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				