

Accreditation Certificate

Synergy Health Ireland Ltd.

IDA Business & Technology Park, Tullamore, Co.Offaly

Testing Laboratory

Registration number: 164T

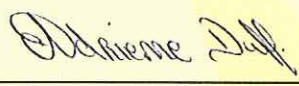
is accredited by the Irish National Accreditation Board (INAB) to undertake testing as detailed in the Schedule bearing the Registration Number detailed above, in compliance with the International Standard ISO/IEC 17025:2005 2nd Edition "General Requirements for the Competence of Testing and Calibration Laboratories"
(This Certificate must only be read in conjunction with the Annexed Schedule of Accreditation)

Date of award of accreditation: 23:05:2005

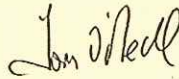
Date of last renewal of accreditation: 30:12:2014

Expiry date of this certificate of accreditation: 30:12:2019

This Accreditation shall remain in force until further notice subject to continuing compliance with INAB accreditation criteria, ISO/IEC 17025 and any further requirements specified by the Irish National Accreditation Board.

Manager: 

Dr Adrienne Duff

Chairperson: 

Mr Tom O' Neill

Issued on 30 December 2014

Organisations are subject to annual surveillance and are re-assessed every five years. The renewal date on this Certificate confirms the latest date of renewal of accreditation. To confirm the validity of this Certificate, please contact the Irish National Accreditation Board.

The INAB is a signatory of the European co-operation for Accreditation (EA) Testing Multilateral Agreement (MLA) and the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement.

Schedule of Accreditation

(Annex to Accreditation Certificate)



Permanent Laboratory:

Category A

Synergy Health Ireland Ltd.

Biological Testing Laboratory

Initial Registration Date : 23-May-2005
Postal Address: IDA Business & Technology Park
(Address of other locations as they apply) Tullamore
Co. Offaly
Telephone: +353 (57) 9349999
Fax: +353 (57) 9349997
E-mail: mary.rijksen@synergyhealthplc.com
Contact Name: Mary Rijksen
Facilities: Public testing service

Schedule of Accreditation



THE IRISH NATIONAL ACCREDITATION BOARD (INAB) is the Irish body for the accreditation of organisations including laboratories.

Laboratory accreditation is available to testing and calibration facilities operated by manufacturing organisations, government departments, educational institutions and commercial testing/calibration services. Indeed, any organisation involved in testing, measurement or calibration in any area of technology can seek accreditation for the work it is undertaking.

Each accredited laboratory has been assessed by skilled specialist assessors and found to meet criteria which are in compliance with ISO/IEC 17025 or ISO/IEC 15189 (medical laboratories). Frequent audits, together with periodic inter-laboratory test programmes, ensure that these standards of operation are maintained.

Testing and Calibration Categories:

- Category A:** Permanent laboratory calibration and testing where the laboratory is erected on a fixed location for a period expected to be greater than three years.
- Category C:** Site calibration and testing that is performed by staff sent out on site by a permanent laboratory that is accredited by the Irish National Accreditation Board.
- Category B:** Site calibration and testing that is performed in a site/mobile laboratory or by staff sent out by such a laboratory, the operation of which is the responsibility of a permanent laboratory accredited by the Irish National Accreditation Board.
- Category D:** Site calibration and testing that is performed on site by individuals and organisations that do not have a permanent calibration/testing laboratory. Testing may be performed using
- (a) portable test equipment
 - (b) a site laboratory
 - (c) a mobile laboratory or
 - (d) equipment from a mobile or site laboratory

Standard Specification or Test Procedure Used:

The standard specification or test procedure that is accredited is the issue that is current on the date of the most recent visit, unless otherwise stated.

Glossary of Terms

Facilities:

- Public calibration/testing service:** Commercial operations which actively seek work from others.
- Conditionally available for public calibration/testing:** Established for another primary purpose but, more commonly than not, is available for outside work.
- Normally not available for public calibration/testing:** Unavailable for public calibration/testing more often than not.

Laboratory users wishing to obtain assurance that calibration or test results are reliable and carried out to the Irish National Accreditation Board criteria should insist on receiving an accredited calibration certificate or test report. Users should contact the laboratory directly to ensure that this scope of accreditation is current. INAB will, on request, verify the status and scope.

Scope of Accreditation



Synergy Health Ireland Ltd.

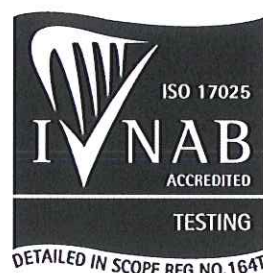
Biological Testing Laboratory

Permanent Laboratory:

Category A

INAB Classification number (P9) Materials/products tested		Type of test/properties measured Range of measurement	Standard specifications Equipment/techniques used
801	Tests on human pharmaceutical and biological products <i>(including medical devices)</i>		
	.10 Endotoxin tests	Endotoxin Units (EU) Turbidimetric method: 0.01 to 10 EU/mL Gel Clot method: 0.007 to 0.25 EU/mL	I-LAB-027-LAL Method based on US and European Pharmacopeia (Current Revision)
802	Tests on veterinary pharmaceutical and biological products <i>(including medical devices)</i>		
	.10 Endotoxin tests	Endotoxin Units (EU) Turbidimetric method: 0.01 to 10 EU/mL Gel Clot method: 0.007 to 0.25 EU/mL	I-LAB-027-LAL Method based on US and European Pharmacopeia (Current Revision)

Scope of Accreditation



Synergy Health Ireland Ltd.

Biological Testing Laboratory

Permanent Laboratory:

Category A

INAB Classification number (P9) Materials/products tested		Type of test/properties measured Range of measurement	Standard specifications Equipment/techniques used
807 .11	Microbiological tests on pharmaceuticals (including medical devices)		
	Sterility Tests	Sterility Test using TSB incubated at 20-25 °C or FTM incubated at 30 - 35 °C	I-LAB-042 based on US and European Pharmacopeia (Current Revision)
		Sterility Test using TSB incubated at 28 °C - 32 °C	I-LAB-042 based on EN ISO 11137-2:2012 and ISO 11737-2:2009
		Bacteriostasis and Fungistasis Test	I-LAB-041 based on US and European Pharmacopeia (Current Revision)
807 .12	Microbiological tests on pharmaceuticals (including medical devices) Microbial Counts	Bioburden Method (Pour plate or membrane filtration)	I-LAB-015 based on ISO 11737-1:2006