

# Equipment List

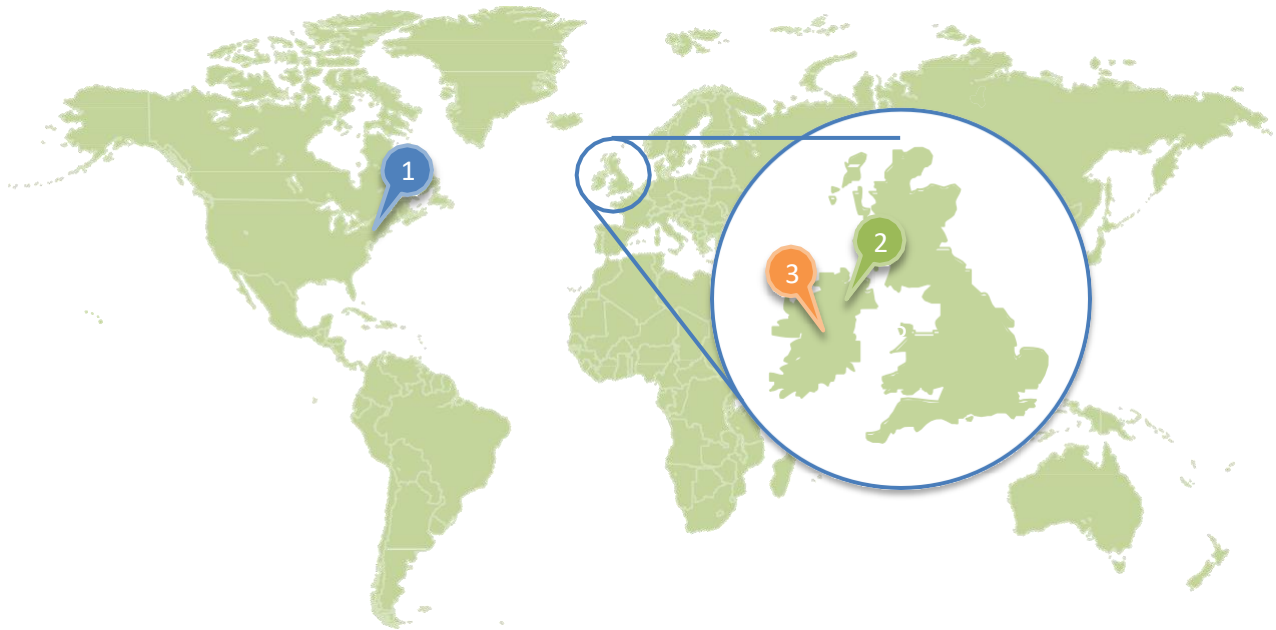
## Analytical Services

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## Location of sites



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# 1. Almac Sciences LLC, Souderton, Pennsylvania, United States

## 1.1 Analytical equipment (cGMP)

Technique	Instruments	Features	Numbers
Chromatography (HPLC)	Agilent 1200 HPLC systems	UV, CAD, RID Detectors	7
Chromatography (HPLC)	Agilent 1260 HPLC system with various detectors (PDA, VWD, CAD, RID)	PDA, UV, CAD, RID) Detectors	3
Chromatography (UPLC)	Agilent 1290 UPLC system with VWD	UV Detectors	1
Chromatography (HPLC)	Waters Alliance HPLC	UV Detectors	2
Chromatography (UPLC)	Waters H-Class systems	UV and PDA Detectors	3
Liquid Chromatography Mass Spectrometry	Waters H Class with QDa	Low resolution LC/MS	1
Chromatography (GC)	Agilent 7890A Agilent 7693 Auto sampler, headspace	FID Direct Inject and Headspace	2
Dissolution	Distek Evolution 6100 Dissolution Baths	Paddles and Baskets	5
Dissolution	Distek Evolution 6300 Dissolution Bath	Paddles and Baskets	1
Dissolution	Evolution 4300 Autosampler with dual pumps		4
Dissolution	Sotax MD Robot	Automated Paddles and Baskets with Camera Monitor	1
Disintegration	VanKel 100	Disintegration Testing	1
Infrared spectroscopy (FTIR)	Perkin Elmer Spectrum 100 FT-IR with ATR, DRIFT, Transmission		1
Ultraviolet-visible spectroscopy (UV-Vis)	Perkin Elmer Lambda 35 UV/VIS spectrophotometer		1
Water Content	Mettler C30 Coulometric Karl Fisher titrator	Karl Fischer coulometry, Stromboli oven	1
Water Content	Mettler V30 Volumetric Karl Fisher titrator	Karl Fischer volumetric titrator	1
Water Content	Metrohm 874 / 851	Karl Fischer coulometry, Stromboli oven	1

