achieve the emission levels given in Table 5.8.	Applicable – BOD will be treated by the local authority WWTP and treated wastewater will be discharged to the receiving waterbody in accordance with the Emission Limit Values (ELVs) in their EPA licence.	In Place (or Ongoing). BAT as it applies to the new development will be in place following completion of construction of the suite and grant of the IE licence.

5.2.4.8 Monitoring of the total effluent		
BAT is to regularly monitor the total effluent to and from the biological WWTP measuring at least the parameters given in Table 5.1. (see Section 4.3.8.21).	Applicable – Monitoring of the wastewater from the proposed facility will be completed by AbbVie in accordance with the requirements of their licence. Monitoring from the offsite biological WWTP will be undertaken by Irish Water in accordance with their discharge licence.	In Place (or Ongoing). BAT as it applies to the new development will be in place following completion of construction of the suite and grant of the IE licence.
5.2.4.8.1 Biomonitoring		
BAT is to carry out regular biomonitoring of the total effluent after the biological WWTP where substances with ecotoxicological potential are handled or produced with or without intention (for examples, see Sections 4.3.8.18 and 4.3.8.19).	Not Applicable – Biological treatment will be undertaken offsite. Bio-monitoring will be undertaken by Irish Water in accordance with the requirements of their discharge licence.	N/A
5.2.4.8.2 Online toxicity monitoring		
BAT is to apply online toxicity monitoring in combination with online TOC measurement if residual acute toxicity is identified as a concern, for examples see Sections 4.3.8.7 and 4.3.8.20.	Not Applicable –Toxicity monitoring may be undertaken as required; however, it is unlikely that residual acute toxicity will be a concern.	N/A
5.3 Environmental management		
BAT is to implement and adhere to an Environmental Management System (EMS) that incorporates, as appropriate to individual circumstances, the following features: • definition of an environmental policy for the installation by top management (commitment of the top management is regarded as a precondition for a successful application of other features of the EMS) • planning and establishing the necessary procedures • implementation of the procedures, paying particular attention to – structure and responsibility – training, awareness and competence – communication – employee involvement – documentation – efficient process control – maintenance	Applicable – The facility is operated in accordance with an Environmental Management System (EMS) which will be amended to account for the new bio-chemical suite and in accordance with the existing IE licence requirements. This is to ISO 14001 standard.	In Place (or Ongoing). BAT as it applies to the new development will be in place following completion of construction of the suite and grant of the IE licence.

programme – emergency preparedness and response – safeguarding compliance with environmental legislation. • checking performance and taking corrective action, paying particular attention to – monitoring and measurement (see also the Reference document on Monitoring of Emissions) – corrective and preventive action – maintenance of records – independent (where practicable) internal auditing in order to determine whether or not the environmental management system conforms to planned arrangements and has been properly implemented and maintained. • review by top management.		