



**OFFICE OF
LICENSING &
GUIDANCE**

INSPECTORS REPORT ON A LICENCE APPLICATION

To:	Directors	
From:	Kevin Motherway	- LICENSING UNIT
Date:	05/09/2007	
RE:	Application for review of an IPPC Licence from Corden Pharma Limited, Wallingstown, Little Island, Co.Cork. Licence Register P0134-03	

Application Details	
Class of activity: 5.16	<i>The use of a chemical process for the production of basic pharmaceutical products</i>
Licence application received:	19/10/2006
Supplementary material submitted by licensee	
Notices under Section 90 issued:	21/5/2007
Information under Section 90 received:	19/6/2007
Submissions received:	Section 99(E) 25/5/2007
Site visits:	28/7/2006,

Company

Corden Pharma Limited (trading as Corden Pharmachem) is a manufacturer of active pharmaceutical ingredients (APIs) and intermediates for generic and manufacturing markets. As such they manufacture a wide range of products on varying scales of production.

Corden Pharma Limited is the new owner of a long-established manufacturing installation at Wallingstown. The company was originally established in 1974 as Irish Fher Limited on the 8 ha site. In 1992 the company was acquired by private

investors and was renamed Irotec Laboratories Ltd. In 1999 the company commissioned a new API manufacturing plant known as PB2 (Production Building 2), which doubled the installation manufacturing capacity. In 1999 Cambrex acquired Irotec Laboratories Ltd. with the company changing its name to Cambrex Profarmaco Cork in October 2002 and subsequently to Cambrex Cork Ltd. Cambrex Cork Ltd. were purchased by International Chemical Investors Group in November 2006 and changed its name to Corden Pharma Limited in January 2007, with a trading name of Corden Pharmachem currently in use.

The infrastructure has developed steadily over the years with 50% of the 8ha site now developed. The site infrastructure now comprises: Production Building 1 (PB1), Production Building 2 (PB2), an administration and laboratory building, a social building, and miscellaneous site infrastructure including a WWTP, two boilers and a thermal oxidiser. The total reactor capacity on-site is 34.6 m³ (18.9 m³ for PB1 and 15.7 m³ for PB2).

The installation is located in industrial-zoned land in the Little Island area and is near several other IPPC licensed installations. The nearest sensitive receptors to the site are the St. Lappan's Housing Estate (c. 400m to the northwest) and the local National School (c. 250m to the north) and Cork Golf Club, which bounds the east of the installation.

The most recent planning permission for the installation dates from 14/5/2003 and relates to the retention of several prefabricated buildings used for offices, an electrical switching room, laboratory stores and a control room.

The number of staff employed at the installation is normally 105 people, with a complement of 101 people at the time of the application. The plant operates on 3-cycle, 24-hour basis, Monday to Friday and is normally closed at the weekend.

Reason for Licence Review

The original licence for the installation (P0134-01) was granted in 1997. A first licence review (P0134-02) was undertaken in 1999 when PB2 was commissioned. This licence review is required to bring the site into compliance with the IPPC directive, with the class of the licence changing from Class 5.6 (EPA Act 1992) to Class 5.16 (PoE Act 2003).

Process Description

The installation has a total of 16 reactor vessels, which are highly flexible in terms of the temperature and pressure environments they can sustain, allowing the installation to manufacture a wide range of products. The manufacturing process consists of charging the reactor vessels with pharmaceutical ingredients and solvents, allowing reactions to occur, followed by centrifuging, drying and milling of the resulting product. Product is then packaged in drums and sent off-site to customers for further processing, tableting, etc. The principal chemicals used in quantity on-site are toluene, Ethyl Acetate, Acetone, THF, isopropyl alcohol, petroleum ether and NaOH.

Air and water emissions arise primarily from the manufacturing process. Solvent emissions occur during the charging of the vessels, during reactions and emptying of the reactants. Water emissions occur from the liquid portion of the reactor

residue, centrifuging of reactants, from caustic and acidic scrubbers and general wash water used in the installation. Noise emissions are also generated by the operation of the installation.

Emissions

Air

The main emission to Air

There are 6 main emission points to air (4 emission points specified in the application with a further 2 “minor” emission points that are more appropriately classed as main emission points. The emission points are associated with HVAC/air handling units used to manage air in the production buildings and a thermal oxidiser used to abate VOCs arising. All air emission from the reactor vessels on-site are directed to acidic/caustic scrubbers and then to a catalytic regenerative thermal oxidiser. It should be noted that the licensee has renumbered their emission points in accordance with the guidance note with a table and revised drawings included in the application.

