


**NO: SAMM 310**(Issue 2, 24 June 2025 replacement  
of SAMM 310 dated 24 June 2025)

Page: 1 of 4

<b>LABORATORY LOCATION/ CENTRAL OFFICE:</b>	Ain Medicare Sdn. Bhd. 6/44, Kawasan Perindustrian Pengkalan Chepa 2, 16100 Kota Bharu, Kelantan , 16100, KELANTAN MALAYSIA
	
<b>ACCREDITED SINCE :</b>	24 JUNE 2025
<b>FIELD(S) OF TESTING:</b>	CHEMICAL MICROBIOLOGICAL
<b>FIELD(S) OF CALIBRATION:</b>	PRESSURE

This laboratory has demonstrated its technical competence to operate in accordance with MS ISO/IEC 17025:2017 (ISO/IEC 17025:2017).

This laboratory's fulfillment of the requirements of ISO/IEC 17025 means the laboratory meets both the technical competence requirements and management system requirements that are necessary for it to consistently deliver technically valid test results and calibrations. The management system requirements in ISO/IEC 17025 are written in language relevant to laboratory operations and operate generally in accordance with the principles of ISO 9001 (see Joint ISO-ILAC-IAF Communiqué dated April 2017).

**\* The uncertainty covered by the CMC is expressed as the expanded uncertainty corresponding to a coverage probability of approximately 95 % and have a coverage factor of k=2 unless stated otherwise.**

<b>CENTRAL LOCATION:</b>	Ain Medicare Sdn. Bhd. 6/44, Kawasan Perindustrian Pengkalan Chepa 2, 16100 Kota Bharu, Kelantan , 16100, Kelantan
<b>FIELD(S) OF TESTING :</b>	CHEMICAL, MICROBIOLOGICAL

**SCOPE OF TESTING : CHEMICAL**

<b>Material / Product Tested</b>	<b>Type Of Test / Properties Measured / Range Of Measurement</b>	<b>Standard Test Methods / Equipment / Techniques</b>
<b>Pharmaceutical Formulation</b> Sodium Chloride Infusion	- Identification - Assay of Active Ingredient; (a) Sodium Chloride - pH	British Pharmacopoeia, Volume III, Sodium Chloride Infusion as documented in QT-SC1-001

# Schedule

Issue date: 24 June 2025  
Valid Until: -



## NO: SAMM 310

(Issue 2, 24 June 2025 replacement of SAMM 310 dated 24 June 2025)

Page: 2 of 4

Material / Product Tested	Type Of Test / Properties Measured / Range Of Measurement	Standard Test Methods / Equipment / Techniques
<b>Pharmaceutical Formulation</b> Sodium Chloride And Glucose Infusion	<ul style="list-style-type: none"> <li>- Identification</li> <li>- Acidity</li> <li>- 5-Hydroxymethyl Furfural and Related Substances</li> <li>- Assay of Active Ingredient:                             <ul style="list-style-type: none"> <li>(a) Sodium Chloride</li> <li>(b) Glucose (Dextrose)</li> </ul> </li> </ul>	British Pharmacopoeia, Volume III, Sodium Chloride and Glucose Infusion as documented in QTSCD-003
<b>Pharmaceutical Formulation</b> Glucose Dextrose Infusion	<ul style="list-style-type: none"> <li>- Identification</li> <li>- Acidity</li> <li>- 5-Hydroxymethyl Furfural and Related Substances</li> <li>- Assay of Active Ingredient:                             <ul style="list-style-type: none"> <li>(a) Glucose</li> </ul> </li> </ul>	British Pharmacopoeia, Volume III, Glucose Dextrose Infusion as documented in QT-DEI-004
<b>Pharmaceutical Water</b> Purified Water	<ul style="list-style-type: none"> <li>- Nitrates</li> <li>- Aluminium</li> <li>- pH</li> <li>- Oxidisable Substances</li> <li>- Conductivity</li> </ul>	British Pharmacopoeia, Volume II, Purified Water as documented in QT-PUWA-113
<b>Pharmaceutical Water</b> Water For Injections	<ul style="list-style-type: none"> <li>- Aluminium</li> <li>- Conductivity</li> <li>- pH</li> </ul>	British Pharmacopoeia, Volume II, Water for Injections as documented in QT-WFHP-110
<b>Water</b> Haemodialysis Water		
	<ul style="list-style-type: none"> <li>- Calcium</li> <li>- Magnesium</li> <li>- Potassium</li> <li>- Sodium</li> </ul>	APHA 3111 B
	<ul style="list-style-type: none"> <li>- Aluminium</li> <li>- Antimony</li> <li>- Arsenic</li> <li>- Barium</li> <li>- Cadmium</li> <li>- Chromium</li> <li>- Copper</li> <li>- Lead</li> <li>- Silver</li> <li>- Zinc</li> </ul>	APHA 3113 B

## SCOPE OF TESTING : MICROBIOLOGICAL

# Schedule

Issue date: 24 June 2025  
Valid Until: -



## NO: SAMM 310

(Issue 2, 24 June 2025 replacement of SAMM 310 dated 24 June 2025)

Page: 3 of 4

Material / Product Tested	Type Of Test / Properties Measured / Range Of Measurement	Standard Test Methods / Equipment / Techniques
Pharmaceutical Products	Bacterial Endotoxin Test	Kinetic Chromogenic Method Gel-Clot Method BP, Appendix XIV C
	Sterility Test	Membrane Filtration Test BP, Appendix XVI A
	Microbiological Examination of Non-sterile Products: 1. Microbial Enumeration Test 2. Test for Specified Microorganism – <i>Escherichia coli</i> , <i>Pseudomonas aeruginosa</i> , <i>Staphylococcus aureus</i> , <i>Salmonella spp.</i> , <i>Bile tolerant gram-negative bacteria</i>	BP, Appendix XVI B

<b>CENTRAL LOCATION</b>	Ain Medicare Sdn. Bhd. 6/44, Kawasan Perindustrian Pengkalan Chepa 2, 16100 Kota Bharu, Kelantan, 16100, Kelantan
<b>FIELD(S) OF CALIBRATION :</b>	PRESSURE,

## SCOPE OF CALIBRATION : PRESSURE

Instrument Calibrated/Measurement Parameter	Range	Calibration and Measurement Capability Expressed as an Uncertainty ( $\pm$ )*	Remarks
<b>Pressure Measuring Device</b> Pneumatic	(0 to 20) bar	0.009 bar	Calibrated using Reference Pressure Calibrator by Comparison Method with reference to AS 1349 – 1986 (R2018)
<b>Differential Pressure Gauge</b> Automatic	(0 to 500) Pa	0.88 Pa	Calibrated using Reference Pressure Calibrator by Comparison Method with reference to AS 1349 – 1986 (R2018)
	(500 – 1000) Pa	1.2 Pa	Calibrated using Automatic Reference Pressure Calibrator by Comparison Method with reference to AS 1349 – 1986 (R2018)

## Schedule

Issue date: 24 June 2025  
Valid Until: -



### **NO: SAMM 310**

(Issue 2, 24 June 2025 replacement  
of SAMM 310 dated 24 June 2025)

Page: 4 of 4

Scan this QR Code or visit <https://accreditation.ism.gov.my/public/listing/cab/samm-ct/3002471> for the current scope of accreditation