

CLIENT:
EirGen Pharma Ltd.

CATEGORY:
Contract Research, Consultancy
and Feasibility Studies

**Innovative Research
Solutions with Industry**
Health and Biotechnology

Identification of Impurities within an Anti-Cancer Drug

ICTI
Institutes of Technology Ireland

EirGen Pharma is a pharmaceutical company based in Waterford, Ireland. Using its purpose built high-containment facility, EirGen Pharma specialises in the development, manufacture and registration of high potency cancer therapy products for global pharmaceutical markets. EirGen Pharma has recently developed Eir-010, a drug treatment for breast cancer, the leading cause of cancer-related deaths among Irish women.

The **Pharmaceutical and Molecular Biotechnology Research Centre (PMBRC)** at **Waterford Institute of Technology (WIT)** is an Applied Research Enhancement (ARE) Centre, funded by Enterprise Ireland. The PMBRC's research expertise includes pharmaceutical characterisation; formulation and polymeric drug delivery technologies; process technologies; biomedical research and biotechnology. The Centre has a range of analytical equipment to support this research.

Pharmaceutical impurities can arise during the manufacture and/or storage of the drug and can influence the efficacy or safety of the product. For EirGen Pharma, an impurity problem represented a significant barrier in the development of their Eir-010 drug as international pharmaceutical regulations require that impurities present above a certain level should be identified. Supported by Enterprise Ireland's Innovation Voucher scheme, EirGen Pharma engaged the PMBRC to analyse and →



Dr. Pat Duggan, lecturer in WIT, explains the operation of the liquid chromatography mass spectrometer.



Nuclear magnetic resonance equipment at the PMBRC

EirGen Pharma | www.eirgen.com

64/65 Westside Business Park,
Old Kilmeaden Road,
Waterford, Ireland.

T: +353 (0)51 591 944
F: +353 (0)51 591 945
E: info@eirgen.com



- > identify three unknown impurities in Eir-010, which were observed to form under storage conditions.

The PMBRC used a combination of analytical techniques, separation and spectroscopic techniques to determine the structure and identity

of the three impurities. EirGen Pharma was able to use the data generated by the PMBRC to support the filing of Eir-010 with the European Medicine Agency (EMA). Eir-010 was subsequently approved by the EMA and will be commercially launched in key European markets with sales worth €20m forecast over the next five years. ■

TESTIMONIALS

Tom Brennan

*Technical Director
and Co-founder,
EirGen Pharma Ltd.*

"We hear a lot of commentary about the 'Smart Economy' and the need for Ireland to move up the value chain – the research work of the PMBRC is a firm example of that going beyond rhetoric in the pharmaceutical sector. Our partnership with the Centre is a key part of our vision for EirGen Pharma and the working relationship has already been a very productive one on several levels – perhaps most starkly when research at the Centre allowed us proceed with a key drug in our portfolio that might otherwise have been abandoned."

Dr. Niall O'Reilly

*Manager, PMBRC,
WIT*

"Partnerships with industry are a huge part of the Centre's work and we very much see our mandate as being to use the talent and facilities we have to support indigenous and multinational companies in this sector. The timeline for EirGen Pharma's growth over the period since their formation in late 2005 has mirrored our own growth under the leadership of people like principal investigator and founder, Dr Peter McLoughlin, and the team that has grown in the same period."



Waterford Institute of Technology
INSTITIÚID TEICNEOLAÍOCHTA PHORT LAIRGE

Head of Research

DR. WILLIE DONNELLY

**Waterford Institute of
Technology**
Cork Road, Waterford
Ireland

T: +353 (0)51 845596

E: wdonnelly@wit.ie

External Services Manager

KATHRYN KIELY

**Waterford Institute of
Technology**
Cork Road, Waterford
Ireland

T: +353 (0)51 302034

E: kkiely@wit.ie

Centre Manager

DR. NIALL O'REILLY

**Pharmaceutical and
Molecular Biotechnology
Research Centre
Waterford Institute
of Technology**

Cork Road, Waterford
Ireland

T: +353 (0)51 306167

E: noreilly@wit.ie