

Non-Technical Summary

1 Introduction

Rottapharm Ltd., trading as Meda Manufacturing Dublin, is part of the Meda Group, which has its headquarters in Solna, Sweden. Rottapharm Ltd. was part of Rotta Research Group, which was founded in Italy in 1961, but has since joined the Meda Group in 2014.

Meda is a leading international specialty pharma company with a broad product portfolio reaching more than 80% of the global pharmaceutical market. There are three key therapy areas – Respiratory, Dermatology and Pain and Inflammation – accounting for around 50% of Group sales.

At the end of 2014 Meda had 5,202 employees. The company's main focus is sales and marketing and Meda has its own sales organizations in more than 60 countries. Sales and marketing activities are carried out via distributors in countries where Meda has no representation and globally Meda's products are sold.

Meda AB is the parent company and its head office is located in Solna, Sweden. Meda was listed in 1995 at the Stockholm stock market and since 2006 listed under Large Cap on NASDAQ Stockholm in Sweden.

The Rottapharm Ltd. facility in Dublin has been constructed to manufacture solid oral dosage products and bulk active material. It is a fully integrated unit incorporating manufacturing, packaging, warehousing, laboratory facilities, utilities and office accommodation.

The Rottapharm Ltd facility in Dublin consists of two discrete buildings: Administration and Production / Warehouse linked by enclosed corridors. Construction was completed in 1999.

The Administration building is a 2-storey steel framed building with a precast concrete first floor and metal deck roofing. The Production building is composed of a steel structure with metal deck roofing and a concrete slab in parts of the first floor to support plant and equipment servicing the production facility. The Warehouse is a single storey steel structured building with a long span roof truss and a combination of block work with architectural sheeting to the perimeter walls.

There are approximately 175 employees on the Dublin site.

The Rottapharm Ltd. plant is located in Damastown Industrial Park, Mulhuddart, Dublin 15 on fully serviced lands zoned for industrial use. The site is located adjacent to the M3/N3 Dual Carriageway within the valley of the Tolka River. The site occupies 12.5 hectares (31 acres). The site is generally surrounded by other industries within the industrial park, e.g. Astellas Pharma, Helsinn Chemicals and Helsinn Pharmaceuticals, and Mallinckrodt Pharmaceuticals.

The nearest sensitive receivers (residential area) are located approximately 500m to the south of the site on the south side of the N3.

Rottapharm Ltd. is applying to the Environmental Protection Agency for a review of its Industrial Emissions Licence (Reg. No. P0886-01) in order to amend current erroneous information in relation to volumetric flow rates from the regenerative thermal oxidiser (RTO) in the current licence and also accommodate a number of minor changes on-site, as follows:

- Fitting out of existing fallow space (Area 4) with new manufacturing operations and associated minor emissions

- Formalise change to the monitoring frequency of Total Organic Compounds (TOC) at the RTO (licensed main emission point A2-1)
- Detail new 26kW hot water boiler installed on-site
- Change one of the licensable activities from activity 12.2.2 to 12.2.1 of the First Schedule of the Environmental Protection Agency (EPA) Act 1992 as amended
- Clarify requirements in relation to firewater retention

2 Hours of Operation

The facility normally operates a 2-cycle shift: 7am-3pm and 3pm-11pm, 5 days a week, with regular overtime working on Saturdays and Sundays, however Production and Packaging may operate 24 hours/5 days or 24 hours/7 days cycles depending on operational needs.

Office hours are from 8am to 5pm.

3 Class of Activity

The main class and nature of the Industrial Emissions Directive (2010/75/EU) activity carried out in accordance with the First Schedule to the Environmental Protection Agency Act 1992 (as amended) is '*5.16 The production of pharmaceutical products including intermediates*'. The equivalent Industrial Emissions Directive category is 4.5.

Another Industrial Emissions Directive activity carried out at the site in accordance with the First Schedule to the Environmental Protection Agency Act 1992 (as amended) is '*12.2.1 The surface treatment of substances, objects or products using organic solvents, in particular for dressing, printing, coating, degreasing, waterproofing, sizing, painting, cleaning or impregnating, with a consumption capacity of more than 150 kg per hour or more than 200 tonnes per year*'. The equivalent Industrial Emissions Directive category is 6.7.

4 Environmental Impact Statement and Planning

The original planning application for the facility was submitted in 1998 and was accompanied by an Environmental Impact Statement (EIS).

There have been a number of subsequent applications made for expansion projects at the Rottapharm site. A full planning history has been included in Section B of the licence review application.

All subsequent applications for the various expansions on site did not require an EIS due to the nature and scale of the works associated with the applications. This was confirmed during correspondence with the relevant planning authority, Fingal County Council.

An assessment has been carried out as part of the licence review application on the environmental impacts from the expansion projects since the original EIS was prepared, which is included in Attachment A.1 of the application. This assessment concluded that these expansion projects do not have the potential to have a significant impact on the environment in the areas of emissions to atmosphere, surface water, sewer, soil and groundwater and noise emissions, in combination with the impacts that were outlined in the original EIS for the site.

5 Best Available Techniques (BAT)

Under the new Industrial Emissions Directive, the emission limits and equivalent control parameters for licensed facilities should be based on the principles of Best

Available Techniques (BAT). A review has been completed of BAT associated with the Rottapharm site.

The Best Available Techniques Reference Documents (BREFs) and EPA BAT Guidance Notes that have been assessed are;

- Manufacture of Organic Fine Chemicals BREF, 2006
- Surface Treatment using Organic Solvents BREF, 2007
- Common Waste Water and Waste Gas Treatment/Management Systems in the Chemical Sector BREF, 2003
- Energy Efficiency BREF, 2009
- Emissions from Storage BREF, 2006
- Monitoring of emissions from IED-installations REF, 2003
- EPA BAT Guidance Note for the Use of Solvents, 2008
- EPA BAT Guidance Note Pesticides, Pharmaceuticals & Speciality Organic Chemicals Sector, 2008

The BAT review tables which are included as part of Section I.8 of the main application, outline whether a particular conclusion is relevant to the site and how it is implemented.