The six main emission points to Air are:

A2/1 Thermal Oxidiser(TO). (Formerly A1/2)

This abatement measure is designed to destroy water immiscible solvents (e.g. toluene, ethyl acetate), which have not been captured by the scrubber system. The TO is of catalytic type and destroys VOCs at temperatures below 450°C. The load on the TO is quite low (average load 4.6 g/hr) with a maximum hourly flow rate of 5,000 m³/hr. There have been numerous bypasses direct to atmosphere, via bypass vent A4/32 (122 between July –December 2006) due to Lower Explosive Limit (LEL) being exceeded, but predominantly due to low bed temperature (41%) and valve/mechanical failures (21%). The licensee is continuing to investigate the issue in conjunction with the manufacturer and have liaised throughout the process with OEE. A retrofit to resolve the issue was carried out during the company’s annual shut-down in July 2007 and initial indications are that no low temperature bypasses have occurred since. The OEE are concerned with the issue and are seeking to have it resolved as soon as possible. Licence P0134-02 specified that a continuous TOC meter be used to monitor emissions from the TO, in conjunction with monthly sampling of VOCs. The licensee has reported metered TOC values as THC values with a maximum loading of 0.09 kg/hr at a maximum emission level of 63 mg/m³. The licensee has stated that the manufacturers specifications for the THC meter state that the THC level is equivalent to TOC and this has been confirmed after consultation with air experts in the Agency. This matter has been noted with the OEE inspector. When the TO is functioning correctly emissions are well below the ELVs set out in P0134-02 (derived from the 1996 Batneec note) and air dispersion modelling submitted as part of the application has demonstrated the very low impact the TO is estimated to have on the local air quality even when on bypass. No ELV was set for TOC in the previous licence and in line with other installations with TOs being reviewed, it is appropriate that such a limit be set. Given the low loading on the TO, it should comfortably meet the TOC limit as specified in the May 2007 Draft BAT note for the activity and this has been applied in the RD for when the TO is functioning properly, with the current emission limit value to be applied when the TO is on bypass. This will mean that the licensee will continue to meet the current applicable standard, while being required to meet the standard for TOC that a new installation would be expected to meet, when the TO is operating correctly. The licensee will be required to notify the Agency of any bypass

incident and under Condition 9.3 will be required to put in place measures to avoid reoccurrence of any such incident.

A2/2 Air Handling Unit (formerly A1/3) Deduster in PB1 Dryer Loading Area HEPA handling 6,200 m³/hr

A2/3 Air Handling Unit (formerly A1/4) Deduster in PB1 Dryer Loading Area HEPA filter handling 6,200 m³/hr

A2/4 Air Handling Unit (formerly A1/5) Deduster in PB1 Dryer Loading Area handling 20,520 m³/hr

The Nature and volume of emissions from the above air-handling units for the PB1 Dryer loading/unloading area are unchanged and the levels set in the RD are already consistent with the May 2007 Draft BAT note.

Air Handling Unit A2/5 (Applied for as A3/10 formerly A2/10) handling 7,500 m³/h from PB1.

This room air emission from PB1 was classed as a minor emission in P0134-02 (with no ELV, specified control parameters or monitoring set) and has a scrubber employed as abatement. However the licensee has supplied monthly monitoring data from 2004-2006 for TA Luft Class I, II and III organics that show emission levels significantly above 20% of the emission limit specified in 1996 Batneec Note. The RD renames this point as A2/5 (to reflect that it is a main (A2/X) and not a minor (A3/X) emission point and requires continued monitoring, with the relevant BAT emission limit imposed. It should be noted that air dispersion modelling has shown that the current emission levels are not having a significant impact on air quality.

HVAC Unit A2/6 (Applied for A3/17 was A2/17) HVAC Unit HEPA filtered Air Exhaust handling 50,000 m³/h from PB2.

This room air emission from PB2 was classed as a minor emission in P0134-02 (with an ELV, specified control parameters and monitoring set) and employs a HEPA filter as abatement. In error the hourly and daily flow rates specified in P0134-02 were 200 m³/hr and 1,600 m³/day (8-hour day) respectively when the actual; values are 50,000 m³/hr and 1,200,000 m³/day (24-hour day). This total air volume is in line with the volume of air being moved by the Air handling units in PB1. These flow rates are corrected in the RD.

The licensee has supplied monthly monitoring data from 2004-2006 for TA Luft Class I, II and III organics that show emission levels significantly above 20% of the emission limit values specified in 1996 Batneec Note and therefore should be classed as a main emission point. The RD renames this point as A2/6. and requires continued monitoring, with the relevant BAT emission limit imposed. It should be noted that air dispersion modelling has shown that the current emission levels are not having a significant impact on air quality.

