

Environment and Resources Authority Report



1. Application details:

1.1	Applicable Policy	Environment Protection Act (CAP. 549) S.L. 549.76 Industrial Emissions (Framework) Regulations, S.L 549.76 S.L. 549.77 Industrial Emissions (Integrated Pollution Prevention and Control) Regulations
1.2	Press dates	21 st April 2018
1.3	Application type	Full Surrender of IPPC Permit
1.4	Applicant	Dr. Patricia Gomez <i>o.b.o Crystal Pharma Ltd.</i>
1.5	Date of receipt of consolidated application	22 February 2018
1.6	Approved documents	Application document is available on the website of the Environment & Resources Authority on the following link: https://era.org.mt/en/Pages/Crystal-Pharma-Ltd.aspx
1.7	Proposal	The decommissioning and dismantling of various structures as per IPPC application received on 27 September 2017. The cessation of <i>activity 4.1 in Schedule 1 of the Industrial Emissions (IPPC) Regulations (S.L. 549.77) ("the Industrial Emissions (IPPC) Regulations")</i> , to the extent authorised by the Permit, i.e. "Production on an industrial scale by chemical or biological processing of pharmaceutical products including intermediates".
1.8	Location	Crystal Pharma Ltd. BLB 200 Bulebel Industrial Estate Zejtun, ZNT 3000

