BIOEQUIVALENCE SUMMARY TABLES FOR AQUEOUS NASAL SPRAY PRODUCTS

Please note that the tables listed in this document only include the bioequivalence summary tables related to the **in vitro** tests recommended in the "Guidance for Industry: Bioavailability and Bioequivalence Studies for Nasal Aerosols and Nasal Sprays for Local Action (April 2003)". For the bioequivalence summary tables related to the **in vivo** BE tests, the sponsor should refer to the Bioequivalence Summary Tables published on the Office of Generic Drugs website at http://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/AbbreviatedNewDrugApplicationANDAGenerics/UCM209446.pdf

Table 1. Formulation Table

INGREDIENTS	TEST			REFERENCE		
	Amount per Actuation	Amount per mL	% (w/w)	Amount per Actuation	Amount per mL	% (w/w)
TOTALS						
NET FILL WEIGHT						

Table 2. Batch Information

Study Type	TEST					REFERENCE		
	Lot No.	Potency***	Lot Size (# of Bottles)		Manufacture Date	Lot No.	Potency***	Expiration Date
			Theoretical	# actually bottled				
Bioequivalence study (PK study)*								
In-Vitro equivalence studies **								

* If recommended
** Include lot numbers from each in vitro test
*** Data obtained from Certificate of Analysis

Table 3. Device Comparability

		TEST	REFERENCE
Container Description			
Protection Cap Description			
Pump (brand/ model/material)			
Actuator (brand/ model/material)			
Actuator Orifice Diameter			
Metering Valve (brand/ model/material)			
Volume of Metering Chamber			
Diptube	**Internal Diameter**		
	Length		

Table 4. Actuation Methods

Which tests (if any) used MANUAL actuation?			
If some tests used manual actuation(s), describe methods used to avoid T to RLD bias in dose release.			
Which tests (if any) used AUTOMATED actuation?			
What were the parameters of automated actuation? (units)*		T	RLD
	Force		
	Velocity		
	Acceleration		
	Initial Delay		
	Hold Time		
	Final Delay		
Are the actuation parameters the same for the test and reference products?	Yes / No		

* Parameters may vary depending on the equipment used.

The Table 5 Series is for Single Actuation Content through Container Life Test

Table 5. 1. Study Information

Study No.	
Study Site	
Principal Investigator	
Study Dates	
SOP No.	
SOP Effective Date	
SOP Title	
Test Method Description	
Testing Equipment Used (e.g., name, model, etc)	
Operating Conditions for Testing Equipment Used (e.g., temperature, humidity, etc..)	
Analytical Method Description	
Analytical Equipment Used (e.g., name, model, etc.)	

Table 5. 2. Analytical Method Validation for HPLC

Information Requested	
Analytical method validation report location	
Study Report Number	
Analyte	
Internal Standard (IS)	Only If Applicable
Method description	
Selectivity or Specificity	
Limit of quantitation	
Detection Limit	
Linearity Range (ng, mcg/mL)	
Linearity (R^2)	
Accuracy (% recovery at the high and low concentrations)	
Precision -- Repeatability	
Precision --Intermediate Precision	
Bench-top stability (hrs(CV%)) (working std solution)	
Refrigerator stability (hrs(CV%)) (working std solution)	Only If Applicable

Stock solution stability (days (CV %))	
Freeze-thaw stability (cycles (CV %))	Only If Applicable
Robustness	
Dilution integrity	Only If Applicable

Calibration of Manual and/or Automated Spray Pump Actuator (For Single Actuation Content and Priming/Repriming studies)

Table 5.3.1. Precision

	Manual		**Automated**	
	Content Assay (µg)	Shot Weight (mg)	Content Assay (µg)	Shot Weight (mg)
Mean				
%RSD				

Table 5.3.2. Ruggedness (By Date)

Day 1	**Manual**		**Automated**	
	Content Assay (µg)	Shot Weight (mg)	Content Assay (µg)	Shot Weight (mg)
Mean				
%RSD				
Day 2	**Manual**		**Automated**	
	Content Assay (µg)	Shot Weight (mg)	Content Assay (µg)	Shot Weight (mg)
Mean				
%RSD				
%Difference Between Content Assay Means (Day 1 vs. Day 2)				
%Difference Between Shot Weight Means (Day 1 vs. Day 2)				

Table 5.3.3. Ruggedness (By Analyst)

