



Metered Dose Inhaler- Chemistry, Manufacturing, and Controls Documentation

Next Breath is a full service cGMP compliant laboratory for analytical testing of inhaled drug products to support your CMC submission. Using the outline below for a model metered dose inhaler 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>Valve Delivery (Shot Weight)</i>	Analytical Balance MDx Actuation Station	Y	<i>Spray Pattern</i>	SprayVIEW NMDI MDx Actuation Station MDI Actuation Station	Y
<i>Dose Content</i>	Unit Dose Collection Tubes HPLC for Drug Assay MDx Actuation Station MDI DW Actuation Station Analytical Balance	Y	<i>Plume Geometry</i>	SprayVIEW NMDI MDx Actuation Station MDI Actuation Station	Y
<i>Dose Content Through Container Life</i>	Unit Dose Collection Tubes HPLC for Drug Assay MDx Actuation Station Analytical Balance	Y	<i>Leak Rate</i>	Analytical Balance	Y
			<i>Net Content (Fill Weight)</i>	Analytical Balance	Y
			<i>Assay: Drug, Excipients including Ethanol</i>	HPLC	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 MDx Actuation Station Mass Flow Meter Vacuum Pump Analytical Balance	Y	<i>Weight Loss</i>	Analytical Balance	Y
			<i>Microbial Limits</i>		N
			<i>Leachables</i>		N
			<i>Extractables</i>		N
			<i>Appearance and Color Identification</i>	Visual	Y
Microscopy	Light Microscope	Y	<i>Impurities and Degradation Products</i>	HPLC, UPLC with UV, CAD & PDA Detection Capabilities	Y
Particulate Matter		Y			
One Time Drug Product Characterization Studies					
Priming and Repriming in Various Orientations		Y	Effect of Dosing Orientation on Dose Content Uniformity & Particle Size		Y
Priming/Effect of Resting Time		Y	Profiling Near Container Exhaustion (Tail-Off)		Y
Temperature Cycling		Y	Effect of Storage Orientation on Particle Size		Y