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Conductivity	Jenway 4510	Conductivity Testing	1
Water Activity	Rotronic	Water Activity Testing	1
Melting Point	Buchi M-565	Melting Point Testing	1

## 2. Almac Sciences Ltd, Craigavon, Northern Ireland, United Kingdom

### 2.1 Analytical equipment (cGMP)

Technique	Instruments	Features	Numbers
X-ray powder diffraction (XRPD)	Panalytical Xpert Pro MPD Pixcel detector	Reflection, transmission, variable temperature, auto-sampling	1
X-ray powder diffraction (XRPD)	PANalytical Aeris Research Edition	Reflection, transmission, variable temperature, auto-sampling	1
X-ray powder diffraction (XRPD)	PANalytical Empyrean with pixel detection	Reflection, transmission, well plates, variable temperature, auto-sampling	1
Differential scanning calorimetry (DSC)	Perkin Elmer Jade & Pyris 7	Sub-ambient, auto-sampling	1
Hyper DSC	Perkin Elmer Diamond	Sub-ambient to 350°C, up to 500K/min heat/cool rates	1
Thermogravimetric analysis (TGA)	Mettler Toledo STARE	Simultaneous DSC & TGA	1
Dynamic vapour sorption (DVS)	Hidden Isochema IGAsorp	Aqueous and organic vapour	1
Particle size analysis	Malvern Mastersizer 3000 Sympatec Helos	Wet and dry dispersion	2
Intrinsic dissolution	Distek Evolution 6300	Modified for small samples	1
Infrared spectroscopy (FTIR)	Thermonicolet Avatar 370 Perkin Elmer Spectrum RX1	ATR golden gate	2
Ultraviolet-visible spectroscopy (UV-vis)	Analytik Jena, Specord 200 & Hitachi U-2001		2
Nuclear magnetic resonance (NMR)	Bruker 500MHz Ultrashield Bruker 400MHz Ultrashield	<sup>15</sup> N to <sup>31</sup> P CryoProbe™ Prodigy <sup>1</sup> H, <sup>13</sup> C Probe 1D and 2D experiments	2
Chromatography (HPLC)	Waters Alliance	RI, CAD, Fluorescence detectors ion and size exclusion systems large prep scale capabilities	33
Chromatography (UHPLC)	Waters H-Class	PDA and UV visible coupled with mass spectrometry	27
Chromatography (HPLC)	Agilent 1260	RI, CAD, Fluorescence detectors ion and size exclusion systems large prep scale capabilities	20
Chromatography (UHPLC)	Agilent 1290	PDA and UV visible coupled with mass spectrometry	10

Chromatography (GC)	Agilent 6890	ECD, TCD and FID detectors Headspace systems	8
Liquid Chromatography Mass Spectrometry High Resolution	Agilent 6530 LC-Q-TOF Agilent 6230 LC-TOF Orbitrap Q-Exactive Plus BioPharma	LC- MS <sup>n</sup> capabilities, accurate mass	2
Liquid Chromatography Mass Spectrometry	Agilent 6460 LC-Triple Quad Sciex API 3000 LC-Triple Quad Waters QDa LC- Single Quad	LC- MS <sup>n</sup> capabilities	3
Inductively Coupled Plasma Mass Spectrometry (ICP- MS)	Agilent 7900 Thermo iCAP Q	Elemental analysis	2
Gas Chromatography Mass Spectroscopy	Agilent 7890/5975 Agilent 8890/5977	Simultaneous FID and MS analysis, liquid and headspace sample capabilities	2
Ion Chromatography	Dionex ICS-3000, ICS- 5000 and IC-6000	Conductivity and electrochemical detectors	5
Dissolution	Distek	USP apparatus I and II	8
Water content	Mettler Toledo DL39, C30, V30	Karl Fischer coulometry & titrimetry, Stromboli oven	8
Water Content	Metrohm 874 / 851	Karl Fischer coulometry, Stromboli oven	3
Polarimetry	Perkin Elmer 341		1
Autotitrator	Mettler Toledo T70		1
Stability testing	All ICH zones	Large humidity chambers	> 300 m <sup>3</sup> Capacity

## 2.2 Analytical equipment (non-GMP)

Technique	Instruments	Features
Microscopy	Smiths IlluminatIR Olympus BX51 Linkam hot-stage Keyence microscope	From 10 - 200X, polarizing filters, digital image capture, ATR & ARO objectives, -196 to 350°C, linked to FTIR
Raman spectroscopy	Perkin Elmer RamanMicro 200F series Raman Microscope Avalon RamanStation Fusion R1	Microscopy and mapping capabilities
Automated solubility determination	Clarity crystallisation station	Multi well reactor block with turbidity probes
Crystallisation development	Jacketed glass reactors (100mL - 20L)	Development of robust crystallization procedures with on-line particle size (cord)

