



PERRY JOHNSON LABORATORY ACCREDITATION, INC.

Certificate of Accreditation

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

Next Breath, A Division of AptarGroup Inc.
1450 South Rolling Road, Baltimore, MD 21227

(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 Testing
(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

<i>Initial Accreditation Date:</i>	<i>Issue Date:</i>	<i>Expiration Date:</i>
November 21, 2012	July 6, 2017	July 6, 2019

<i>Accreditation No.:</i>	<i>Certificate No.:</i>
72963	L17-284

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.pjlab.com



Certificate of Accreditation: Supplement

Next Breath, A Division of AptarGroup Inc.

1450 South Rolling Road, Baltimore, MD 21227

Contact Name: Kimberley MacLean Phone: 410-455-5614

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 ^F	Inhalation Products	Automated Actuation of Nasal Spray Pump Using Viota Software and a Proveris Scientific Automated Actuator	NB-SOP-020	FDA guidance for industry; nasal spray and inhalation solutions, suspensions, and spray drug products, chemistry manufacturing and control documentation July 2002
		Determination of Spray Content Uniformity of a Nasal Spray	NB-SOP-023	
		Spray Pattern Tests Using Viota Software and SprayVIEW NSP	NB-SOP-029	
		Plume Geometry Tests Using Viota Software and SprayVIEW NSP	NB-SOP-032	
		Plume Geometry Testing Using Viota Software with the SprayVIEW NMDI and MDx	NB-SOP-038	
		Spray Pattern Testing Using Viota Software with the SprayVIEW NMDI and MDx	NB-SOP-040	
		Droplet Size Distribution Measurement of a Drug Delivery Device Using Malvern Spraytec STP2000	NB-SOP-044	
		Determination of Particle Size Distribution from a Nebulizer Using the Next Generation Pharmaceutical Impactor (NGI)	NB-SOP-037	
		Determination of Aerodynamic Particle Size Distribution (APSD) from Inhalation and Nasal drug product: Aerosols, Sprays, and Powders Using the Next Generation Impactor (NGI)	NB-SOP-090	
		Plume Geometry Testing Using Viota Software with SprayVIEW NOSP and Vereo NSx	NB-SOP-083	
	Spray Pattern Testing Using Viota Software with SprayVIEW NOSP and Vereo NSx or Vereo SSx	NB-SOP-084		
Drug Containing Substances	Performing Liquid Chromatography Assignments	NB-SOP-016	Drug product specific per ICH guidelines, USP, BP and Brazilian pharmacopeia	

1. The presence of a superscript F means that the laboratory performs testing of the indicated parameter at its fixed location. Example: Outside Micrometer ^F would mean that the laboratory performs this testing at its fixed location.
2. For spray content uniformity 85-115% of label claim.