2. Background

2.1	Policy Context	Environment Protection Act (CAP. 549) S.L. 549.76 requires an application for the permit to be surrendered as per requirements delineated in regulation 13: <i>"Applications for a permit (including for the variation, transfer, renewal or surrender thereof) shall be accompanied by such a fee as may be from time to time prescribed by the competent authority."</i> Additionally S.L. 549.77 also requires installations carrying out the abovementioned activities to take all necessary actions aimed at the removal, control, containment and reduction of relevant hazardous substances, so that the site ceases to pose any significant risk to human health and the environment due to the contamination of soil and water as a result of the permitted activities per requirements delineated in regulation 16:
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		<p>16 (3) (a) Upon definitive cessation of the activities, the operator shall assess the state of soil and groundwater contamination by relevant hazardous substances used, produced or released by the installation. Where the installation has caused significant pollution of soil or groundwater by relevant hazardous substances compared to the state established in the baseline report referred to in sub-regulation (2), the operator shall take the necessary measures to address that pollution so as to return the site to that state. For that purpose, the technical feasibility of such measures may be taken into account.</p> <p>b) Without prejudice to paragraph (a), upon definitive cessation of the activities, and where the contamination of soil and groundwater at the site poses a significant risk to human health or the environment as a result of the permitted activities carried out by the operator before the permit for the installation is updated for the first time after 7 January 2013 and taking into account the conditions of the site of the installation established in accordance with regulation 5(1)(d), the operator shall take the necessary actions aimed at the removal, control, containment or reduction of relevant hazardous substances, so that the site, taking into account its current or approved future use, ceases to pose such a risk.</p> <p>16 (4) Where the operator is not required to prepare a baseline report referred to in sub-regulation (2), the operator shall, upon definitive cessation of the activities, take the necessary actions aimed at the removal, control, containment or reduction of relevant hazardous substances, so that the site, taking into account its current or approved future use, ceases to pose any significant risk to human health or the environment due to the contamination of soil and groundwater as a result of the permitted activities and taking into account the conditions of the site of the installation established in accordance with regulation 5(1)(d).</p>																														
2.2	Justification for Application	Application for full surrender of the IPPC permit IP 0005/07/C has been submitted. The IPPC permit shall supersede IP 0005/07/C.																														
2.3	Permit History	<p>A summary of the IP permit processing is indicated below</p> <table border="1" data-bbox="555 1193 1359 2033"> <thead> <tr> <th data-bbox="555 1193 826 1234">Detail</th> <th data-bbox="826 1193 1090 1234">Date</th> <th data-bbox="1090 1193 1359 1234">Comment</th> </tr> </thead> <tbody> <tr> <td data-bbox="555 1234 826 1323">Application IP 0005/07</td> <td data-bbox="826 1234 1090 1323">Received between May & July 2007 (in various parts).</td> <td data-bbox="1090 1234 1359 1323">Not 'duly made'</td> </tr> <tr> <td data-bbox="555 1323 826 1469">Response to request for information</td> <td data-bbox="826 1323 1090 1469">Request dated 06 September 2007</td> <td data-bbox="1090 1323 1359 1469">Response dated 27 September 2007 & 17 October 2007 'Duly made': 12 December 2007</td> </tr> <tr> <td data-bbox="555 1469 826 1615">Response to request for information</td> <td data-bbox="826 1469 1090 1615">Request dated 12 December 2007</td> <td data-bbox="1090 1469 1359 1615">Response received 10 January 2008 Consolidated version received 07 February 2008</td> </tr> <tr> <td data-bbox="555 1615 826 1677">Proposal for monitoring of gaseous emissions</td> <td data-bbox="826 1615 1090 1677">Proposal submitted 23 January 2008</td> <td data-bbox="1090 1615 1359 1677">Proposal accepted by MEPA 28 January 2008</td> </tr> <tr> <td data-bbox="555 1677 826 1740">Response to request for information</td> <td data-bbox="826 1677 1090 1740">Request dated 30 January 2008</td> <td data-bbox="1090 1677 1359 1740">Response received 07 July 2008</td> </tr> <tr> <td data-bbox="555 1740 826 1830">Response to request for information on HVAC system</td> <td data-bbox="826 1740 1090 1830">Request dated 08 May 2008</td> <td data-bbox="1090 1740 1359 1830">Response received 26 May 2008</td> </tr> <tr> <td data-bbox="555 1830 826 1892">Public consultation</td> <td data-bbox="826 1830 1090 1892">Commenced on 14 February 2008</td> <td data-bbox="1090 1830 1359 1892">Concluded on 15 March 2008</td> </tr> <tr> <td data-bbox="555 1892 826 1955">Permit determined (IP 0005/07/A)</td> <td data-bbox="826 1892 1090 1955">Permit determined: 27 November 2008</td> <td data-bbox="1090 1892 1359 1955">Permit issued: 14 May 2009</td> </tr> <tr> <td data-bbox="555 1955 826 2033">Application for renewal of the IPPC permit IP 0005/07</td> <td data-bbox="826 1955 1090 2033">Request dated 18 June 2010</td> <td data-bbox="1090 1955 1359 2033">Response received by March 2011</td> </tr> </tbody> </table>	Detail	Date	Comment	Application IP 0005/07	Received between May & July 2007 (in various parts).	Not 'duly made'	Response to request for information	Request dated 06 September 2007	Response dated 27 September 2007 & 17 October 2007 'Duly made': 12 December 2007	Response to request for information	Request dated 12 December 2007	Response received 10 January 2008 Consolidated version received 07 February 2008	Proposal for monitoring of gaseous emissions	Proposal submitted 23 January 2008	Proposal accepted by MEPA 28 January 2008	Response to request for information	Request dated 30 January 2008	Response received 07 July 2008	Response to request for information on HVAC system	Request dated 08 May 2008	Response received 26 May 2008	Public consultation	Commenced on 14 February 2008	Concluded on 15 March 2008	Permit determined (IP 0005/07/A)	Permit determined: 27 November 2008	Permit issued: 14 May 2009	Application for renewal of the IPPC permit IP 0005/07	Request dated 18 June 2010	Response received by March 2011
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		<i>Public consultation</i>	<i>Commenced on 19 March 2011</i>	<i>Concluded on 18 April 2011</i>
		<i>Permit determined (IP 0005/07/B)</i>	<i>Permit determined: 21 July 2011</i> <i>Permit issued: 22 September 2011</i>	<i>Permit expires on 22 September 2015</i>
		<i>Application for variation of the IPPC permit IP 0005/07 (to include an additional emission point from the plant)</i>	<i>Request dated 25 September 2012</i>	<i>Response received on 04 December 2012</i>
		<i>Public consultation</i>	<i>Commenced on 08 December 2012</i>	<i>Concluded on 16 January 2013</i>
		<i>Permit determined (IP 0005/07/C)</i>	<i>Permit determined: 22 January 2015</i>	
		<i>Permit Issued</i>	05 October 2015	<i>Permit expired on 22 September 2015, however it was renewed on 5 October 2015 until the subsequent application for variation and renewal was determined.</i>
		<i>Application for the variation of the IPPC permit 0005/07 (to include the installation of a water purification system and the modification of an emission point</i>	<i>Request dated 27 July 2015</i>	<i>Application withdrawn by applicant on 4 August 2017</i>
		<i>Application for full surrender of the IPPC permit</i>	<i>Request dated 27th September 2017</i>	<i>Response received between November 2017 and February 2018</i>
		<i>Public consultation</i>	<i>Commence on 22nd February 2018</i>	<i>Concluded 8th March 2018</i>

