

### SCOPE OF ACCREDITATION TO ISO/IEC 17025:2005

ARL BIOPHARMA, INC. D.B.A ANALYTICAL RESEARCH LABORATORIES (ARL) 840 Research Parkway, Ste. 546 Oklahoma City, OK 73104 Tommy Means Phone: 405 271 1144

#### **CHEMICAL**

Valid To: April 30, 2018 Certificate Number: 2992.01

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 2015 "AOAC 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:

On drug substance (API / active material) and drug product (finished dosage form):

<u>Test Description</u>	<b>Method</b>
Antimicrobial Effectiveness	USP <51>
Microbial Limits	USP <61>
Sterility Test	USP <71>, ARL Method MBI-138
Bacterial Endotoxin Test	USP <85>, ARL Method MBI-128

On drug substance (API / active material) using USP-NF monographs:

<u>Test Description</u>	<b>Method</b>
Gas Chromatography	USP <621>, ARL Method EQI-406
High Performance Liquid Chromatography	USP <621>, ARL Method EQI-401
Spectrophotometric Identification Test (UV)	USP <197>, ARL Method EQI-433
Spectrophotometric Identification Test (FTIR)	USP <197>. ARL Method EOI-431

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(A2LA Cert. No. 2992.01) 05/03/2016



## Accredited Laboratory

A2LA has accredited

# ARL BIOPHARMA, INC. D.B.A. ANALYTICAL RESEARCH LABORATORIES (ARL)

Oklahoma City, OK

for technical competence in the field of

## **Chemical Testing**

This laboratory is accredited in accordance with the recognized International Standard ISO/IEC 17025:2005

General requirements for the competence of testing and calibration laboratories. This laboratory also meets the requirements of any additional program requirements in the Chemical field. 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 8 January 2009).



Presented this 3rd day of May 2016.

Senior Director of Quality & Communications For the Accreditation Council

Certificate Number 2992.01

Valid to April 30, 2018