



Nasal Spray Chemistry, Manufacturing and Controls Documentation—Stability and Batch Release Testing

Next Breath is a full service cGMP compliant laboratory for analytical testing of nasal spray drug products to support your CMC submission. Using the outline below for a model suspension nasal spray product, Next Breath will customize a program, including method development and validation, to meet your requirements according to the appropriate stability storage conditions, conduct the relevant experiments according to the Guidance for Industry: Nasal Spray and Inhalation Solution, Suspension, and Spray Drug Products – Chemistry Manufacturing and Controls Documentation, interpret the test results and generate a report suitable for inclusion in your regulatory submission. Next Breath will use these analytical tests to perform stability studies, drug product characterization studies, clinical batch release testing and finished product release testing.

Specifications for the Drug Product					
In Vitro Test	Equipment	Stability	In Vitro Test	Equipment	Stability
<i>Pump Delivery</i>	Analytical Balance NSx Actuation Station MightyRunt Actuation Station	X	<i>Spray Pattern</i>	SprayVIEW NSP NSx Actuation Station EZ-Spray Analysis Software MightyRunt Actuation Station Analytical Balance	X*
<i>Spray Content Uniformity</i>	Unit Dose Collection Tubes HPLC for Drug Assay MightyRunt Actuation Station NSx Actuation Station Analytical Balance	X	<i>Plume Geometry</i>	SprayVIEW NSP NSx Actuation Station MightyRunt Actuation Station Analytical Balance	
<i>Droplet Sizing by Laser Diffraction</i>	Malvern Spraytec NSx-MS Actuation Station MightyRunt Actuation Station Analytical Balance	X	<i>Viscosity</i>	Brookfield Viscometer	X
<i>Drug in Small Droplets by Cascade Impaction</i>	Andersen Cascade Impactor 2L Glass Nasal Induction Port Preseparator Next Generation Impactor (alternate) NSx Actuation Station MightyRunt Actuation Station Mass Flow Meter Vacuum Pump Analytical Balance		<i>Net Content</i>	Weight	
			<i>Assay: Drug, Excipients and Preservatives</i>	HPLC	X
			<i>pH</i>	pH Meter	X
			<i>Weight Loss on Stability</i>	Analytical Balance	X
			<i>Microbial Limits</i>	USP <81>	X
<i>Microscopy (suspensions)</i>	Light Microscope	X	<i>Osmolality</i>	Osmometer	
			<i>Particulate Matter</i>	USP <788>	X
			<i>Leachables</i>		X
<i>Extractables</i>		X			
One Time Drug Product Characterization Studies					
<i>Priming and Repriming in Various Orientations</i> <i>Repriming / Effect of Resting Time</i> <i>Temperature Cycling</i> <i>Preservative Effectiveness</i> <i>Device Robustness</i>			<i>Effect of Dosing Orientation on Spray Content Uniformity & Droplet Size</i> <i>Profiling Near Container Exhaustion - Tail-Off</i> <i>Photostability</i> <i>Plume Geometry</i>		

*Recommended