6 Seveso Classification

The quantities of chemicals stored on site are below applicable thresholds of the EU (Control of Major Accident Hazards Involving Dangerous Substances) Directive 2012/18/EU and The Chemicals Act (Control of Major Accident Hazards Involving Dangerous Substances) Regulations 2015 (S.I. No. 209 of 2015). These regulations do not apply to the facility.

7 Materials and Processes

The main products currently manufactured at Rottapharm Ltd. are as follows;

- API - Bulk Crystalline Glucosamine Sulphate (CGS)
- CGS Capsules
- CGS Sachets
- CGS Tablets/Caplets
- Extranase Tablets
- Fortilase Tablets
- Ananase Tablets
- Tromalyt Capsules
- Plantaben Sachets

The following products are manufactured in the new Area 4, where they are being introduced and validated prior to commercial production. Floor plans of Area 4 are included in Attachment D.

- Liquid Drops
- Uralyt-U Granulate

- Zymafluor Tablets

Other minor products may also be packaged on site such as Spagulax, Colofiber and Legalon.

Glucosamine Sulphate is a low molecular weight and chemically defined compound ($C_{12}H_{28}N_2O_{14}S$). It is the sulphate salt of the natural amino-monosaccharide glucosamine which is physiologically present in the human body. CGS is a stable, non-hygroscopic crystalline substance synthesized in a 3:1 Glucosamine Hydrochloride: Sodium Sulphate reaction ratio (in the presence of purified water) in a biconic-rotating blender. CGS is the only active ingredient used in the manufacture of CGS capsules, sachets and tablets/caplets. It is a selective symptom-modifying drug for osteoarthritis.

The CGS capsules, sachets and tablet/caplets are medicinal products used for the treatment of all forms of degenerative osteoarticular disease.

The process to manufacture the capsules involves weighing, sieving, blending, filling and packaging.

The process to manufacture the sachets involves weighing, sieving, blending, filling and packaging.

The process to manufacture the caplets involves weighing, granulating, blending, compressing and pre-insulation of tablet cores, and film coating.

Extranase tablets are beige, sugar coated, broad spectrum anti-inflammatory tablets. The active ingredient in Extranase is the active Bromelain. The process to manufacture the tablets involves weighing, sieving, blending, compressing, coating, polishing and packaging.

Fortilase tablets are yellow sugar coated tablets and are used as a food supplement. It contains the nutritional ingredient known as Bromelain as the active. The process to manufacture the tablets involves weighing, sieving, blending, compressing, coating, polishing and packaging.

Ananase tablets are orange sugar coated tablets, used as an anti-inflammatory; it also contains the active Bromelain. The process to manufacture the tablets involves weighing, sieving, blending, compressing, coating, polishing and packaging.

Tromalyt capsules are a medicinal product which contains acetylsalicylic acid in the form of prolonged release micro-pellets. The process to manufacture this blend involves two phases of coating, sieving, blending and encapsulation.

The Plantaben sachet product is a medicinal product containing the husk (Ispaghula) of the Plantago ovata seed. This husk is a source of natural, concentrated, soluble fibre, which is often used as a source of insoluble fibre and is well-accepted as a safe and effective intestinal regulator. The product is a palatable orange-flavoured, sugar-free powder formulation for the oral administration of Plantago ovata husk. The process to manufacture this sachet involves weighing, sieving, blending, and packaging.

The process to manufacture the "Liquid Drops" involves dispensing and sieving, solution preparation and transfer, filling and packaging. Excipients are generally pharmacologically inactive substances used as a carrier for the active ingredients of a medication.

The Uralyt-U Granulate process is composed of dispensing and sieving, solution preparation, spray drying and granulation, milling, granulation, filling and packaging. Excipients are generally pharmacologically inactive substances used as a carrier.

The Zymafluor tablet process is composed of dispensing and sieving, blending, milling, granulation, compression and packaging. Excipients are generally pharmacologically inactive substances used as a carrier for the active ingredients of a medication.

Other activities at the facility include the main plant laboratory where central quality control and quality assurance activities are carried out, and the various utility systems for the site, e.g. boilers, air conditions, purified water, compressed air, and water chiller.

8 Atmospheric Emissions

There is one main emission point at the facility - the Regenerative Thermal Oxidiser (RTO) (Emission point A2-1). This abatement unit treats emissions from the pharmaceutical coating systems on-site that use solvents.

There are a total of 35 No. minor emission points at the facility, A3-1 to A3-35.

There are no significant boiler emissions points at the facility, i.e. all gas fired boilers on site are below 5MW. Furthermore there are no liquid fired boilers at the facility. All boiler emissions are included in the site's minor emission points.

Details of all of the above emission points are included in the Tables contained within Section E of the application form.

Rottapharm Ltd. produces an annual Solvent Management Plan, in order to comply with Condition 6.19 of its current licence Industrial Emissions Licence. This documents a solvent mass balance for the installation and compares the calculated VOC (Volatile Organic Compounds) emissions to determine solvent emissions from the installation and verify compliance with the stated limits in their Industrial Emissions Licence for emissions in waste gases and fugitive emissions.

There is no significant potential for emissions to cause odour nuisance off-site.

9 Emissions to Surface Waters

Surface water from the impervious areas on-site is discharged from the site at two locations, SW1 and SW2.

SW1 is the outfall from the on-site surface water attenuation pond and this water discharges to the River Pinkeen. SW2 discharges surface water to the River Pinkeen on-site upstream of the administration building.