Analyst 1	**Manual**		**Automated**	
	Content Assay (µg)	Shot Weight (mg)	Content Assay (µg)	Shot Weight (mg)
Mean				
%RSD				
Analyst 2	**Manual**		**Automated**	

	Content Assay (µg)	Shot Weight (mg)	Content Assay (µg)	Shot Weight (mg)
Mean				
%RSD				
%Difference Between Content Assay Mean (Analyst 1 vs Analyst 2)				
%Difference Between Shot Weight Means (Analyst 1 vs Analyst 2)				

Table 5.3.4. Ruggedness (Unit to Unit if more than one unit is used)

Unit 1	**Manual**		**Automated**	
	Content Assay (µg)	Shot Weight (mg)	Content Assay (µg)	Shot Weight (mg)
Mean				
%RSD				
Unit 2	**Manual**		**Automated**	
	Content Assay (µg)	Shot Weight (mg)	Content Assay (µg)	Shot Weight (mg)
Mean				
%RSD				
%Difference Between Content Assay Means (Unit 1 vs. Unit 2)				
%Difference Between Shot Weight Means (Unit 1 vs. Unit 2)				

Table 5. 4. Results Summary

SINGLE ACTUATION CONTENT THROUGH CONTAINER LIFE														
		Spray #	**Mean**				**Variability (%CV)**					**Mean Ratio (T/R)**	
			Drug Mass		**% label claim**		**Within Lot (n=10)**			**Between Lot (n=3)**	**Total (n=30)**		
			Arith	Geo	Arith	Geo	Lot 1	Lot 2	Lot 3			Arithm (n=30)	Geo (n=30)
BEG	**Test**												
	Ref												
END	**Test**												
	Ref												

The Table 6 Series is for Priming & Re-priming Test

Table 6.1. Study Information

Study No.	
Study site	
Principal Investigator	
Study dates	
SOP No.	
SOP Effective Date	
SOP Title	
Test Method Description	
Testing Equipment Used (e.g., name, model, etc)	
Operating Conditions for Testing Equipment Used (e.g., temperature, humidity, etc..)	
Analytical Method Description	
Analytical Equipment Used (e.g., name, model, etc)	

Table 6. 2. Analytical Method Validation for HPLC

To be completed only if different from Table 5.2

Information Requested	
Analytical method validation report location	
Study Report Number	
Analyte	
Internal Standard (IS)	Only If Applicable
Method description	
Selectivity or Specificity	
Limit of quantitation	
Detection Limit	
Linearity Range (ng, mcg/mL)	
Linearity (R^2)	
Accuracy (% recovery at the high and low concentrations)	
Precision -- Repeatability	
Precision --Intermediate Precision	
Bench-top stability (hrs(CV%)) (working std solution)	
Refrigerator stability (hrs(CV%)) (working std solution)	Only If Applicable

Stock solution stability (days (CV %))	
Freeze-thaw stability (cycles (CV %))	Only If Applicable
Robustness	
Dilution integrity	Only If Applicable

Table 6. 3. Results Summary – Priming & Re-Priming

PRIMING												
Number of actuations used to **prime** each product =												
Actuation number used for testing each product =												
	Spray #	**Mean**				**Variability (%CV)**					**Mean Ratio (T/R)**	
		Drug Mass		**% label claim**		Within Lot (n=10)			Between Lot (n=3)	Total (n=30)		
		Arith	Geo	Arith	Geo	Lot 1	Lot 2	Lot 3			Arithm (n=30)	Geo (n=30)
Test												
Ref												

RE-PRIMING												
Period of time each product was stored in the vertical position following priming (nasal sprays only) =												
Number of actuations used to **re-prime** each product =												
Actuation number used for testing each product =												
	Spray #	**Mean**				**Variability (%CV)**					**Mean Ratio (T/R)**	
		Drug Mass		**% label claim**		Within Lot (n=10)			Between Lot (n=3)	Total (n=30)		
		Arith	Geo	Arith	Geo	Lot 1	Lot 2	Lot 3			Arithm (n=30)	Geo (n=30)
Test												
Ref												

The Table 7 Series is for Droplet Size Distribution by Laser Diffraction Test

Table 7. 1. Study Information

Study No.	
Study site	
Principal Investigator	
Study dates	
SOP No.	
SOP Effective Date	
SOP Title	
Testing Method Description (including DSD measurement over entire life of spray, fully developed phase, etc)	
Study Distances (distances from actuator orifice)	
Testing Equipment Used (e.g., name, model, etc)	
Operating Conditions for Testing Equipment Used (e.g., temperature, humidity, etc..)	
Analytical Method Description	If applicable
Analytical Equipment Used (e.g., name, model, etc)	If applicable