Boiler emissions

There are two 2.5 MW Natural Gas boilers on-site with stacks A1/1 (formerly (A1/1) and A1/2 (formerly A1/6). One boiler is operated on duty and the other on cold standby. The licensee wishes to have the provision to use Gas Oil as a back up fuel, should it be required, with a condition allowing this specified in the RD. Given their size and current use of natural gas fuel, the boilers are classed as minor emission, with the RD requiring annual monitoring of NO_x, and combustion efficiency, with monitoring for SO_x and particulates required only when fuel other than Natural Gas is being burned.

Minor emissions description

There are 33 minor emission points consisting of the two boilers (A1/1 and A1/2), laboratory fume cupboards, room air emissions and minor vents, and an emergency generator. There are eight new minor emission points applied for in the application, with these all consisting of laboratory fume cupboards.

Fugitive emissions arising.

There are 30 fugitive emission points in the application with twenty-three of these (including ten new points) being potential emission points (bursting discs on vessels). There are also breathing vents and pressure relief valves itemised among the fugitive emission points. There have been complaints relating to odour from the WWTP in 2006, but none related to the main plant.

Impact of Air Emissions on Receiving Environment.

HCl

Due to a 2.5 fold increase in the level of hydrogen chloride (HCl) being detected from the TO analyser between May and June of 2006, the licensee commissioned an air dispersion model (ISCST3). Subsequent inorganic sampling showed the actual level of HCl to be lower than that detected in the TO analyser. The predicted modelled ground level concentrations at the closest receptors were two orders of magnitude below United Kingdom Environment Agency (EA) hourly and 24-hour concentration limits specified for IPPC facilities and the 1/40th HSA 8-hour OEL derived value of 175 µg/m³. The HCl step has since been eliminated from a number of reactions and a HCl scrubber has been installed, ensuring that HCL will not reach the TO. Given the nature of the production on-site and the scrubbers in use the risk of dioxin formation is minimal as demonstrated by bi-annual monitoring. The operation parameters of the TO and the low risk of dioxin formation were outlined in the IR for P0134-02 when the TO was being installed and the TO is operated as specified by the manufacturer to prevent the formation of dioxin or damaging the TO. Given the low volume of Chlorinated substances used and the effectiveness of the scrubbers as outlined by the licensee the RD specifies that Waste gas streams going to the Thermal Oxidiser shall contain less than 1% halogenated organic substances expressed as Chlorine. The continued monitoring of the TO will ensure compliant operation.

VOCs from TO/Room Air/Combustion gases

A second ISCST3 air dispersion model was commissioned by the licensee to model emission of VOCs from the TO (A1/2), room air emission from A2/5 and the HVAC process area exhaust (A2/6) and combustion gases from the two boilers A1/1 and A1/2.

The model for VOCs assumed a worst-case scenario of a maximum volume of VOCs emanating from the TO (A1/1) on bypass, and room air exhausts A1/5 and A1/6. In all, twelve solvents were modelled, with all parameters below the relevant EA short term 1-hour concentration limit by one to two orders of magnitude. The exception was toluene which at a predicted concentration of 3,037 µg/m³ was 38% of the EAL short term 1-hour concentration of 8,000 µg/m³. All substances were also well below 1/40th HSA 8-hour OEL derived values. Predicted concentrations at the nearest receptors (the local national school, St. Lapians estate and Cork Golf Club) were predicted to be one to three orders of magnitude below the EAL short term 1-hour concentration for the relevant parameters.

The model for combustion gases also modelled a worst-case scenario of the two boilers running as well as the thermal oxidiser on bypass (running on natural gas to maintain bed temperature). The maximum predicted levels of NO_x, SO_x and CO were all well below the relevant Air Quality Standards, with the highest predicted level expressed as percentage of a standard being 25%, for the predicted 1-hour maximum ground level concentration for NO₂. The continued application of the air emission limit values will ensure compliance with all the relevant air standards.

Emissions to Sewer

The licensee has, with the agreement of the Water Services Authority (WSA), decided to connect to a different sewer, as the integrity of the WSA sewer in use, up to July 2007, was in question. Emission point SE1 has therefore been

relocated on the site to connect to a newer WSA sewer. This sewer connects to the WSA WWTP at Carrigrennan before discharging to Cork Harbour. Apart from a separate connection for sanitary water arising on-site all emissions to sewer emanate from the on-site WWTP. The WWTP can handle 1,500 kg/day (as carbon) of solvent waste and remove 150 kg/day of Nitrogen from liquid wastes containing ammonia and amines. It is licensed to handle 250 m³/day, but generally handles only 110-120 m³/day.