Petrol interceptors are provided on the drainage system upstream of the two emission points to prevent emissions of hydrocarbon pollutants to surface waters in the unlikely event of a spill on-site. Furthermore there is an automatic shut-off valve on the outlet of the surface water attenuation pond allowing it to be isolated if required.

Both discharge locations are monitored quarterly for pH and TOC (Total Organic Carbons) and are visually inspected weekly, in accordance with the site's current licence requirements.

10 Emissions to Sewer

Rottapharm Ltd. currently has one licensed emission point to sewer, SE1. This has not changed and will not change as part of this licence review. Process emissions are discharged to sewer at emission point SE1. It is noted that there is a second emission point, SE2, which only emits foul/sanitary effluent to the local authority sewer. This has not changed since the previous licence application.

Rottapharm Ltd. carries out a programme of monitoring and maintenance of its effluent system. The licensed trade effluent is held in a balancing tank prior to discharge to the sewer. As well as the continuous final effluent flow and pH monitoring, effluent discharge is monitored for the following parameters on a monthly basis:

- Temperature
- COD
- BOD
- Suspended Solids
- Sulphates (as SO₄)
- Oils, Fats and Grease
- Methylene Blue Active Substances (MBAS)

11 Emissions to Ground/Groundwater

There are no emissions to ground or groundwater from the facility.

12 Noise Emissions

There have been no significant changes to the number and nature of noise sources since the original licence application. There are no new significant external noise sources associated with any of the changes on-site. Any changes to the facility under review as part of this application are housed indoors.

Noise emissions from site are reported in the Annual Environmental Report. Any changes as part of this review will be monitored as part of the periodic noise surveys.

13 Waste

Rottapharm Ltd produces waste on an on-going basis throughout the year. Both non-hazardous and hazardous wastes are produced at the site. As outlined in the SOP for waste management at the site the main waste streams are as follows:

Non-Hazardous Waste

- Cardboard
- Plastic
- Mixed dry waste (mix of hard plastics and cardboard that needs to be compacted and cannot be baled)
- Non-hazardous solid pharmaceutical waste (powders and capsules)
- Metals
- Waste Electrical and Electronic Equipment (WEEE)
- Timber
- Canteen and office waste (food, mixed dry recyclables, and municipal waste)

Hazardous Waste

- Machine oil
- Manufacturing and lab chemical waste
- Hazardous solid pharmaceutical waste

Rottapharm Ltd.'s approach to dealing with waste arisings is based on the internationally adopted hierarchy of options which places greatest emphasis on:

- Waste Prevention
- Minimisation
- Reuse/Recycling
- Energy recovery
- Environmentally sustainable disposal of waste which cannot be prevented or recovered

Various measures for waste control and minimisation have been implemented by Rottapharm Ltd. including the use of aqueous based coating solutions to reduce solvent waste, and inventory control to prevent over-ordering of raw materials.

All recyclables from Rottapharm Ltd. are collected and managed by an approved waste contractor and suitably permitted/licensed facility.

Food waste is managed in accordance with the Waste Management (Food Waste) Regulations 2009. The canteen area has dedicated waste containers for food waste.

All wastes are stored, collected, transferred, disposed of and/or recovered in accordance with national and European waste management legislation.

14 Control and Monitoring

At the time of design an assessment of various types of abatement technologies for the treatment of VOC (Volatile Organic Compounds) emissions was carried out to determine which method is most appropriate for the abatement requirements. It was concluded that emissions to air of solvent vapours would be treated and controlled by the use of regenerative thermal oxidation.

The regenerative thermal oxidiser (RTO) installed on-site is designed and built in accordance with all recognised standards including:

- European Standards for "Best Available Techniques" (BAT)
- British standard or European Norm where applicable
- ATEX where applicable
- CE certification
- Irish and European Environmental emission regulations

Quarterly emissions monitoring is carried out on the RTO. According to Rottapharm Ltd.'s Annual Environmental Report for 2014, there was one non-compliance in relation to hourly flow rates from the RTO, however this is due to the on-going issue that the incorrect flow rates for the RTO are contained in the licence. Monitoring of all other parameters/pollutants was compliant with the limits set out in the existing Industrial Emissions Licence.

The site's two licensed surface water discharge points are monitored quarterly for pH and TOC (Total Organic Carbons) and are visually inspected weekly, in accordance with the site's current licence requirements. Based on recent monitoring carried out on the site's surface water discharges it can be concluded that the overall impact on emissions to surface water from Rottapharm Ltd. is not significant, and any expansion projects since the previous licence application have not had a significant impact on the site's surface water discharges.

Rottapharm carries out a programme of monitoring and maintenance of its effluent system. The licensed trade effluent is held in a balancing tank prior to discharge to the sewer in order to carry out pH adjustment if required. Control of the balancing system is achieved through influent flow and pH monitoring, output pH monitoring, and final effluent flow and pH monitoring. Daily inspection of sludge condition/volume is also carried out.

As well as the continuous final effluent flow and pH monitoring, the following parameters are monitored on a monthly basis:

- Temperature
- COD
- BOD
- Suspended Solids
- Sulphates (as SO₄)
- Oils, Fats and Grease
- Methylene Blue Active Substances (MBAS)

There are no discharges to ground or groundwater, therefore no monitoring is applicable.

Periodic noise monitoring is carried out at 3 noise sensitive locations off-site. Noise monitoring carried out as part of the 2015 reporting period demonstrated that there were some levels higher than those limits in the site's licence. However, the consultants who carried out the survey noted that these limit breaches were due to traffic noise in the area and could not be attributable to the facility's operations. Furthermore there were no noise complaints received during the 2015 reporting period.

15 Environmental Considerations

Rottapharm Ltd. has continually invested in BAT (Best Available Techniques) based technologies. The on-site RTO for the abatement of Volatile Organic Compounds complies with European Standards for Best Available Techniques.