Validation Summary Tables for Droplet Size Distribution by Laser Diffraction

Table 7.2.1. Precision

	D10		**D50**		**D90**		**Span**	
	Dist1 e.g., 3 cm	Dist2 e.g., 6 cm	Dist1 e.g., 3 cm	Dist2 e.g., 6 cm	Dist1 e.g., 3 cm	Dist2 e.g., 6 cm	Dist1 e.g., 3 cm	Dist2 e.g., 6 cm
Mean								
%RSD								
Range								

Table 7.2.2. Intermediate Precision (By Date)

Day 1	**D10**		**D50**		**D90**		**Span**	
	Dist1 e.g., 3 cm	Dist2 e.g., 6 cm	Dist1 e.g., 3 cm	Dist2 e.g., 6 cm	Dist1 e.g., 3 cm	Dist2 e.g., 6 cm	Dist1 e.g., 3 cm	Dist2 e.g., 6 cm
Mean								
%RSD								
Day 2	**D10**		**D50**		**D90**		**Span**	
	Dist1 e.g., 3 cm	Dist2 e.g., 6 cm	Dist1 e.g., 3 cm	Dist2 e.g., 6 cm	Dist1 e.g., 3 cm	Dist2 e.g., 6 cm	Dist1 e.g., 3 cm	Dist2 e.g., 6 cm
Mean								
%RSD								
%Difference (Day 1 vs Day 2)								
Interday %RSD								

Table 7.2.3. Intermediate Precision (By Analyst)

Analyst 1	**D10**		**D50**		**D90**		**Span**	
	Dist1 e.g., 3 cm	Dist2 e.g., 6 cm	Dist1 e.g., 3 cm	Dist2 e.g., 6 cm	Dist1 e.g., 3 cm	Dist2 e.g., 6 cm	Dist1 e.g., 3 cm	Dist2 e.g., 6 cm
Mean								
%RSD								
Analyst 2	**D10**		**D50**		**D90**		**Span**	
	Dist1 e.g., 3 cm	Dist2 e.g., 6 cm	Dist1 e.g., 3 cm	Dist2 e.g., 6 cm	Dist1 e.g., 3 cm	Dist2 e.g., 6 cm	Dist1 e.g., 3 cm	Dist2 e.g., 6 cm
Mean								
%RSD								
%Difference (Analyst 1 vs Analyst 2)								

Inter analyst %RSD									

Table 7.3. Results Summary – Droplet Size Distribution by Laser Diffraction

D_{50} Summary											
		Test Dist (cm)	**Mean**		**Variability (%CV)**					**Mean Ratio (T/R)**	
					Within Lot (n=10)			Between Lot (n=3)	Total (n=30)		
			Arithm	Geo	Lot 1	Lot 2	Lot 3			Arithm (n=30)	Geo (n=30)
Test	**BEG**										
	END										
Ref	**BEG**										
	END										

SPAN Summary											
		Test Dist (cm)	**Mean**		**Variability (%CV)**					**Mean Ratio (T/R)**	
					Within Lot (n=10)			Between Lot (n=3)	Total (n=30)		
			Arithm	Geo	Lot 1	Lot 2	Lot 3			Arithm (n=30)	Geo (n=30)
Test	**BEG**										
	END										
Ref	**BEG**										
	END										

The Table 8 Series is for Drug in Small Particles / Droplets by Cascade Impactor (CI) Test

Table 8.1. Study Information

Study No.	
Study site	
Principal Investigator	
Study dates	
SOP No.	
SOP Effective Date	
SOP Title	
Testing Method Description	
Testing Equipment Used (e.g., name, model, etc)	
Operating Conditions for Testing Equipment Used (e.g., temperature, humidity, etc..)	
Analytical Method Description	
Analytical Equipment Used (e.g., name, model, etc)	

Validation Summary Table for Particle Size Distribution by Cascade Impactor

Table 8.2. Analytical Method Validation for HPLC

Information Requested	
Analytical method validation report location	
Study Report Number	
Analyte	
Internal Standard (IS)	Only If Applicable
Method description	
Selectivity or Specificity	
Limit of quantitation	
Detection Limit	
Linearity Range (ng, mcg/mL)	
Linearity (R^2)	
Accuracy (% recovery at the high and low concentrations)	
Precision -- Repeatability	
Precision -- Intermediate Precision	
Bench-top stability (hrs) (working std solution)	

