



## Dry Powder Inhaler- Product Development and Chemistry, Manufacturing and Controls Documentation

Next Breath is a full service cGMP compliant laboratory for analytical testing of inhaled and nasal spray drug products to support your CMC submission. Using the outline below for a model dry powder inhaler or nasal dry powder product, Next Breath will customize a program to meet your requirements according to the appropriate stability storage conditions, conduct the relevant experiments according to the Guidance for Industry: Metered Dose Inhaler (MDI) and Dry Powder Inhaler (DPI) Drug Products – Chemistry, Manufacturing, and Controls Documentation, interpret the test results and generate a report suitable for inclusion in your regulatory submission.

Specifications for the Drug Product					
In Vitro Test	Equipment	In-House	In Vitro Test	Equipment	In-House
<i>Shot Weight</i>	Analytical Balance	Y	Microscopy	Light Microscope	Y
<i>Drug Content</i>	HPLC, UPLC for Drug Assay	Y	<i>Assay: Drug, Excipients And Preservatives</i>	HPLC, UPLC with UV, CAD & PDA Detection Capabilities	Y
<i>Dose Content Through Container Life</i>	Unit Dose Collection Tubes TPK Controller HPLC for Drug Assay Analytical Balance	Y	<i>Moisture Content</i>	Karl Fisher Titration	Y
<i>Particle Size By Cascade Impaction</i>	Andersen Cascade Impactor Next Generation Impactor USP Throat HPLC TPK Controller Mass Flow Meter Vacuum Pump Analytical Balance	Y	<i>Microbial Limits</i>		N
			<i>Net Content (Fill Weight)</i>	Analytical Balance	Y
			<i>Appearance and Color Identification</i>	Visual	Y
			<i>Impurities and Degradation Products</i>	HPLC, UPLC with UV, CAD & PDA Detection Capabilities	Y
			<i>Leachables</i>		N
			<i>Extractables</i>		N
One Time Drug Product Characterization Studies					
Stability of Primary Package (for foil overwrapped products)		Y	Effect of Flow Rate on Dose Content Uniformity and Particle Size		Y
Dose Buildup		Y	Effect of Storage Orientation on Dose Content Uniformity & Particle Size		Y
Device Ruggedness		Y	Photostability		Y
Temperature Cycling		Y	Drop Test and Vibration Tests		Y
Effect of Moisture on Device Performance		Y			
Formulation Support, Device Selection and Development Studies					
Spray Pattern (Nasal DPI)		Y	Powder Flow		Y
Plume Geometry (Nasal DPI)		Y	Surface Properties and Amorphous Content		N
Device Resistance		Y	Effect of Device Orientation and Patient Handling		Y
Excipient Selection		Y	Effect of Flow Rate of Particle Deaggregation		Y