Rottapharm Ltd. endeavours to recover and recycle waste where possible. Where this is not feasible, disposal of waste is conducted using licensed waste hauliers and licensed waste facilities in order to minimise any environmental impact.

Rottapharm Ltd.'s Emergency Response Procedure outlines the accident prevention and emergency response procedures in place at Rottapharm Ltd. in the event of a fire, a spill of flammable or environmentally harmful material, or any other major industrial accident. Emergency response training is also provided to all Rottapharm Ltd. employees.

16 Accidental Emissions

All operations and activities are carried out in accordance with the relevant Rottapharm Ltd. procedures, which are designed to minimise accidents. Rottapharm Ltd. has developed an Emergency Response Procedure which sets out the responses to such events in order to minimise any consequences for the environment.

17 Energy Efficiency

Rottapharm Ltd monitors and reviews energy use to identify and achieve energy efficiencies.

An energy policy with an updated energy action plan is drafted each year and a review report is written on energy management at the end of the year. An energy management team consisting of a cross functional selection of representatives from different departments is in place to champion the efficient use of energy across the plant. The energy management system follows the SEAI Energy MAP (Management Action Plan). All teams within the plant have access to an electrical energy measurement and reporting platform. Teams highlight a visual display of the electrical energy usage for their area or in shared areas (offices) on their visual management board. Teams are questioned on energy use during senior management reviews, best practice methods have been introduced to promote the shutdown of equipment when not in use. Rottapharm Ltd. also held an energy awareness competition raising ideas to reduce energy and waste. Some of the ideas were simple such as putting stickers on lights to remind people to turn them off and to investigate ways to reduce heating requirements within the building.

Over the last number of years Rottapharm Ltd. have implemented a number of projects to reduce energy usage, including implementing changes in the de-humidification system to dehumidify machine cabinets rather than complete rooms; implementing a reduction in chilled water pump speed; and replacing lighting with energy efficient LED lighting.

Rottapharm Ltd. continuously looks to improve its energy usage and have a number of further projects which it plans to implement in the coming years, such as investigating the possibility of changing the chilled water system from a 3 port operated system to a 2 port on demand control with the pump controlled by differential pressure, for example.

An external audit was conducted in 2009 by SEAI; many of the recommendations have been implemented. An internal audit for opportunities was carried out in July 2013 and recommendations are also being implemented.

Internal checks on equipment shutdown during off peak periods are conducted twice a year within each team/area and scores of compliance to shutdown rules are trended for each team.

The most recent full year data for energy use is available in the 2014 Annual Environmental Report for the facility. The 2014 Annual Environmental Report reported total energy use for the facility of 6,766MWhrs, which comprises electricity consumption of 4,225MWhrs, and natural gas consumption of 2,541MWhrs.

18 Statutory Requirements

The emissions from the Rottapharm Ltd. facility will not result in any significant environmental pollution as required by the relevant legislation.

Air dispersion modelling was carried out for the RTO in October 2010 with the correct volumetric flow rate at the licensed emission limits and it demonstrates that the emissions from the RTO have no significant effect on the environment and do not breach statutory Air Quality Standards.

The changes proposed in this licence review will not result in any change to emissions to surface water or sewer. Emissions to sewer and surface water will continue to comply with the conditions of the current Industrial Emissions Licence.

The proposed facility will not lead to a contravention of any relevant standard prescribed under the European Communities Act 1972, or under any other enactment. There are no predicted significant impacts associated with the proposed facility.

The proposed changes will not result in a significant increase in noise emissions from the facility. The operation of the facility does not contribute to elevated noise levels at noise sensitive locations surrounding the site. Furthermore, the plant does not contribute to tonal or impulsive components at these locations. Therefore, it is concluded that the facility will continue to comply with section 106 of the EPA act, 1992.

Site waste management procedures ensure that waste is managed based on the waste management hierarchy and ensures that all waste is handled, stored, labelled, transported and treated/disposed off-site in accordance with statutory requirements and best practice.

Rottapharm Ltd. has employed BAT in construction and upgrades at the works to ensure it minimises its impact on the local environment. Where possible, the generation of waste streams at source is avoided. Where this is not achievable, suitable abatement and recovery systems are put in place.

There are no ecological designated areas in the vicinity of the Rottapharm Ltd. site. Screening for Appropriate Assessment was undertaken as part of this licence review application. The conclusions from the screening report are that there will be no adverse effect on any Natura 2000 sites.

Rottapharm Ltd. and the management are fit and proper persons, with the necessary skills, experience and resources to operate the facility in full compliance with the licence requirements. Neither Rottapharm Ltd. nor any staff involved with managing the operations at the facility has been convicted of any offence under the Environmental Protection Agency Act 1992 to 2011, the Waste Management Acts 1996 to 2011, the Local Government (Water Pollution) Acts 1997 and 1990, the Air Pollution Act 1987 and the Air Pollution Act 1987 (Environmental Specifications for Petrol and Diesel Fuels) (Amendment) Regulations 2004.

19 Cessation of Activity

Rottapharm Ltd. intends to operate at the Damastown site for the foreseeable future. However, in the event of definitive cessation of activities at the site, Rottapharm Ltd. will ensure that appropriate measures are taken to avoid any pollution risk and return the site to a satisfactory state in accordance with the Closure Plan that has been prepared for the site. This Closure Plan has been submitted to and agreed with EPA.

20 Site Management and Control

The structures for the management and responsibility for the operation and control of abatement/treatment systems on-site are set out in Rottapharm Ltd.'s Environmental, Health and Safety (EHS) Statement.

The Managing Director has ultimate responsibility for safety, health and welfare. The Department Managers have overall responsibility for safety, health and welfare within their departments. The Engineering Manager has overall responsibility for the operational control of environmental, health and safety matters, and for the effective implementation of the EHS Statement.