The water treated at the WWTP is mostly from production area floor washing, reactor vessel washings, regeneration water from the de-ionised water plant and laboratory wastewater. Strong caustic, acidic and cyanide based liquid is treated in neutralisation tanks in PB1 and PB2 before being sent to the WWTP balancing tank. The neutralisation process is a manual operation with samples being confirmed as neutral by the on-site laboratory before the liquid is pumped from the neutralisation tank to the WWTP.

If the waste is unsuitable for the WWTP it is occasionally consigned off-site for incineration.

In terms of loading the emission limits specified by the WSA are unchanged from those specified in P0134-02 apart from the addition of a limit of 10 mg/l for VOCs and a limit of 1 mg/l for total heavy metals and the specification of respirometry in lieu of toxicity testing.

Emissions to Waters

All process water is sent to WSA Sewer via the WWTP.

Surface Water

All storm water arising on the site is sent to a WSA storm drain. Water from production areas and overflow from bunded storage areas is sent to a Process Area Storm Drain (PASD). The system consists of two 57 m³ tanks (one each from PB1 and PB2) with these overflowing to an 87 m³ holding tank and then to a 2,500 m³ firewater retention pond. Any rainwater falling within the PASD area is stored in the tanks and inspected daily and emptied as necessary to ensure sufficient storage capacity. Water stored in the PASD is visually inspected and tested for COD (which on-site studies have related to TOC on a 3:1 ratio). If the water is of acceptable standard it is released to the WSA storm water sewer. If the water is not of acceptable quality it can be either sent to the WWTP or tankered off-site if required. Two redundant 100 m³ oil tanks have been converted to provide additional overflow capacity at the WWTP, providing more back-up storage capacity. A firewater retention report submitted as part of the application demonstrates ample capacity in the system to cope with the storm water and fire flow demands of the installation.

Storm water from non-production areas such as car parks and roof water (with the exception of roof water from PB1 which goes to the PASD) is sent to the storm water sewer via a continuous TOC meter, with water being diverted in the event of TOC being above 33 mg/l or in the event of a fire on-site. Cooling water from 3 dryers onsite is also sent direct to the storm drain via the TOC meter. This cooling water comes from three dryers, which use water alone as coolant and so is low risk, unlike older water/glycol units which were used on-site in the past. The RD

requires the volume of this cooling water to be measured on a daily basis to allow it proportion of the storm water emissions to be determined. In the event of a fire, all surface water is automatically diverted to the PASDS storage. The receiving water for the WSA storm water sewer is Lough Mahon.

Emissions to ground

Apart from a soakaway for stormwater emanating from a construction road in the region of the Firewater Retention pond, there are no emissions to ground. An on-site septic tank has been decommissioned, with foul water now sent to the WSA sewer. There is historical groundwater contamination (predominantly THF and MTBE) issue on-site, with the cause identified being up gradient sources located off-site. OEE is dealing with the issue and is satisfied with the cooperation of the licensee.

Waste

- Hazardous waste generated on-site is handled by an appropriate contractor with OEE kept fully informed of arrangements for same.
- Any liquid wastes on-site not suitable for treatment in the WWTP are sent off-site for disposal by an appropriately licensed contractor.
- No Class 11.1 activities are carried out on site.

Noise

The site is located in an industrially zoned area, with several industrial noise sources (some of which are IPPC licensed), as well as traffic noises, with previous studies showing noise at the site boundaries to be elevated. The previous licensing inspector's report highlighted that the installation had exceeded noise limits due to two noise sources and that a work programme was in place to improve matters. This work programme has been carried out and noise emissions from the installation are compliant and no complaints regarding noise have been received. Noise levels in the area of the installation appear to be dominated by noise sources outside the installation boundary.

Use of Resources

In 2005 the consumption of resources are reported as:

Fuel	7,846,632 kWh (Natural Gas)
Electricity	5,086,679 kWh
Water	46,844 m ³

The installation uses a variety of solvents with the principal ones being: Ethyl Acetate, Isopropanol, Tetrahydrofuran, Toluene and Acetone.

Compliance with EU Directives

IPPC Directive (91/61/EC)

This installation falls within the scope of category 4.5 (Installations using a chemical or biological process for the production of basic pharmaceutical process) of Annex I of Council Directive 96/61/EC concerning integrated pollution prevention and control.

