



# PERRY JOHNSON LABORATORY ACCREDITATION, INC.

## Certificate of Accreditation

*Perry Johnson Laboratory Accreditation, Inc. has assessed the Laboratory of:*

### ***Boston Analytical***

**8 Industrial Way, Bldg. D, Unit 8, Salem, NH 03079**

*(Hereinafter called the Organization) and hereby declares that Organization is accredited in accordance with the recognized International Standard:*

### **ISO/IEC 17025:2005**

This accreditation demonstrates technical competence for a defined scope and the operation of a laboratory quality management system (as outlined by the joint ISO-ILAC-IAF Communiqué dated January 2009):

***Chemical and Microbiological Testing of Pharmaceutical Products, Medical Devices, and Raw Materials***  
*(As detailed in the supplement)*

Accreditation claims for such testing and/or calibration services shall only be made from addresses referenced within this certificate. This Accreditation is granted subject to the system rules governing the Accreditation referred to above, and the Organization hereby covenants with the Accreditation body's duty to observe and comply with the said rules.

For PJLA:

Tracy Szerszen  
President/Operations Manager

*Initial Accreditation Date:*

May 20, 2014

*Issue Date:*

December 21, 2016

*Expiration Date:*

December 21, 2018

*Accreditation No.:*

76858

*Certificate No.:*

L16-512

Perry Johnson Laboratory  
Accreditation, Inc. (PJLA)  
755 W. Big Beaver, Suite 1325  
Troy, Michigan 48084

*The validity of this certificate is maintained through ongoing assessments based on a continuous accreditation cycle. The validity of this certificate should be confirmed through the PJLA website: [www.pjlabs.com](http://www.pjlabs.com)*



# Certificate of Accreditation: Supplement

## Boston Analytical

8 Industrial Way, Bldg. D, Unit 8, Salem, NH 03079  
Contact: Eric J. Ward Phone 603-893-3758

Accreditation is granted to the facility to perform the following testing:

FIELD OF TEST	ITEMS, MATERIALS OR PRODUCTS TESTED	SPECIFIC TESTS OR PROPERTIES MEASURED	SPECIFICATION, STANDARD METHOD OR TECHNIQUE USED	RANGE (WHERE APPROPRIATE) AND DETECTION LIMIT
Chemical <sup>F</sup>	Pharmaceutical products and raw materials	Loss on Drying	USP <731>	0 % to 100 %
		Karl Fischer Water	USP <911>	2 mg water to 250 mg water
		HPLC Assay	USP <621>	D.L. = S/N ≥ 3
	Tablets	Dissolution	USP <711>	D.L. = S/N ≥ 3
	Water and pharmaceutical products	Total Organic Carbon	USP <643>	N/A
Biological <sup>F</sup>	Pharmaceutical Products	Sterility	USP <71>	N/A
		KQCL	USP <85>	D.L = 0.005 EU/mL
Non-destructive <sup>F</sup>	Pharmaceutical products and raw materials	Appearance	USP	Appearance

1. The presence of a superscript F means that the laboratory performs testing of the indicated parameter at its fixed location. Example: Outside Micrometer<sup>F</sup> would mean that the laboratory performs this testing at its fixed location.