2.4	Compliance History	<p>In terms of compliance checks</p> <p>Since the issue of the first permit, numerous inspections were carried out on site in which several non-compliances were noted over the years as highlighted in the table below.</p> <table border="1"> <thead> <tr> <th>Date</th> <th>Compliance Issue</th> <th>ERA follow-up</th> </tr> </thead> <tbody> <tr> <td>5 March 2009</td> <td> <ul style="list-style-type: none"> Follow-up inspection to explosion </td> <td> <ul style="list-style-type: none"> Following the incident the Authority requested that a follow-up report is to be submitted. </td> </tr> <tr> <td>4/5 March 2010</td> <td> <ul style="list-style-type: none"> Inappropriate air mitigation in areas of API handling. Additionally an extraction fan and an open door were noted in the production area. </td> <td> <ul style="list-style-type: none"> Requirement for the installation to install abatement for the exhaust air. Instructions so that storage and handling of APIs were only to occur in a closed </td> </tr> </tbody> </table>			Date	Compliance Issue	ERA follow-up	5 March 2009	<ul style="list-style-type: none"> Follow-up inspection to explosion 	<ul style="list-style-type: none"> Following the incident the Authority requested that a follow-up report is to be submitted. 	4/5 March 2010	<ul style="list-style-type: none"> Inappropriate air mitigation in areas of API handling. Additionally an extraction fan and an open door were noted in the production area. 	<ul style="list-style-type: none"> Requirement for the installation to install abatement for the exhaust air. Instructions so that storage and handling of APIs were only to occur in a closed
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			and controlled environment.
		5 April 2011	<ul style="list-style-type: none"> Ongoing discussions in relation to air abatement in areas of API handling .
		9 July 2012	<ul style="list-style-type: none"> Complaint received in relation to strong chemical odors emanating from the installation. Source of which was identified as being from an extractor which was located close to the main entrance gate. The extractor was connected to an underground reservoir which catered for rainwater. Moreover there was a possibility that the rainwater may have been accidentally contaminated with chemicals which may have been accidentally discharged through runoff.
		11 July 2012	<ul style="list-style-type: none"> Strong foul odours emanating from the reservoir's extractor when switched on. It is to be noted that the extractor fan was not an authorized emission point to air.
			<ul style="list-style-type: none"> Operator was instructed to connect extractors and any other emission point/s to HVAC system with appropriate filtration. Operator was instructed to clean the reservoir. Requirement to switch off the wastewater reservoir's extractor Ensuring that the accumulated gases within the reservoir do not reach unsafe levels; Removal of all contents from the wastewater reservoir Testing of the reservoir for impermeability and to provide certification from a warranted architect or engineer; Analyses of the sample of wastewater from reservoir Instructions to carry out a redesign of the spillage and overflow system to ensure that

