



SCOPE OF ACCREDITATION TO ISO/IEC 17025:2017

NORTH AMERICAN SCIENCE ASSOCIATES, LLC (NAMSA)
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Mendota Heights, MN 55120
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CHEMICAL

Valid To: May 31, 2028

Certificate Number: 6597.01

In recognition of the successful completion of the A2LA evaluation process, accreditation is granted to this laboratory to perform the following types of tests on medical devices, including but not limited to: polymers, metals & alloys, ceramics, drug compounds, and natural macromolecules:

<u>Test/Technology¹</u>	<u>Test Method</u>	<u>Categories of Measurement</u>
Elemental Scan by Inductively Coupled Plasma / Mass Spectrometry (ICP/MS)	ISO 10993-18	Quantitative
Extraction	ISO 10993-12	Qualitative / Quantitative
Screening of Residual Solvent Headspace by Gas Chromatography / Mass Spectrometry (HSGC/MS)	ISO 10993-18	Quantitative
Screening of Semi-Volatile and Non-Volatile Compounds by Ultra Performance Liquid Chromatography / Mass Spectrometry (UPLC/MS) and Ultra-High Performance Liquid Chromatography-Quadrupole Time-of-Flight Mass Spectrometry (UHPLC/Q-TOF-MS)	ISO 10993-18	Quantitative
Screening of Semi-Volatile and Volatile Compounds by Direction Injection Gas Chromatography / Mass Spectrometry (GC/MS)	ISO 10993-18	Quantitative
Exhaustive Extractions (SOP-00767)	ISO 10993-12	Qualitative / Quantitative
Semi-Quantitative Scan by Ion Chromatography (IC)	ISO 10993-18	Semi-Quantitative
Sample Preparation and Analysis for FT-IR and SEM/EDS	ISO 10993-18	Qualitative / Quantitative
Plastic Components and Systems Used to Manufacture Pharmaceutical Drug Products and Biopharmaceutical Drug Substances and Products	USP <665>	Quantitative
Assessment of Extractables Associated with Pharmaceutical Packaging/Delivery Systems	USP <1663>	Quantitative
Best Practices Guide for Evaluating Leachable Risk from Polymeric Single-use Systems used in Biopharmaceutical Manufacturing (BioPhorum)	USP <1664>	Quantitative
Extractables Testing of Polymeric Single-use Components used in Biopharmaceutical Manufacturing (BioPhorum)	USP <1664>	Quantitative

¹This scope meets the A2LA *P112 Flexible Scope Policy*



Accredited Laboratory

A2LA has accredited

NORTH AMERICAN SCIENCE ASSOCIATES, LLC (NAMSA)

Mendota Heights, MN

for technical competence in the field of

Chemical Testing

This laboratory is accredited in accordance with the recognized International Standard ISO/IEC 17025:2017 *General requirements for the competence of testing and calibration laboratories*. This accreditation demonstrates technical competence for a defined scope and the operation of a laboratory quality management system (refer to joint ISO-ILAC-IAF Communiqué dated April 2017).



Presented this 26th day of May 2026.

A blue ink signature of Mr. Trace McInturff.

Mr. Trace McInturff, Vice President, Accreditation Services
For the Accreditation Council
Certificate Number 6597.01
Valid to May 31, 2028

For the tests to which this accreditation applies, please refer to the laboratory's Chemical Scope of Accreditation.