The Proposed Determination (PD) as drafted takes account of the requirements of the Directive. BAT is taken to be represented by the guidance given in the EIPPCB reference documents, and BAT and BATNEEC Guidance notes for the Pharmaceutical and Chemical Sectors.

Large Combustion Plant Directive (2001/80/EC)

The Large Combustion plant directive does not apply.

Solvents Directive (1999/13/EC)

The licensee states that the installation does not fall within the remit of the Solvents Directive.

European Communities (Control of Major Accident Hazards involving Dangerous Substances) Regulations, 2006 (S.I. 74 of 2006)

The licensee states that the installation does not fall within the remit of the Seveso Directive, as the installation is no longer using or storing Sodium Cyanide. The National Authority for Occupational Safety and Health (NAOSH) is the competent authority responsible for administration and enforcement of these regulations.

Air Quality Directive (1999/30/EC)

The installation complies with the Air quality Directive (1999/30/EC).

Emissions Trading Directive (2003/87/EC)

The installation is not licensed under the Emission Trading Directive.

Habitats Directive (92/43/EC) & Birds Directive (79/409/EEC)

The site is located on Little Island in an area zoned as an industrial estate. The operation of the activity in accordance with the RD will not impact on any designated area, the closest being Lough Mahon (Special Area of Conservation (SAC) – Great Island Channel – Site Code 001058 and Special Protection Area (SPA) - Cork Harbour SPA -Site Code: 004030)

Best Available Techniques (BAT)

A comprehensive BAT assessment carried out by the licensee shows the installation to have a high level of compliance with BAT. However several aspects of PB1 when compared to PB2 would not be considered BAT. These include:

- A less efficient heating/cooling system
- The reactor design
- The reactor solids charging system
- The process control system
- The subsurface effluent drainage system for weak effluent

However due to the age and restrictive design of PB1, the application of the above techniques are not practically or economically feasible i.e. “Available”. I am satisfied that none of the above is causing significant environmental impact. The licensee has indicated that the inefficiencies of running PB1 means that the medium to long-term plan is to replace the manufacturing capacity with a more modern installation which would be fully compliant with BAT.

The installation’s method of local bunding is undersized and the licensee has submitted a firewater retention report, which outlines the ample storage capacity for any firewater, contaminated water or spillage by use of the PASD. This “remote bunding” system complies with the usual licence condition, which specifies, “All tank and drum storage areas shall, as a minimum, be bunded, either locally or remotely”. The OEE inspector has also indicated that they are satisfied the system is sufficient.

The licensee has achieved and is regularly audited for ISO14001 and has implemented several programmes of improvements across the installation to continuously improve their environmental performance.

I have examined and assessed the application documentation and I am satisfied that the site, technologies and techniques specified in the application and as confirmed, modified or specified in the attached Recommended Decision comply with the requirements and principles of BAT. I consider the technologies and techniques as described in the application, in this report, and in the RD, to be the most effective in achieving a high general level of protection of the environment

having regard - as may be relevant - to the way the installation is located, designed, built, managed, maintained, operated and decommissioned.

Environmental Impact Statement

The application was not accompanied by an EIS.

Fit & Proper Person Assessment

The licensee has a long history of compliant operation, with no prosecution by the Agency recorded or pending. Although they have undergone a recent change of ownership, they have provided financial information regarding their level of assets and environmental liability and they would qualify as a fit and proper person to continue to operate an IPPC licensed installation. It is my view, and having regard to the provisions of Section 84(5) of the EPA Acts and the Conditions of the RD, that the licensee can be deemed a Fit & Proper Person for the purpose of this review.

Compliance Record:

The OEE inspector for the installation has indicated that the site has a high level of compliance, with the licensee being open and communicative about any issues on-site and being proactive in solving problems.

Complaints

There are six complaints on file relating to five dates between July and November in 2006 regarding odours from the WWTP. The WWTP aeration basin was drained and washed out and no other complaints regarding the WWTP have been received since. Apart from these there are no other complaints on record for the installation.

Submissions

Apart from a response to a Section 99(E) notice from the Water Services Authority, no submissions were received.

Recommended Determination (RD)

The RD permits the licensee permission to continue to operate the installation in accordance with the conditions set out.

Charges

The current enforcement charge for the licence is €16,800 with the PD proposing a charge of €16,800.

Recommendation

I recommend that a Proposed Determination be issued subject to the conditions/refused and for the reasons as drafted in the RD.

Signed

Kevin Motherway

Procedural Note

In the event that no objections are received to the Proposed Determination of the application, a licence will be granted in accordance with Section 87(4) of the Environmental Protection Agency Acts 1992 and 2003 as soon as may be after the expiration of the appropriate period.