Refrigerator stability (hrs) (working std solution)	Only If Applicable
Stock solution stability (days)	
Freeze-thaw stability (cycles)	Only If Applicable
Robustness	
Dilution integrity	Only If Applicable

Validation Tables for Cascade Impaction

Note: Mass of drug above and below the top stage of the cascade impactor is requested. The 9.0 micron cut point for the top stage assumes use of the Andersen Cascade Impactor. The cut point may be different for other impactors.

Table 8.3.1. Precision

	>9.0 um*	**<9.0 um***	**Sum**	**Mass Balance%**
Mean of n (Amount/spray)**				
% RSD				

* Based on the cutpoint for the top stage of the USP Apparatus I (<601>) operated at 28.3 LPM.
** n is the number of runs in the validation study.

Table 8.3.2. Intermediate Precision (By Date)

Day 1	**>9.0 um**	**<9.0 um**	**Sum**	**Mass Balance%**
Mean of n* (Amount/spray)				
%RSD				
Day 2				
Mean of n* (Amount/spray)				
%RSD				
% Difference in RSD (Day 1 vs Day 2)				
Interday %RSD				

* n is the number of runs in the validation study.

Table 8.3.3. Intermediate Precision (By Analyst)

Analyst 1	**>9.0 um**	**<9.0 um**	**Sum**	**Mass Balance%**
Mean of n* (Amount/spray)				
%RSD				
Analyst 2				
Mean of n* (Amount/spray)				
%RSD				
%Difference in RSD (Analyst 1 vs Analyst 2)				
Inter analyst %RSD				

* n is the number of runs in the validation study.

Table 8.4. Results Summary – Drug in Small Particles / Cascade Impactor (CI)

DRUG MASS IN SMALL PARTICLES / DROPLETS PER GROUPING										
		Drug Deposition		**Variability (%CV)**					**Mean Ratio (T/R)**	
				Within Lot (n=10)			Between Lot (n=3)	Total (n=30)		
		Arithm	Geo	Lot 1	Lot 2	Lot 3			Arithm (n=30)	Geo (n=30)
Total A* (expressed as mass)	**Test**									
	Ref									
Total B (expressed as mass)**	**Test**									
	Ref									
Total B (expressed as % of label claim)**	**Test**									
	Ref									

* **Total A** = Total mass of drug collected from stages and accessories **below stage 1 (e.g., < 9 µm in size)**

** **Total B** = Total mass (or % of label claim) of drug collected from **ALL stages and accessories** of cascade impactor

MASS BALANCE (% of label claim)		
		Arithmetic Mean and Range (Min – Max) (n=30)
Mass Balance (%)	**Test**	
	Ref	

The Table 9 Series is for Spray Pattern Test

Table 9.1. Study Information

Study No.	
Study site	
Principal Investigator	
Study dates	
SOP No.	
SOP Effective Date	
SOP Title	
Testing Method Description	
Study Distances (distances from actuator orifice)	
Testing Equipment Used (e.g., name, model, etc)	
Image Analysis Apparatus Used	(i.e., automated = Laser Imaging; or manual = TLC)
Operating Conditions for Testing Equipment Used (e.g., temperature, humidity, etc..)	
Analytical Method Description	If applicable
Analytical Equipment Used (e.g., name, model, etc)	If applicable

Validation Summary Tables for Spray Pattern

Table 9.2.1. Precision

	Area*		**Ovality Ratio**	
	Dist1 e.g., 3 cm	Dist2 e.g., 6 cm	Dist1 e.g., 3 cm	Dist2 e.g., 6 cm
Mean				
%RSD				
Range				

*This parameter varies with the type of spray pattern analysis. If it is an automated analysis, e.g., Laser imaging, "area" should be used. If it is a manual analysis, e.g., TLC, "Dmax" should be used.