			<p>any releases from the sump and the warehouse are appropriately contained.</p> <ul style="list-style-type: none"> • Instructions were also given to ensure that reservoir shall only be utilised for the collection of rainwater and shall be continually monitored to ensure no accumulation of gases. Rainwater shall be segregated from all process areas that are potentially contaminated with raw materials, intermediates, products or other wastes. • The extractor shall be removed, as this is not an authorised emission point. A plan for implementation of this system.
		22 July 2013	<ul style="list-style-type: none"> • Issues with waste storage of IBCs. • Issues with site drainage. • Issued with air emission points.
		26 June 2014	<ul style="list-style-type: none"> • Issues with waste storage. • Issues with site drainage. • Issues with contracted waste disposal Crystal Pharma had put up a sign stating that wood pellets were being given away for use in Barbeques. <ul style="list-style-type: none"> • The Authority at the time highlighted that such an activity is not permitted and alternative means of disposal should be sought.
		30 September 2015	<ul style="list-style-type: none"> • Issues with waste storage outside the site cartilage. • Issues with waste storage on site. Waste oil iso-tanks did not have the any spill mitigation. • Issues with site drainage <ul style="list-style-type: none"> • Crystal Pharma was instructed to abide by waste handling best practices. • Crystal Pharma was instructed

			in relation to the boundary of the warehouse and the boiler room.	to immediately seek alternative storage methods for the waste oil tank and to ensure that hazardous liquid waste requires the appropriate abatement. <ul style="list-style-type: none"> Operator was instructed at the time to block the drain leading from the boiler room to the car park.
		N/A	A long period of time in which site was not covered by an Environment Management System and Environmental SOPs were not in place.	Documentation was only submitted in October 2015.
	<p><u>Moreover, all improvement programme items have been implemented through Permit C.</u></p> <p>In terms of annual reporting</p> <p>AERs from the years 2009-2017 have been submitted consistently. No discrepancies or exceedances in AERs were noted.</p> <p>In terms of incidents on site</p> <p>In terms of compliance assessment during the operative years, annual inspections were carried out in years 2009 till 2015, during which no particular operational non-compliances were identified. It should however be noted that in March 2009, an explosion took place when during grinding works carried out by a third party over the wastewater sump. The presence of heptane (solvent) in the wastewater provoked a fire. The explosion caused the collapse of the roof of a wastewater sump. Following the incident an inspection was held shortly afterwards in which it was ultimately agreed that a re-design of the spillage and overflow system was required. Additionally connections to the wastewater sump should be sealed off completely. In the follow-up of an IPPC audit in 2010, the Operator had implemented all the recommendations of the incident report, and the Authority at the time had not requested any further measures. No further environmental incidents have occurred since.</p>			
2.5	Planning History	PA file	Title	Date of Issue
		PA 7583/06	Alterations to factory BLB 200 at Bulebel Industrial Estate, Zejtun	11 June of 2008
		PA 430/05	Extension and additions and alterations to factory.	Withdrawn

