

# CERTIFICATE OF ACCREDITATION

## The ANSI National Accreditation Board

Hereby attests that

DYNALABS, LLC 2327 Chouteau Ave. 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 <a href="www.anab.org">www.anab.org</a>.

5D

R. Douglas Leonard Jr., VP, PILR SBU

Expiry Date: 14 June 2024 Certificate Number: AT-3104





#### SCOPE OF ACCREDITATION TO ISO/IEC 17025:2017

#### DYNALABS, LLC

2327 Chouteau Ave. St. Louis, MO 63103

Lauren Sarver 314-241-3962 <u>lsarver@dynalabs.us</u>

#### **TESTING**

Valid to: June 14, 2024 Certificate Number: AT-3104

#### Chemical

| Specific Tests and/or<br>Properties Measured | Specificat <mark>ion, Standard,</mark><br>Method, or Test Technique | Items, Materials or<br>Product Tested | Key Equipment or<br>Technology |
|--|---|---------------------------------------|--------------------------------|
| Potency                                      | Chromatography USP <621>;<br>Ion Chromatography USP<br><1065>       | Pharmaceutical                        | HPLC, IC                       |
| Validation                                   | USP <1225>  | Pharmaceutical                        | HPLC, IC                       |
| рН   | USP <1065>  | Pharmaceutical                        | pH Meter                       |
| Titrimetry                                   | USP <541>   | Pharmaceutical                        | Glassware, Hot/Stir Plate      |
| Spectroscopy                                 | USP <851>   | Pharmaceutical                        | FT-IR                          |

#### **Biological**

| Specific Tests and/or<br>Properties Measured | Specification, Standard,<br>Method, or Test Technique | Items, Materials or<br>Product Tested | Key Equipment or<br>Technology  |
|--|---|---------------------------------------|---|
| Sterility                                    | USP <71>  | Pharmaceutical                        | Steristart Pump, ISO Class 7<br>Cleanroom, ISO Class 5<br>Testing Hood, Incubators                              |
| Particulate Matter                           | USP <788>;<br>USP <789>                               | Pharmaceutical                        | Laser Particle Analyzer, Particle Free Water System, Biological Safety Cabinet, Filtration Manifold, Microscope |
| Endotoxin                                    | USP <85>  | Pharmaceutical                        | Biological Safety Cabinet,<br>Kinetic Turbidimetric Reader  |



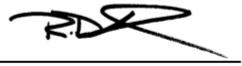


#### **Biological**

| Specific Tests and/or<br>Properties Measured | Specification, Standard,<br>Method, or Test Technique | Items, Materials or<br>Product Tested | Key Equipment or<br>Technology                          |
|--|---|---------------------------------------|---|
| Preservative Challenge Test                  | USP <51>  | Pharmaceutical                        | Biological Safety Cabinet,<br>Incubators                |
| Container Closure Integrity                  | WI-SL-095   | Ph <mark>arm</mark> aceutical         | Vacuum Chamber /<br>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.



R. Douglas Leonard Jr., VP, PILR SBU