Table 9.2.2. Intermediate Precision (By Date)

Day 1	**Area***		**Ovality Ratio**	
	Dist1 e.g., 3 cm	Dist2 e.g., 6 cm	Dist1 e.g., 3 cm	Dist2 e.g., 6 cm
Mean				
%RSD (Precision/Repeatability)				
Day 2	**Area**		**Ovality Ratio**	
	Dist1 e.g., 3 cm	Dist2 e.g., 6 cm	Dist1 e.g., 3 cm	Dist2 e.g., 6 cm
Mean				
%RSD (Precision/Repeatability)				
%Difference (Day 1 vs. Day 2)				
Interday %RSD**				

*This parameter varies with the type of spray pattern analysis. If it is an automated analysis, e.g., Laser imaging, "area" should be used. If it is a manual analysis, e.g., TLC, "Dmax" should be used.
** RSD of all day 1 and day 2 data.

Table 9.2. 3. Intermediate Precision (By Analyst)

Analyst 1	**Area***		**Ovality Ratio**	
	Dist1 e.g., 3 cm	Dist2 e.g., 6 cm	Dist1 e.g., 3 cm	Dist2 e.g., 6 cm
Mean				
%RSD (Precision/Repeatability)				
Range				
	Area*		**Ovality Ratio**	
Analyst 2	Dist1 e.g., 3 cm	Dist2 e.g., 6 cm	Dist1 e.g., 3 cm	Dist2 e.g., 6 cm
Mean				
%RSD (Precision/Repeatability)				
Range				

%Difference (Analyst 1 vs. Analyst 2)				
Inter analyst %RSD**				

*This parameter varies with the type of spray pattern analysis. If it is an automated analysis, e.g., Laser imaging, "area" should be used. If it is a manual analysis, e.g., TLC, "Dmax" should be used.
** RSD of all Chemist 1 and Chemist 2 data.

Table 9.3. Results Summary – Spray Pattern

Area* – Spray Pattern Summary										
	Dist (cm)	**Mean**		**Variability (%CV)**					**Mean Ratio (T/R)**	
				Within Lot (n=10)			Between Lot (n=3)	Total (n=30)		
		Arithm	Geo	Lot 1	Lot 2	Lot 3			Arithm (n=30)	Geo (n=30)
Test										
Ref										

*This parameter varies with the type of spray pattern analysis. If it is an automated analysis, e.g., Laser imaging, "area" should be used. If it is a manual analysis, e.g., TLC, "Dmax" should be used.

OVALITY RATIO – Spray Pattern Summary										
	Dist (cm)	**Mean**		**Variability (%CV)**					**Mean Ratio (T/R)**	
				Within Lot (n=10)			Between Lot (n=3)	Total (n=30)		
		Arithm	Geo	Lot 1	Lot 2	Lot 3			Arithm (n=30)	Geo (n=30)
Test										
Ref										

The Table 10 Series is for Plume Geometry Test

Table 10.1. Study Information

Study No.	
Study site	
Principal Investigator	
Study dates	
SOP No.	
SOP Effective Date	
SOP Title	
Testing Method Description	
Criteria for defining plume angle, width, & height borders	
Testing Equipment Used (e.g., name, model, etc)	
Image Analysis Apparatus Used	
Operating Conditions for Testing Equipment Used (e.g., temperature, humidity, etc..)	
Analytical Method Description	If applicable
Analytical Equipment Used (e.g., name, model, etc)	If applicable

Validation Summary Tables for Plume Geometry

Table 10.2.1. Precision

	Plume Width	Plume Angle
Mean		
%RSD		
Range		

Table 10.2.2. Intermediate Precision (By Date)

Day 1	**Plume Width**	**Plume Angle**
Mean		
%RSD (Precision/Repeatability)		
Range		
Day 2		
Mean		
%RSD (Precision/Repeatability)		
Range		
%Difference (Analyst 1 vs. Analyst 2)		
Inter day %RSD*		

** RSD of all day 1 and day 2 data.

Table 10.2.3. Intermediate Precision (By Analyst)

Analyst 1		
Mean		
%RSD (Precision/Repeatability)		
Range		
Analyst 2		
Mean		
%RSD (Precision/Repeatability)		
Range		
%Difference (Analyst 1 vs Analyst 2)		
Inter Analyst %RSD*		

* RSD of all analyst 1 and analyst 2 data.

Table 10.2.4. Robustness for varies parameters (the selection of parameters is optional)

	Plume Width				Plume Angle			
Parameter*	**camera distance** 1*	**camera distance** 2*	**camera distance** 3*	**camera distance** 4*	**camera distance** 1*	**camera distance** 2*	**camera distance** 3*	**camera distance** 4*
Mean								
%RSD (Precision/Repeatability)								

* The selection of parameters is optional. Examples of parameters of robustness study include camera distance, delay time, velocity, acceleration, etc...