3. Non Technical Summary of Activities

Proposed activities

3.1	Activity listed in Schedule 1 of the Industrial Emissions (IPPC) Regulations / Associated Activity	Description of specified activity	Limits of specified activity
	Associated activity of storage, treatment and disposal/recycling of waste materials	Handling, storage, treatment and disposal/recovery of wastes from installation.	From generation of waste to disposal or recycling onsite or offsite.
	Decommissioning and Dismantling	Decommissioning of the structures outlined in the IPPC application submitted on 21 February 2018	From the decommissioning as per approved method statements to the appropriate disposal of all resulting wastes
3.2	Applicable BREFs	<p>During the operational phase of the installation the following BREFs were applicable:</p> <p><i>Best available techniques (BAT) specified in the BREF for Manufacture of Organic Fine Chemicals (published August 2006).</i></p> <p><i>Best available techniques (BAT) specified in the BREF for emissions from storage (published July 2006);</i></p> <p><i>Best available techniques (BAT) specified in the BREF for the common waste water and waste gas treatment/ management systems in the chemical sector.</i></p>	
3.3	Proposed emissions and mitigation during the decommissioning activities for site closure.	<p>Timeline of activities</p> <p>The scheduled dismantling timeline must be adhered to. Any deviations must be notified to ERA.</p> <hr/> <p>Extent of Decommissioning</p> <p>Extent of decommissioning as established in the consolidated IPPC application received on 22 February 2018 and in the termination agreement reached between Malta Industrial Parks Limited and Crystal Pharma Limited.</p> <hr/> <p>Waste Management</p> <p>Issues pertaining to waste characterization, quantification of the various waste streams and final disposal locations will be disclosed as part of the Site Closure Plan.</p> <p>Provisions for thorough waste auditing for each of the identified waste streams through the submission of the Waste Log (Schedule 3).</p> <p>Waste generated as part of the decommissioning, dismantling and demolition must be stored in the designated approved temporary waste storage site.</p> <p>Provisions for the handling of hazardous material and appropriate segregation of waste included.</p> <hr/> <p>Land & groundwater testing</p> <p>A field study was carried out between 16 and 19 January 2018. Eight boreholes with a depth ranging between 1m to 14 m were drilled.</p> <p>Soil samples were analyzed for the following:</p> <ul style="list-style-type: none"> • VOCs +TICs • Metals • Acetone and alcohols 	

- Total Petroleum Hydrocarbons
- Dioxins
- Polychlorinated Biphenyls
- Asbestos
- Total Organic Carbon.

A water sample collected was analyzed for the following:

- VOCs +TICs
- Metals
- Acetone and alcohols
- Total Petroleum Hydrocarbons
- Total Organic Carbon
- Chemical Oxygen Demand
- Biochemical Oxygen Demand

From the results obtained two samples showed exceedances.

1) Alcohols (methanol and butanol) were detected in the soil sample around the **sump** in:

- BH - 6 (71mg/kg and 34 mg/kg)
- BH -7 (107 mg/kg and 54 mg/kg)

(Dutch Indicative level of severe contamination 30 mg/kg for both)

The impact was vertically delineated until 11.5m in BH-6. Other alcohols compounds with no international reference levels were also detected (ethyl alcohol, hexyl alcohols)

2) From the groundwater analytical results, water was detected at a very shallow depth of 1.6 m it is thought to be perched groundwater and not connected to any aquifer. At an external storage area the following compounds were detected.

- Arsenic- 19 µg/L (Maltese reference level 5 µg/L)
- Total Petroleum Hydrocarbons- 4,820 µg/L (Maltese reference level 350 µg/L)

For the remaining compounds analyzed in soil and groundwater samples were detected below the reference levels or below the laboratory detection limits.

Based on the results, a Quantitative Risk assessment (QRA) was conducted. The results of which have been used to define the future use of the site. From the QRA *the results indicated that there is no risk for on-site workers in both source areas (utilities area and external storage area) and adjacent indoor areas, considering both outdoor and indoor vapor inhalation exposure pathways.* The QRA ascertained that the environmental risk posed by these exceedances is well below the acceptable risk level and thus no remediation works are required.

With regards to the sump area, it has been argued that the current sump is impermeable as it has been certified leak proof in 2015. Consequently it is assumed that the alcohol concentrations detected in soil samples originated from former industrial activities carried out at the Site. Given that alcohols have low toxicity and biodegrade easily it is understood that no particular remediation/soil investigation is considered to be necessary. With regards to the arsenic it is presumed that these elevated results are due to background levels. In relation to the elevated TPH levels no remarks on whether remediation is required has been indicated. The monitoring well will however be sealed.

The site shall be entirely sealed to ensure no further infiltration of rainwater causing downward leaching of substances identified.