The responsibilities allocated to the EHS Manager/Officer(s), to the Supervisor(s), to the Safety Representative(s) and to employees are set out in the EHS Statement.

Training is provided to all employees and managers, including induction training, and training records are maintained.

Consultation between management and employees is facilitated by the Safety Representative and the EHS Committee. Accidents and incidents are recorded and reported as required via an Accident/incident report form. Concerns can be notified to management using a Safety Observation Report.

The written procedures for the calibration and maintenance systems for engineering and quality control departments have been prepared by Rottapharm Ltd.

As per design, there is no control system interlock between the RTO and the solvent coating pans; therefore the shutdown of the coating pans in the event of an RTO failure is a manual process. Upon a failure of the RTO a beacon sounder alarm is triggered in the production building, Area 2, where the solvent processes take place (in addition to any other local and remote RTO alarms). If the alarm is triggered, SOP PRO-MAN2-033 requires the operators to stop the coating process immediately and to record that using the forms within the SOP.

The written procedures for waste control systems have been prepared by Rottapharm Ltd. Each department is responsible for the segregation and presentation of waste as generated by that department.

Rottapharm Ltd.'s emergency response procedure outlines the functions of the chemical spill team. This requires the spill team to attend the spill, isolate and evacuate the spill area, determine substances and quantities involved and to report to the Engineering Manager/EHS Manager.

Product quality is monitored throughout the process at the Rottapharm Ltd. facility via an established quality control system. This system is in accordance with ISO 13485 for medical device products. A Quality Management System for all pharmaceutical products has also been prepared in accordance with cGMP standards. This Quality Management System is in accordance with EU 93/42/EEC.

An Environmental Management System has been developed and is in operation at Rottapharm Ltd. The Environmental Management Plan for the facility is reviewed annually and updates of objective and targets are included in the Annual Environmental Reports for the facility. The Rottapharm Ltd. Environmental Management System is not an accredited system; however it was developed in line with the ISO14001 environmental management system standard. Rottapharm Ltd. is currently in the preparation phase for attaining accreditation for their Environmental Management System in line with ISO14001. It is currently expected that accreditation will be achieved by the end of 2016.

EIA Screening Report

Rottapharm Ltd
Industrial Emissions Licence Review
IE0311736-22-RP-0004, Issue: A

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Document Sign Off

EIA Screening Report

Rottapharm Ltd
 Industrial Emissions Licence Review
 IE0311736-22-RP-0004, Issue A

File No: IE0311736.22.040

CURRENT ISSUE					
Issue No: A	Date: 15/01/16	Reason for issue: For EPA Submission			
Sign Off	Originator	Checker	Reviewer	Approver	Customer Approval (if required)
Print Name	Paul O'Sullivan	Rory O'Dwyer		Rory O'Dwyer	
Signature	Authorised Electronically				
Date	15/01/16	15/01/16		15/01/16	

PREVIOUS ISSUES							
Issue No	Date	Originator	Checker	Reviewer	Approver	Customer	Reason for issue

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Attachment 1

Letter from Fingal County Council dated 26 November 2015

1 Introduction

1.1 General

Rottapharm Ltd. operates a pharmaceutical manufacturing facility located in Damastown Industrial Park, Mulhuddart, Dublin 15.

Rottapharm Ltd. received planning permission in 1998 to build its facility which incorporates manufacturing areas, warehousing, offices, a laboratory, and utility areas (Planning Ref. F98A/0312). An Environmental Impact Statement (EIS) was submitted as part of this planning application.

Since 1998, Rottapharm Ltd. has received planning permission for a number of expansions to the facility (refer to Table 2.1). Due to the nature and scale of each of these expansions, an EIS was not required to be submitted as part of any of their planning applications. This was confirmed in a letter from Fingal County Council to Rottapharm Ltd. dated 26 November 2015 (see Attachment 1).

Rottapharm Ltd. received an IPPC (Integrated Pollution and Prevention Control) Licence from the Environmental Protection Agency (EPA) in 2010 (Ref No. P0886-01). This licence was amended to an Industrial Emissions Licence in 2013. This report has been prepared to accompany a Licence Review application which Rottapharm Ltd. is submitting to the EPA. The application for the Licence Review is being prepared in order to amend current erroneous information in relation to volumetric flow rates from its regenerative thermal oxidiser (RTO) in the current licence and also accommodate a number of minor changes on-site since the granting of the previous licence, and to formalise a number of other agreements in relation to changes to the licence.

The purpose of this report is to review the planning applications that have been submitted since the original EIS was prepared for the site to determine if there are any significant changes to the conclusions that were made in the EIS with regards to impacts to the external environment.

1.2 Reasons for Licence Review

A brief summary of the main reasons for this licence review are outlined as follows:

1. Amend Schedule B.1 to increase the flow rate limit for licensed emission point A2-1. Incorrect flow rate information was provided in the original licence application which was transferred to the licence as limits. A technical amendment request to increase these flow limits was submitted to the EPA in October 2010 and January 2011. However this request for a technical amendment was refused in April 2011 by the EPA on the grounds that it would be more appropriate to deal with the proposed change to the schedule by licence review as opposed to technical amendment.
2. Formalise in the licence review the agreement in relation to the monitoring programme for emission point A2-1, whereby quarterly monitoring was deemed sufficient and continuous TOC monitoring not required. An agreement from the EPA was received 9 March 2010 (EPA Ref: P0886-01/ap01ec), so this change is proposed to be formalised in the Schedule C.1.2 of the licence as part of this review application.
3. Provide details on the new Area 4 operations and associated new minor air emission points. The Area 4 processes do not involve any solvent. Area 4 is being fitted out in an existing fallow space at the facility and new products and processes are being introduced, from development through scale up and eventually commercial production. There was also a new plant room constructed above Area 4. Area 4 contains new processing equipment including a fluid bed processor, high sheer granulator and milling room, 2 new solution vessels with a nitrogen supply for the vessels, and an oven dryer. Waste water emissions from Area 4 arise only due to the CIP of the solution vessels.
 - New products and production processes will also be detailed in the licence review for the following products; Liquid Drops process, Uralyt-U process, and Zymafluor process.