Table 10. 3. Results – Plume Geometry

	Mean		**Variability (%CV)**					**Mean Ratio (T/R)**	
			Within Lot (n=10)			Between Lot (n=3)	Total (n=30)		
	Arith	Geo	Lot 1	Lot 2	Lot 3			Arith	Geo
Plume Angle (°)									
Test									
Ref									
Plume Width									
Test									
Ref									
Plume Height									
Test									
Ref									

SAS Data Tables for Aqueous Nasal Spray Product In Vitro Bioequivalence Study Data Submission

Data in these tables should be arranged in columns as shown in examples. Data sets should be submitted as SAS Transport files.

Table 1. Single Actuation Content through Container Life

Variable Name	Variable Label	Variable Type	Content	Notes
PRODUCT	**Product Name**	**Character**	**TEST or REF**	**Identifier for product**
SECTOR	**Lifestage**	**Character**	**B, or E**	**B=Beginning; E=End**
LOT	**Lot number**	**Alphanumeric/ Numeric**	**Alphanumeric/ Numeric**	**Identifier for product lot**
CONTAIN	**Bottle or container Number**	**Numeric**	**Numeric values**	**Identifier for bottle or container. Must be unique for each product (e.g. #1-30 for test and #31-60 for ref).**
ACTUAT	***Spray Number***	***Numeric***	***Numeric values***	***Actual spray number corresponding to B or E life stages.***
AMOUNT	**Actual delivered amount of drug mass**	**Numeric**	**Numeric values**	**Drug mass per single actuation**
PCTLABEL	**Percentage of label claim**	**Numeric**	**Numeric values**	**Percentage of drug mass per single actuation**

Example

PRODUCT	SECTOR	LOT	CONTAIN	ACTUAT	AMOUNT	PCTLABEL
TEST	B	1234	1			
			2			
			3			
			4			
			5			
			6			
			7			
			8			
			9			
			10			

Table 2. Priming and Repriming

Variable Name	Variable Label	Variable Type	Content	Notes
PRODUCT	**Product Name**	**Character**	**TEST or REF**	**Identifier for product**
SECTOR	**Lifestage**	**Character**	**B**	**B=Beginning. Lifestage not specified for repriming data.**
LOT	**Lot number**	**Alphanumeric/ Numeric**	**Alphanumeric/ Numeric**	**Identifier for product lot**
CONTAIN	**Bottle or container Number**	**Numeric**	**Numeric values**	**Identifier for bottle or container. Must be unique for each product (e.g. #1-30 for test and #31-60 for ref).**
ACTUAT	***Spray Number***	***Numeric***	***Numeric values***	***Actual spray number***
AMOUNT	**Actual delivered amount of drug mass**	**Numeric**	**Numeric values**	**Drug mass per single actuation**
PCTLABEL	**Percentage of label claim**	**Numeric**	**Numeric values**	**Percentage of drug mass per single actuation**

Example

PRODUCT	SECTOR	LOT	CONTAIN	ACTUAT	AMOUNT	PCTLABEL
TEST	B	1234	1			
			2			
			3			
			4			
			5			
			6			
			7			
			8			
			9			
			10			

Table 3. Droplet Size Distribution by Laser Diffraction

Variable Name	Variable Label	Variable Type	Content	Notes
PRODUCT	**Product Name**	**Character**	**TEST or REF**	**Identifier for product**
SECTOR	**Lifestage**	**Character**	**B, or E**	**B=Beginning; E=End**
LOT	**Lot number**	**Alphanumeric/Numeric**	**Alphanumeric/Numeric**	**Identifier for product lot**
DISTANCE	**Distance**	**Numeric**	**Numeric values**	**Distance from the actuator tip to the laser beam (cm)**
CONTAIN	**Bottle or container Number**	**Numeric**	**Numeric values**	**Identifier for bottle or container. Must be unique for each product (e.g. #1-30 for test and #31-60 for ref at each distance).**
ACTUAT	***Spray Number***	***Numeric***	***Numeric values***	***Actual spray number corresponding to B or E life stages.***
D10	**D10**	**Numeric**	**Numeric values**	**D10**
D50	**D50**	**Numeric**	**Numeric values**	**D50**
D90	**D90**	**Numeric**	**Numeric values**	**D90**
SPAN	**SPAN**	**Numeric**	**Numeric values**	**SPAN calculated as ((D90-D10)/D50)**