4. Consultations

4.1	Internal	<p>The feedback indicated below refers to consultations carried on the application as well as the permit:</p> <hr/> <p><i>Air & Waste; Air Quality Team</i></p> <hr/> <p>No feedback received.</p> <hr/> <p><i>Air & Waste; Waste Management Team</i></p> <hr/> <p><u>Comments on application:</u></p> <p>After reviewing the documents in relation to the Full Surrender of permit for Crystal Pharma, please note that the waste team has no particular comments with regards to the decommissioning of the site and the procedures outlined for the testing of soil/land contamination.</p> <p>It should be highlighted that any waste related activities need to be carried out in line with S.L. 549.63 – the Waste Regulations, waste planned to be disposed of in a landfill would need to meet the criteria set out in Council Decision 2003/33/EC, and any shipment of waste needs to be in line with Regulation No. 1013/2016. Updated Annex 11- Waste logbook is to be provided.</p> <p><u>Comments on permit:</u></p> <p>No further comments</p> <hr/> <p><i>Air & Waste; Noise Team</i></p> <hr/> <p>There are no comments from a Noise perspective on the application and the permit.</p> <hr/> <p><i>Biodiversity & Water Unit</i></p> <hr/> <p>No further comments.</p> <hr/> <p><i>Compliance & Enforcement Unit</i></p> <hr/> <p>Feedback provided regarding the permit has been taken on board.</p> <hr/> <p><i>Environmental Assessment Unit</i></p> <hr/> <p>No further comments.</p> <hr/> <p><i>Permitting Unit; Waste Permitting</i></p> <hr/> <p>No further comments.</p> <hr/> <p><i>Permitting Unit; Nature Permitting</i></p> <hr/> <p>No further comments.</p>
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4.2	<p>External</p> <p>(in terms of regulation 19(2) of S.L. 549.77)</p>	<p><i>Civil Protection Department</i></p> <p>The Civil Protection Department does not find any objection for the proposals to take place, provided the dismantling of the plant is made or carried out according to the decommissioning report prepared. It was requested that no flammable or hazardous chemical materials are to be left on site. Additionally the fire hydrant system is to be left active at least until the whole dismantling process takes place. A competent person is also to remain available throughout the whole dismantling process to advise the fire service with any hazardous materials kept there until the whole area is made safe.</p> <hr/> <p><i>Malta Resources Authority</i></p> <p>No comments were received from this entity but referred documentation to EWA.</p> <hr/> <p><i>EWA</i></p> <p>The 'groundwater' in question does not refer to a groundwater body but is most probably a 'lens' in the globigerina limestone – usually of very limited extent. The Tarxien area includes such lenses – so the situation is plausible.</p> <p>The values encountered were of concern to the agency since slowly these would leach to the mean sea level aquifer. EWA recommended that ERA undertakes an independent risk assessment, given these results – and assesses if the conditions exist to request the decontamination of the site.</p> <p>Following further discussions with EWA it transpired that concerns would be addressed through site sealing and, in the event of future works within the site, ERA would ensure that wastes generated are duly characterized and disposed of accordingly.</p> <hr/> <p><i>Malta Competition and Consumer Affairs Authority</i></p> <p>No comments were received from this entity.</p> <hr/> <p><i>Occupational Health and Safety Authority</i></p> <p>OHSA requested that the Operator is to conform to all applicable OHS legislation. It was noted that the documents submitted the operator declared adherence to all Occupational Health and Safety regulations.</p> <hr/> <p><i>Planning Authority</i></p> <p>PA commented that the surrender of the IPPC does not constitute a development and hence there is no objection from a planning point of view.</p> <hr/> <p><i>REWS</i></p> <p><u>Comments on application</u></p> <p>The Regulator notes the following from documents provided in the CD :</p>
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1. "A diesel tank and a waste liquids process tank are present on site. These will be emptied and cleaned by a licensed waste contractor. Equipment will remain on site for reuse as per agreement with MIP".

and

2. "... In addition, raw materials were properly handled and stored."

And

3. "The Site ceased production on the 31st July 2017 and is currently conducting the decommission process. ERM conducted a Site visit in May 2017 with the aim of conducting a preliminary environmental assessment within the context of the potential Site Closure Process. At the time, sale of the Site was also being considered."

Crystal Pharma has sent a letter dated 23/01/18 informing the Regulator that the tank was cleaned by waste carriers and fuel has been safely disposed.