4. Provide details on a new 26kW hot water boiler that has been installed in the administration building. This boiler like all others on-site is fuelled by natural gas.
5. It is proposed as part of the review to apply for a change in the class of one of the activities from 12.2.2 (IPC activity) to 12.2.1 (IED activity).

12.2.2 The manufacture or use of coating materials in processes with a capacity to make or use at least 10 tonnes per year of organic solvents, and powder coating manufacture with a capacity to produce at least 50 tonnes per year, not included in paragraph 12.2.1.

12.2.1 The surface treatment of substances, objects or products using organic solvents, in particular for dressing, printing, coating, degreasing, waterproofing, sizing, painting, cleaning or impregnating, with a consumption capacity of more than 150 kg per hour or more than 200 tonnes per year.

Currently the site does not consume more than the thresholds outlined in Activity 12.2.1, however there is the potential for that consumption capacity in the future. The main IED activity at the site is still *5.16 The production of pharmaceutical products including intermediates.*
6. This licence review application will clarify the site's requirements in terms of firewater retention facilities. A firewater risk assessment has been carried out as required by the license which has determined the firewater risk throughout the site as low and therefore no dedicated firewater retention facilities was deemed necessary. This risk assessment will be included in the application documentation.

2 Planning History

Table 2.1 contains a list of all historical planning applications that have been made for the site. The original planning application for the facility was submitted in 1998 and was accompanied by an EIS.

All subsequent applications did not include an EIS due to the nature and scale of the expansions associated with the applications. This was confirmed in a letter from Fingal County Council to Rottapharm Ltd. dated 26 November 2015 (see Attachment 1).

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Table 2.1: Site Planning History

Planning or Appeal Reference Number	Planning Authority / An Bord Pleanála	Date of Planning Decision (Final)	Brief Description	EIS Required with Planning Application	If “no”, Letter of confirmation from planning authority/An Bord Pleanála that EIA was not required?
F98A/0312	Fingal County Council	15/07/1998	A Pharmaceutical Finishing Plant, incorporating Manufacturing Areas, Warehousing Offices, Laboratory, and Utility Areas. Damastown, Mulhuddart, Dublin 15	Yes	N/A
F04A/0308	Fingal County Council	09/06/2004	Install temporary accommodation comprising a single storey modular building of 95m ² for use as offices, to install a fire escape single door on the east side of their existing building and to construct 11 additional car parking spaces with an area of 138m ² .	No	See Attachment 1
F05A/0114	Fingal County Council	26/04/2005	Expand existing car parking facilities by the construction of an additional car park to accommodate 102 cars at the facility in Mulhuddart.	No	See Attachment 1
F05A/0114/E1	Fingal County Council	03/03/2010	Extension of planning permission expiry only.	No	See Attachment 1
F06A/0235	Fingal County Council	31/05/2006	Construction of new single storey 49.95m ² extension, with three no. roof lights, to existing canteen in existing two storey Administration Building forming part of pharmaceutical production facility.	No	See Attachment 1

Planning or Appeal Reference Number	Planning Authority / An Bord Pleanála	Date of Planning Decision (Final)	Brief Description	EIS Required with Planning Application	If “no”, Letter of confirmation from planning authority/An Bord Pleanála that EIA was not required?
F08A/0483	Fingal County Council	21/08/2008	Construction of a 3992m ² expansion to our existing warehouse and production building. The expansion will consist of a 2160m ² x 14.7m high single storey Warehouse, a 150m ² x 6.2m high single storey Production Office, a 1080m ² x 10.7m high single storey Production Area with an adjoining 80m ² x 4.8m high access corridor and a 522m ² x 6.2m high single storey Product Storage Area. The development will be constructed as an expansion of the existing building located along the north and east faces. The development will also consist of the construction of a Fire Tender Access Road around the proposed expansion, an additional dock leveler and associated landscaping works.	No	See Attachment 1
F08A/0483/E1	Fingal County Council	31/05/2013	Extension of planning permission expiry only.	No	See Attachment 1
FW13A/0084	Fingal County Council	21/10/2013	The development will consist of the construction of a first floor internal production area (384 m ²) within the footprint of the existing facility, the construction of a roof level plant room enclosure of 143 m ² X 5.3m high above the production area and an enclosed access stairs to access the plant room of 6 m X 3.5 m X 13.9 m high all to the rear of the existing facility. This application relates to development on a site which comprises an activity requiring an integrated pollution prevention and control licence.	No	See Attachment 1

Planning or Appeal Reference Number	Planning Authority / An Bord Pleanála	Date of Planning Decision (Final)	Brief Description	EIS Required with Planning Application	If “no”, Letter of confirmation from planning authority/An Bord Pleanála that EIA was not required?
FW15A/0088	Fingal County Council	29/09/2015	Permission for the construction of a single storey 8.8m wide x 12.97m long x 3.75m high extension with a floor area of 105m ² to the existing canteen to the South West corner of the existing two storey administration building, the construction of a 52 no. car space car park expansion to the North of the existing car park, and associated works. This application relates to development on a site which comprises an activity requiring an integrated pollution prevention and control licence.	No	See Attachment 1

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3 Environmental Considerations

As stated previously, only the planning application for the original facility in 1998 required an EIS. Due to the nature and scale of subsequent projects, no EIS was required for these applications.

