



SCOPE OF ACCREDITATION TO ISO/IEC 17025:2017

Nelson Laboratories Fairfield, Inc.
122 Fairfield Road
Fairfield, NJ 07004
Dan Carrino Phone: 973 227 6882

CHEMICAL

Valid To: December 31, 2024

Certificate Number: 0056.02

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 raw materials, excipients, intermediate and finished product pharmaceuticals, dietary supplements, human cells, tissues, tissue products, and medical devices:

Monograph Testing Employing the Following:

| <u>Test/Technology</u> | <u>Reference Method(s)</u> | <u>In-House SOP</u> |
|---|-----------------------------------|----------------------------|
| Arsenic Limit Test | USP <211> | STP0234 |
| Atomic Absorption ¹ | USP <852> | N/A |
| Chloride and Sulfate Limit Test | USP <221> | N/A |
| Chromatography (GC and HPLC) ¹ | USP <621> | N/A |
| Dissolution | USP <711> | N/A |
| Ethylene Oxide Sterilization Residuals | ISO 10993 Part 7 | STP0235 |
| Heavy Metals Limit Test ¹ | USP <231> | STP0249 |
| ICP-MS ¹ | USP <232>, <233>, <730> | N/A |
| Identification Tests – General | USP <191> | N/A |
| Iron Limit Test | USP <241> | STP0231 |
| Lead Limit Test | USP <251> | STP0233 |
| Loss on Drying | USP <731> | N/A |
| Loss on Ignition | USP <733> | N/A |
| Melting Range | USP <741> | N/A |
| Nitrogen and Oxygen Determination in Nitrogen | USP-NF | STP0244 |
| Optical Rotation | USP <781> | SOP0590 |
| Particulate Matter in Injections | USP <788> | STP0247 |
| pH | USP <791> | SOP0516 |
| Readily Carbonizable Substances Limit Test | USP <271> | |
| Refractive Index | USP <831> | SOP0587 |
| Residual Solvents (Organic Volatile Impurities) ¹ | USP <467> | STP0222 |
| Residue on Ignition Limit Test | USP <281> | STP0230 |
| Specific Gravity | USP <841> | STP0236 |
| Spectrophotometric Identification Tests (FTIR, UV/VIS) ¹ | USP <197> | N/A |
| Thin Layer Chromatography Identification Tests | USP <201> | N/A |

| <u>Test/Technology</u> | <u>Reference Method(s)</u> | <u>In-House SOP</u> |
|-------------------------------------|-----------------------------------|----------------------------|
| Total Organic Carbon | USP <643> | STP0241 |
| Water Conductivity | USP <645> | STP0243 |
| Water Determination by Karl Fischer | USP <921> | STP0272 |

¹Portions of this scope meets A2LA *P112 – Flexible Scope Policy*.



Accredited Laboratory

A2LA has accredited

NELSON LABORATORIES FAIRFIELD, INC.

Fairfield, NJ

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 27th day of February 2023.

A blue ink signature of Mr. Trace McInturff.

Mr. Trace McInturff, Vice President, Accreditation Services
For the Accreditation Council
Certificate Number 0056.02
Valid to December 31, 2024

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