



SCOPE OF ACCREDITATION TO ISO/IEC 17025:2017

DHHS/FDA/ORA PHILADELPHIA LABORATORY

US Customs House
Room 900, 200 Chestnut St.
Philadelphia, PA 19106
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CHEMICAL¹

Valid To: September 30, 2023

Certificate Number: 5807.13

In recognition of the successful completion of the A2LA evaluation process (including an assessment of the laboratory's compliance with the A2LA Food Testing Program Requirements, containing the 2018 "AOAC International Guidelines for Laboratories Performing Microbiological and Chemical Analyses of Food, Dietary Supplements, and Pharmaceuticals"), accreditation is granted to this laboratory to perform the following tests with the associated technologies:

Technology:

Electrometric (pH)
FTIR Spectroscopy
Gas Chromatography (GC)
GC-FID
HPLC
Thin Layer Chromatography (TLC)
Titrimetry
UV-VIS

On the following materials: Active Pharmaceutical Ingredients (API's), Compounded Drugs, and Finished Dosage Forms

Using the following method references: United States Pharmacopeia (USP)

Typical Routine Test Methods:

<u>Test(s)</u>	<u>Method(s)</u>
Assay, Content Uniformity, Identification, Dissolution/Drug Release, Impurities and/or Related Compounds	USP <621> USP Monographs
Identification	FTIR USP (197K) TLC USP General Chapter <201> UV USP General Chapter <197U>

<u>Test(s)</u>	<u>Method(s)</u>
pH	USP <791>
Residual Solvents	USP <467>
Water Content (Karl Fischer)	USP <921>

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

WITHDRAWN





Accredited Laboratory

A2LA has accredited

DHHS/FDA/ORA/PHILADELPHIA LABORATORY

Philadelphia, PA

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 laboratory also meets the requirements of A2LA R204 – *Specific Requirements – Food and Pharmaceutical Testing Laboratory Accreditation Program*. 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 September 2021.

A blue ink signature of the Vice President, Accreditation Services.

Vice President, Accreditation Services
For the Accreditation Council
Certificate Number 5807.13
Valid to September 30, 2023

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