

CERTIFICATE OF ACCREDITATION

The ANSI National Accreditation Board

Hereby attests that

Fairfield Labs, LLC 2327 Chouteau Avenue St. Louis, MO 63103

Fulfills the requirements of

ISO/IEC 17025:2017

In the field of

TESTING

This certificate is valid only when accompanied by a current scope of accreditation document. The current scope of accreditation can be verified at www.anab.org.

Jason Stine, Vice President

Expiry Date: 14 June 2026 Certificate Number: AT-3104





SCOPE OF ACCREDITATION TO ISO/IEC 17025:2017

Fairfield Labs, LLC

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TESTING

Valid to: June 14, 2026 Certificate Number: AT-3104

Chemical

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
Potency	Chromatography USP <621>; Ion Chromatography USP <1065>	Pharmaceutical	HPLC, IC
Validation	USP <1225>	Pharmaceutical	HPLC, IC
pH	USP <1065>	Pharmaceutical	pH Meter
Titrimetry	USP <541>	Pharmaceutical	Glassware, Hot/Stir Plate

Biological

Version 005 Issued: July 22, 2024

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
Sterility	USP <71>	Pharmaceutical	Steristart Pump, ISO Class 7 Cleanroom, ISO Class 5 Testing Hood, Incubators
Particulate Matter	USP <788>; USP <789>	Pharmaceutical	Laser Particle Analyzer, Particle Free Water System, Biological Safety Cabinet, Filtration Manifold, Microscope

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Biological

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
Endotoxin	USP <85>	Ph <mark>ar</mark> maceutical	Biological Safety Cabinet, Kinetic Turbidimetric Reader
Preservative Challenge Test	USP <51>	P <mark>harm</mark> aceutical	Biological Safety Cabinet, Incubators
Container Closure Integrity	WI-SL-095	Pharmaceutical	Vacuum Chamber / Sphygmomanometer
Visual Inspection	USP <797>	Pharmaceutical	Black and White Visual Inspection Background with Light

Note:

1. This scope is formatted as part of a single document including Certificate of Accreditation No. AT-3104.



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