As for the surrender of the IPPC permit the REWS has no further comments.

Since the equipment including the thermal oil reservoir and diesel reservoir for boiler will remain on site, if you are in communication with MIP or any other applicant interested in this site's communication, then the applicant should get in touch with the Regulator for Energy and Water Services (REWS) for guidance in authorisations/notifications of any secondary storages facilities of petroleum.

Comments on permit

No further comments.

Environmental Health Directorate

Comments on application

EHD advised ERA that the Directorate did not have any comments/recommendations regarding the full surrender. Additionally the cooling towers on site have been deregistered with EHD.

Comments on permit

No further comments.

Water Services Corporation

Comments:

1. Feedback to ERA comment no.13 (Section 4 no. 1.6) – All cleaning/rinsing operations of pipework, equipment and tanks which will be channeled to the existing waste water sump shall not be discharged to sewer prior to testing of this effluent is performed and approval given by the Discharge Permit Unit.
2. Upon surrendering of the Sewer Discharge Permit, Crystal Pharma are to give a report of all waste waters generated by the decommissioning process including a description of the source of waste water, approximate volume, mode of disposal and name of waste contractor.
3. During transport/relocation of chemicals, it is important that spillage mitigation measures are observed and any spillages of chemicals should not be directed to sewer but contained and disposed of through approved waste contractors. Same applies for the storage/transport/relocation of raw materials.

Clarifications were required as to whether the cooling tower and scrubber will be

		drained and cleaned given these structures will remain on site. Clarification was also required on the disposal location of such waste waters and as to whether the back-up waste water tank will also be removed. Operator informed WSC that the waste water generated after cleaning the scrubber and the cooling tower were treated as non-halogenated aqueous waste and disposal through PT Matic. With regards to the cooling tower, the Authority was informed that it will remain on site and that it had been cleaned on September 12th 2017 by Falzon group.
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5. Public consultation