Example

PRODUCT	SECTOR	LOT	DISTANCE	CONTAIN	ACTUAT	D10	D50	D90	SPAN
TEST	B	1234		1					
				2					
				3					
				4					
				5					
				6					
				7					
				8					
				9					
				10					

Table 4. Plume Geometry

Variable Name	Variable Label	Variable Type	Content	Notes
PRODUCT	**Product Name**	**Character**	**TEST or REF**	**Identifier for product**
SECTOR	**Lifestage**	**Character**	**B**	**B=Beginning**
LOT	**Lot number**	**Alphanumeric/Numeric**	**Alphanumeric/Numeric**	**Identifier for product lot**
CONTAIN	**Bottle or container Number**	**Numeric**	**Numeric values**	**Identifier for bottle or container. Must be unique for each product (e.g. #1-30 for test and #31-60 for ref).**
HEIGHT	**Height**	**Numeric**	**Numeric values**	**Plume height**
WIDTH	**Width**	**Numeric**	**Numeric values**	**Plume width**
ANGLE	**Angle**	**Numeric**	**Numeric values**	**Cone angle of one side view at one delay time**

Example

PRODUCT	SECTOR	LOT	CONTAIN	HEIGHT	WIDTH	ANGLE
TEST	B	1234	1			
			2			
			3			
			4			
			5			
			6			
			7			
			8			
			9			
			10			

Table 5. Spray Pattern

Variable Name	Variable Label	Variable Type	Content	Notes
PRODUCT	**Product Name**	**Character**	**TEST or REF**	**Identifier for product**
SECTOR	**Lifestage**	**Character**	**B, or E**	**B=Beginning; E=End**
LOT	**Lot number**	**Alphanumeric/Numeric**	**Alphanumeric/Numeric**	**Identifier for product lot**
DISTANCE	**Distance**	**Numeric**	**Numeric values**	**Distance from the actuator tip to the laser beam (cm)**
CONTAIN	**Bottle or container Number**	**Numeric**	**Numeric values**	**Identifier for bottle or container. Must be unique for each product (e.g. #1-30 for test and #31-60 for ref at each distance).**
ACTUAT	***Spray Number***	***Numeric***	***Numeric values***	***Actual spray number corresponding to B or E life stages.***
DMAX	**Dmax**	**Numeric**	**Numeric values**	**Dmax**
DMIN	**Dmin**	**Numeric**	**Numeric values**	**Dmin**
OVALITY	**Ovality**	**Numeric**	**Numeric values**	**Ovality ratio (Dmax divided by Dmin)**
AREA	**Pattern Area**	**Numeric**	**Numeric values**	**Pattern area**

Example

PRODUCT	SECTOR	LOT	DISTANCE	CONTAIN	ACTUAT	DMAX	DMIN	OVALITY	AREA
TEST	B	1234		1					
				2					
				3					
				4					
				5					
				6					
				7					
				8					
				9					
				10					

Table 6. Drug in Small Particles/Droplets by Cascade Impactor

Variable Name	Variable Label	Variable Type	Content	Notes
PRODUCT	Product Name	Character	TEST or REF	Identifier for product
SECTOR	Lifestage	Character	B	B=Beginning
LOT	Lot number	Alphanumeric/Numeric	Alphanumeric/Numeric	Identifier for product lot
CONTAIN	Bottle or container Number	Numeric	Numeric values	Identifier for bottle or container. Must be unique for each product (e.g. #1-30 for test and #31-60 for ref).
AMT_ACT	Actual Amount of drug	Numeric	Numeric value	Actual amount of drug per spray
AMT_TOT	Total Amount at all Stages and Accessories	Numeric	Numeric values	Drug mass collected on all Stages and Accessories
AMT_LT 9	Amount for Equal or Less Than 9 μm	Numeric	Numeric values	Drug mass collected for particles equal or less than 9 μm
MB_TOTAL	Mass Balance Total	Numeric	Numeric value	Mass balance for total drug mass collected on all stages and accessories

See an example below:

Table 6. Drug in Small Particles/Droplets by Cascade Impactor:

PRODUCT	SECTOR	LOT	CONTAIN	AMT_ACT	AMT_TOT	AMT_LT 9	MB_TOTAL
TEST	B	1234	1				
			2				
			3				
			4				
			5				
			6				
			7				
			8				
			9				
			10				