The following sections outline the potential impacts that the various expansions could have on the following environmental factors, in addition to the impacts outlined in the EIS prepared in 1998:

- Ambient air quality and climate
- Surface water
- Sewer
- Soil and groundwater
- Ambient noise levels
- Flora and fauna
- Landscape
- Material assets
- Cultural heritage
- Human beings

3.1 Impact on Ambient Air Quality and Climate

There is only one main emission point as defined by EPA guidelines on the site, which is at the Regenerative Thermal Oxidiser (RTO) (Emissions point A2-1). This abatement unit treats emissions from the pharmaceutical coating systems on-site that use solvents. At the time of design an assessment of various types of abatement technologies for the treatment of VOC (Volatile Organic Compounds) emissions was carried out to determine which method is most appropriate for the abatement requirements. It was concluded that emissions to air of solvent vapours will be treated and controlled by the use of the RTO.

The RTO installed is designed and built in accordance with all recognised standards including:

- European Standards for "Best Available Techniques" (BAT)
- British standard or European Norm where applicable
- ATEX were applicable
- CE certification
- Irish and European Environmental emission regulations

All boilers at the site are gas fired boilers are below 5MW and are included in the site's minor emission points. There are a total of 35 no. minor emission points at the site.

The facility has been designed to minimise potential sources of fugitive emissions arising from process areas and buildings. Fugitive emission sources are limited to minor leakages from connections, isolation and control valves, relief valves/vents, equipment seals and analysers. Dust emissions are vented to specific extract systems and house cleaning vacuum systems. Good housekeeping practices, including preventative maintenance and routine monitoring of equipment on-site minimise the potential for any equipment leaks. Conservation vents are fitted on all tanks to minimise any fugitive emissions during storage of materials.

Rottapharm Ltd. produces an annual Solvent Management Plan, in order to comply with Condition 6.19 of its current Industrial Emissions Licence. This documents a solvent mass balance for the installation and compares the calculated VOC emissions to determine solvent emissions from the installation and verify compliance with the stated limits in their Industrial Emissions Licence for emissions in waste gases and fugitive emissions. The details of the latest Solvent Management

Plan are included in the 2014 Annual Environmental Report (AER). According to the site's AER for 2014, the site was in compliance with the limits in its licence with regards VOC emissions to atmosphere.

As part of the expansion projects at the facility since the original EIS was prepared, all emissions to atmosphere are considered to be minor in accordance with EPA guidelines; therefore it is considered that these projects do not have the potential to have any significant impacts to the environment in addition to the potential impacts outlined in the original EIS. Also, it is not considered that the expansion projects were of a size or nature that could have an impact on climate.

3.2 Impact on Surface Water

The only emissions to surface waters are from on-site surface water collection systems. There have a number of expansions to the Rottapharm Ltd. building and also car parking being provided at the site since the original planning application was made. This has increased the amount of surface water being generated at the facility since the original EIS was prepared for the site. In order to mitigate this an underground attenuation tank has been installed on-site to minimise the potential impact of large rainwater flow to the river.

As part of the planning application for the expansion to the warehouse and production building (Planning Ref.: F08A/0483), a stormwater attenuation pond was constructed at the site to cater for this additional surface water generated at the site.

Surface water generated on the site from the western side of the River Pinkeen passes through a petrol/oil interceptor prior to discharging to the River Pinkeen; while surface water generated on the site from the eastern side of the River Pinkeen passes through the petrol/oil interceptor and the attenuation pond prior to discharging to the River Pinkeen.

Various SUDS (Sustainable Urban Drainage Systems) have been included in the design of all extensions to the on-site surface water collection systems since the original EIS was prepared. The petrol/oil interceptors are provided on the drainage system to prevent emissions of hydrocarbon pollutants to surface waters in the unlikely event of a spill on-site.

Quarterly monitoring of pH and TOC monitoring on surface water discharges from the site is carried out as well as weekly visual inspections.

It is considered that the increase in surface water generated at the site since the original EIS was prepared does not have the potential to have significant impacts on the surrounding surface water network.

3.3 Impact on Sewer

Rottapharm Ltd. currently has one licensed emission point to sewer (SE1). Process emissions are discharged to sewer at this emission point. It is noted that there is a second emission point, SE2, which only emits foul/sanitary effluent to the local authority sewer. This has not changed since the previous licence application. All effluent is ultimately discharged to Ringsend Wastewater Treatment Plant (WWTP).

Rottapharm Ltd. carries out a programme of monitoring and maintenance of its effluent system. The licensed trade effluent is held in a balancing tank prior to discharge to the sewer. Trade effluent requiring pH adjustment is transferred to an alternative tank.

There have not been any significant changes to the effluent being discharged from the site as a result of the expansion projects that have taken place at the site. Therefore it is concluded that these expansion projects do not have the potential to add any additional significant impacts to those already covered in the original EIS.

3.4 Impact on Soil and Groundwater

There are no emissions to ground or groundwater from the site, including from any of the expansion projects that have taken place since the original EIS was prepared.

The storage and containment of hazardous materials on site is governed by the conditions of Rottapharm Ltd.'s existing Industrial Emissions Licence (EPA Licence Reg. No. P0886-01). As well as the conditions outlined in its licence, Rottapharm Ltd. has a number of relevant internal control procedures and policies in place. The storage and transfer of materials at the Rottapharm Ltd. site is carried out in accordance with the EPA guidance note "*IPC Guidance Note on Storage and Transfer of Materials for Scheduled Activities, 2004*".

Raw materials are received in a variety of packages such as fibre board drums, cardboard boxes, stainless steel IBCs, flexible IBCs and paper and plastic sacks. These are often stored in double lined containers. Final products stored in these areas are normally packaged in small quantities, such as bottles, blister packs etc.

Spill kits and emergency containment are provided where appropriate, with a trained Chemical Spill Team and dedicated emergency response procedure. The functions of the chemical spill team are contained in the emergency response procedure. This requires the spill team to attend the spill, isolate and evacuate the spill area, determine substances and quantities involved and to report to the Engineering Manager/EHS Manager.