5.1	Public consultation	22 nd February 2018 – 8 th March 2017
5.2	Response	<i>No responses were received.</i>

6. Conditions

		<p>Residual Operating condition for operational plant</p> <p>The Permitted Installation is subject to the conditions of the Permit, be managed, controlled and operated using the techniques and in the manner described in the original IPPC application and in the subsequent applications for renewal and variation, or as otherwise agreed in writing by the Authority</p> <p>General Conditions</p> <p>General outline of the permit.</p> <p>Permitted Activities</p> <p>Conditions are in place to allow specific operations as described in section 1.1 above and in Table 1.1.1 of the permit. Only dismantling operations are allowed. Production of Active Pharmaceutical Ingredients is not allowed.</p> <p>Site</p> <p>Boundary outline for the permitted activities above.</p> <p>Overarching Management Conditions</p> <p>Condition for the implementation of Environmental Management System (EMS).</p> <p>Improvement Programme</p> <p>Refer to section 7.2</p> <p>General Considerations</p> <p>Conditions include provisions regarding saving third party rights and duty of care of the environment and reporting of incidents.</p> <p>Closure and Decommissioning</p> <p>Specific conditions relating to the dismantling and handling of hazardous waste and general adherence to waste management regulations. Various conditions regarding the storage on site of own waste pending disposal at permitted facilities. Conditions in this section mainly deal with storage, transport, disposal and record keeping.</p> <p>Emissions to Air</p> <p>No Emissions to air are allowed.</p> <p>Discharges to surface water</p>
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		<p>No discharges to surface waters are allowed.</p> <p>Discharges to sewer</p> <p>The operator shall also abide by the general provisions of the Sewer Discharge Control Regulations (S.L. 545.08) and the Sewer Discharge Permit.</p> <p>Discharges to groundwater</p> <p>No discharges to groundwater are allowed as per requirement of S.L. 549.53. Conditions also include provisions to safeguard the good chemical and quantitative status of ground waters as required under the Water Policy Framework Regulations, S.L. 549.100.</p> <p>Odour</p> <p>Operator shall use BAT so as to prevent or where that is not practicable to reduce odorous emissions from the Permitted Installation.</p> <p>Emissions to Land</p> <p>No emissions to land are allowed.</p> <p>Noise and Vibration</p> <p>The Operator shall use BAT so as to prevent or limit emissions of noise and vibration. Various mitigation measures apply to alleviate noise and vibration from the installation.</p> <p>Accident Prevention and Control</p> <p>In the case of an accident, the Operator is being required to follow the Emergency Plan, which was also submitted to the Civil Protection Department.</p> <p>Management and Technically competent person</p> <p>Conditions have been included to address training of staff, personnel proficiency and issues pertaining to the Technically competent person</p> <p>Records, Reporting and Notification</p> <p>The operator is required to maintain records on several aspects of the permit and have these available for inspection by the Authority should the need arise. A notification system has also been set up so as to ensure that any exceedances from ELVs, incidents on site or fugitive emissions are reported within a specific timeframe and through a set process.</p> <p>Interpretation</p> <p>This section includes an explanation of terminology utilised in the permit where it is deemed to require an explanation.</p>
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7.2	Improvement Programme	<table border="1"> <thead> <tr> <th data-bbox="555 1682 687 1711">Reference</th> <th data-bbox="687 1682 1098 1711">Requirement</th> <th data-bbox="1098 1682 1366 1711">Date</th> </tr> </thead> <tbody> <tr> <td data-bbox="555 1711 687 1803">4</td> <td data-bbox="687 1711 1098 1803">Submission of a letter notifying the Authority of the completion of the dismantling works</td> <td data-bbox="1098 1711 1366 1803">Within 1 week of completion of works</td> </tr> <tr> <td data-bbox="555 1803 687 2011">5</td> <td data-bbox="687 1803 1098 2011">Submission of certification by an independent, warranted civil engineer or engineer showing that any catchment pits, reservoirs and bunds on site have been visually inspected and ascertained free from visual surface contamination.</td> <td data-bbox="1098 1803 1366 2011">Within 1 month of completion of works</td> </tr> <tr> <td data-bbox="555 2011 687 2033">6</td> <td data-bbox="687 2011 1098 2033">For each waste stream arising from</td> <td data-bbox="1098 2011 1366 2033">Finalized schedule 3</td> </tr> </tbody> </table>	Reference	Requirement	Date	4	Submission of a letter notifying the Authority of the completion of the dismantling works	Within 1 week of completion of works	5	Submission of certification by an independent, warranted civil engineer or engineer showing that any catchment pits, reservoirs and bunds on site have been visually inspected and ascertained free from visual surface contamination.	Within 1 month of completion of works	6	For each waste stream arising from	Finalized schedule 3
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			the dismantling of the structures listed in the IPPC application.	form to be updated and submitted to ERA within 2 months of completion of works
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8. Financial matters

8.1	Financial guarantee	A financial guarantee of € 12,600 to secure the obligations under this permit has been established.
8.2	Annual Fee	Prior to issue of the permit, the applicant shall pay ERA the sum of €5,100 to cover the annual contributions for 2016-2018 (€1,500 per year) and inspections carried out in 2015-2018 (3 inspections at €200 each)
8.3	Other fees	Future remittances will consist of the fixed annual amount of €1,500 and a variable addition reflecting ERA's cost for inspections. The latter variable component depends on the actual number of site inspections, which is determined by the performance of the operator. The total annual contribution has to be paid before the anniversary of the date of issue of this permit. Variations in ERA's inspection expenditure will be reflected in the following year's contribution.

9. Recommendation

IP 0005/07/D is being recommended for issue, subject to the conditions indicated in section 7 for a period of 2 years.	
This report to the ERA Board has been prepared and endorsed by:	
Case Officer:	Gabriella Grima Environment Protection Officer
Endorsed by:	Anthony Aquilina Unit Manager
Signature:	Signature:
Date:	Date:
ERA Board Decision	