	BlazeMetrics 900 probe with Raman spectrophotometer	length) distribution, morphology and polymorph monitoring
Formulation development	Freeze dryer Spray dryer High shear mixing (Ultra Turrax) Rotary evaporators (Buchi) Ball mill (Retsch)	Development of stabilised amorphous formulations
Software modelling tools	ACDLabs Percepta Dynochem suite Mercury HighScore Plus	pKa, log P, solubility modelling, crystal structure visualisation, unit cell indexing

### 3. Almac Sciences Ireland Ltd, Athlone, Ireland

#### 3.1 Analytical equipment (cGMP)

Description	
ICH stability storage	-80°C and -20°C freezers
	5°C refrigerated storage
	25°C/60%RH long term stability storage
	30°C/65%RH intermediate stability storage
	40°C/75%RH accelerated stability storage
Mass spectrometry	Sciex (X2) API 3000
	Sciex (X2) API 4000
	Sciex API 4000 QTRAP
Amino Acid Analyser	Sykam S433 Amino Acid Analyser
Chromatography	HPLC Shimadzu LC20 Prominence
	HPLC Waters (X5) UV, PDA, RI and fluorescence detection
	HPLC Perkin Elmer (X2) Series 200
	HPLC Shimadzu UFLC XR
	HPLC Shimadzu UFLC
	GC Agilent 7890A, 6890 (x3) with FID, ECD and NPD detection.
	Agilent Headspace units (x3)

	GC Hewlett Packard 6890														
	UPLC Waters H-Class Bio, (TUV, FLR, ELSD detection)														
Spectroscopy	Perkin Elmer Wallac Victor 1420														
	Molecular Devices Spectramax Plus 384														
	FT-IR Bruker Alpha-P														
	UV-Vis Analytik Jena Speedcord 205														
	SoloVPE from C-Technologies (Slope Spectroscopy)														
Electrophoresis	BioRad ChemiDoc MP (Comprehensive imaging system for gels and Western Blots)														
	BioRad TransBlot Turbo (Western Blots)														
	BioRad Tetra cell (SDS-PAGE, Native PAGE, 2-D PAGE, DGGE, Gel IEF)														
	Sciex PA 800 Plus (CE-SDS, CIEF, CZE)														
Drug product analysis	Dissolution baths Caleva 10+ST														
	Disintegration bath Caleva Dist 2														
	Friability tester Erweka TA 120														
Particle size distribution	Shimadzu SALD-2201														
	Malvern (ZSP Nano series) ZEN5600														
Bacterial Identification system	<p>Biolog Micro station - identification of Bacterial Isolates</p> <ul style="list-style-type: none"> <li>• Gram positive Rods</li> <li>• Gram Positive cocci</li> <li>• Gram negative rods.</li> </ul>														
Micro	<table> <tr> <td>QCELL260Cooler Incubator</td> <td>20-25°C</td> </tr> <tr> <td>Memmert Incubator INE 800</td> <td>30-35°C</td> </tr> <tr> <td>Memmert Incubator IFE 600</td> <td>42-44°C</td> </tr> <tr> <td>Memmert Incubator INE 600</td> <td>35-37°C</td> </tr> <tr> <td>Memmert Incubator INE 600</td> <td>30-35°C</td> </tr> <tr> <td>Memmert Cooled Incubator</td> <td>20-25°C</td> </tr> <tr> <td>IPC450 Memmert Incubator IFE</td> <td>37+/-1°C</td> </tr> </table>	QCELL260Cooler Incubator	20-25°C	Memmert Incubator INE 800	30-35°C	Memmert Incubator IFE 600	42-44°C	Memmert Incubator INE 600	35-37°C	Memmert Incubator INE 600	30-35°C	Memmert Cooled Incubator	20-25°C	IPC450 Memmert Incubator IFE	37+/-1°C
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Endotoxin	Pyros ® EQS v 1.2, Pyros Kinetic ® Flex System														
Particle Counter	Beckman Coulter 9703+ with HRLD150														
Osmometer	Osmol 1 TM Single Sample Micro Osmometer (Advanced Instruments)														
Other technologies	Perkin Elmer 2470 Wizard2 (Gamma counter)														
	Perkin Elmer Filtermate (Cell harvester)														
	ASYS Atlantis (Microplate washer - ELISA)														



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	CEM Technologies Mars6 (Microwave assisted digester)
	Savant Speedvac SPD2010 (Vacuum centrifuge)
	AA with flame and graphite furnace
	Metrohm Karl Fischer
	Mettler Toledo T70 Auto-Titrator
	Caleva Hardness tester
	Colorimeter
	CEM Microwave digester Mars 6
	Microscope
	Refractometer
	Polarimeter
	Melting Point