No substances, including hazardous chemicals and wastes, are stored outside of bunded/contained areas/stores. Bunds are provided at the following locations:

- Effluent treatment
- QC lab store
- Solvent stores
- Plant Room
- Mobile bund across the site

Bund inspection takes place on a regular basis to ensure that they are working correctly and that they will retain any spillage of chemicals which may occur. Bunds are tested every 3 years in accordance with the conditions of Rottapharm Ltd.'s Industrial Emissions Licence.

All chemical unloading areas have been designed such that any spills in the loading or unloading operation will drain to a collection point and will not cause contamination of the ground.

Therefore it is concluded that the activities carried out on site, including those within the scope of the expansion projects, do not have the potential to have a negative impact on soil and groundwater.

3.5 Impact on Ambient Noise Levels

There have been no significant changes to the number and nature of noise emissions since the original planning application. There are no new significant external noise sources associated with any of the changes on-site. Any changes to the facility under review as part of this application are all housed indoors.

As stated in the EIS prepared for the original planning application for the site, the dominant noise source in the area is traffic due to the proximity of the N3/M3. This road is heavily used by traffic between Dublin and Navan, and the north-west of the country, travelling at high speed. This has been confirmed by on-going periodic noise monitoring.

Therefore it is concluded that any noise sources installed at the facility since the original planning application for the site do not have the potential to have a significant impact on local residents in addition to the impacts outlined in the original EIS.

3.6 Impact on Flora and Fauna

The EIS that was prepared for the original planning application for the site concluded that there would be a minimal impact on local flora and fauna. Due to the nature and scale of the subsequent expansions of the site, it is considered that these do not have the potential to have an impact on flora and fauna, in addition to the impacts outlined in the original EIS.

Furthermore, the potential impacts on Natura 2000 sites¹ within a 15km radius of the site have been assessed in an Appropriate Assessment (AA) Screening Statement which accompanies this licence review application (PM Group Report No. IE0311736-22-RP-0002). There was only one Natura 2000 site identified within a 15km radius of the site – the Rye Water Valley / Carton SAC (Special Area of Conservation) (Site Code: 001398). This AA screening exercise concluded that there are no source-pathway-receptor-links between the SAC and the Rottapharm Ltd. site; therefore there is no potential for the Rottapharm Ltd. site, including the expansion projects previously described, to have an impact on Natura 2000 sites within a 15km radius of the site.

3.7 Impact on Landscape and Visual Impact

The expansion projects that have taken place at the site have consisted of small extensions to the various buildings on site, as well as extensions to the car park on site. It is not considered these projects have had a significant impact on the landscape character of the area, and it is considered that they have had a minimal impact on views of the site from both short range and long range given the site's location within industrially zoned land and the fact that other industrial facilities are located in close proximity to the Rottapharm Ltd. site.

3.8 Impact on Material Assets

The material assets provided within Damastown Industrial Park have the capacity to cater for the full industrial estate. Given the scale and nature of the expansion projects at the Rottapharm Ltd. site, it is concluded that they do not have the potential to have a significant impact on the material assets of the area.

3.9 Impact on Archaeology and Cultural Heritage

As stated in the EIS that was prepared for the original planning application for the Rottapharm Ltd. site and according to the current Fingal County Development Plan², there are no known protected structures or recorded monuments within the site confines or in the vicinity of the site. Therefore, it can be concluded that the expansion projects did not have any impact on the archaeology and cultural heritage of the area.

3.10 Impact on Human Beings

The potential impacts from the expansion projects that have taken place at the Rottapharm Ltd. facility on human beings have been outlined in the previous sections in Section 3 of this report. In conclusion, due to the low level of emissions from the facility, the scale and nature of and the various expansion projects that have taken place on site, the proximity of other plants, and the distance to residential areas, the Rottapharm Ltd. facility, including the expansion projects is not considered to be a threat nor a nuisance to human beings.

¹ Natura 2000 sites are part of an EU-wide network of nature protection areas established under the EU Habitats Directive. The aim of the network is to aid long-term survival of Europe's most valuable and threatened species and habitats. It is comprised of Special Areas of Conservation (SAC) designated by member states under the Habitats Directive, and also incorporates Special Protection Areas (SPA) designated under the EU Birds Directive.

² Fingal County Development Plan 2011-2017, Sheet No. 12 (2011)

4 Conclusion

As outlined in the previous sections of this report it is considered that the expansion projects that have been carried out at the site since the original planning application was submitted and the original EIS for the site was prepared in 1998, do not have the potential to have a significant impact on the environment in the areas of emissions to atmosphere and climate, surface water, sewer, soil and groundwater, noise emissions, flora and fauna, landscape and visual impact, materials assets, archaeology and cultural heritage, and human beings, in addition to the impacts that were outlined in the original EIS for the site.

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Attachment 1

Letter from Fingal County Council dated 26 November 2015

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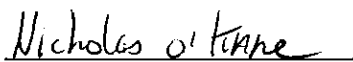
Jesu Caballo
EHS Manager
MEDA Group
Rottapharm Ltd
Damastown Industrial Park
Mulhuddart
Dublin 15

Re: Rottapharm Ltd. Section B.6 (d) of Industrial Emissions Licence Review
Application Form

Dear Sir/Madam,

The Planning Authority did not require an Environmental Impact Statement to be submitted as part of planning applications in relation to reg. ref. F04A/0308, F05A/0114, F05A/0114/E1, F06A/0235, F08A/0235, F08A/0483/E1, FW13A/0084 and FW15A/0088.

Yours sincerely,



Nicholas O'Kane
Senior Executive Planner
Planning Department – Blanchardstown Office

Date: 26th November 2015