BIOEQUIVALENCE SUMMARY TABLES FOR IN VITRO FEEDING TUBE TESTING

Please note that the tables listed in this document only include the bioequivalence summary tables related to the **in vitro feeding tube** (e.g. Nasogastric (NG), Gastrostomy (G) or Jejunal (J)) testing. Please provide the following tables if they are applicable to the in vitro feeding tube tests for your drug product. 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/UCM120957.pdf

Table 1. Product Information

(Please list the product information for each strength of test and reference products used in the *in vitro* feeding tube studies as needed)

	Test	Reference
Product Name		
Manufacturer		
Strength		
Batch / lot No.		
Manufacturing Date		
Expiration Date		
Is it the same batch number used in *in vivo* BE studies? (Yes/No)		

Table 2.1 Information for Oral Syringe *

Oral Syringe	Material of construction	Volume (mL)	Lot #	Manufacturer

***If Funnel is used for G tube testing, please provided funnel information accordingly.**

Table 2.2 Information for Feeding Tube (e.g., NG/G/J)

Feeding Tubing	Material of construction	Tube Size (e.g. Fr)	Inner Diameter (mm)	Length (cm)	Lot #	Expiry Date	Manufacturer

Table 3. Comparative Sedimentation Data*

Testing Date	pH of water**	Soaking Time (min)	Strength	No. of Dosage Units		Sedimentation (mL)	
						Test	RLD
				12	Mean		
				12	Mean		

*Please provide this table if it is applicable.

** Please add sedimentation data in oral syringe in water with various pHs and soaking times for each strength of the test and reference products as needed. If it is not water, please indicate the medium used for testing (e.g. apple juice).

Table 4. Particle Size Distribution Method Validation

Particle Size Distribution Method Validation	
Method validation report location	
Study Report No.	
Study Tile	
Instrument Parameters	
Method Description	
Precision	
Intermediate Precision	
Repeatability	
Ruggedness	

Table 5. Particle Size Distribution Data* (Arithmetic Mean)

Testing Date	pH of water **	Soaking time (min)	Formulation	Strength (batch#)	No. of Dosage Units		D10 (μm)	D50 (μm)	D90 (μm)	D-span***
			Test		12	Mean				
						Range				
						%CV				
			Reference		12	Mean				
						Range				
						%CV				

*Please provide particle size distribution data at the exit of feeding tube and/or oral syringe if applicable. **Please add particle size distribution data in water with various pHs and soaking times for each strength of the test and reference products as needed. If it is not water, please indicate the medium used for testing (e.g. apple juice). ***Span = (D90-D10)/D50

Table 6. pH Profiles before Dispersion (Initial pH) and after Administration Through Feeding Tube

Initial pH of Water*	Soaking Time (min)	Strength (batch #)	Dispersion pH (average) after delivering through feeding tube (at exit of feeding tube)	
			Test	RLD

* Please add pH profiles in water with various pHs and soaking times for each strength of the test and reference products as needed. If it is not water, please indicate the medium used for testing (e.g. apple juice).

Table 7.1 Comparative Recovery Study at Exit of Oral Syringe (Arithmetic mean)

(Only required if the labeling indicates that product can be administered via oral syringe in addition to via the feeding tube)

Testing Date	pH of water*	Formulation	Strength /Batch #	No. of Dosage Units		Soaking Time	
						(e.g., 0 min)	(e.g., 15 min)
		Test		12	Mean		
					Min		
					Max		
					%CV		
		Reference		12	Mean		
					Min		
					Max		
					%CV		

* Please add recovery data at exit of oral syringe in water with various pHs and soaking times for each strength of the test and reference products as needed. If it is not water, please indicate the medium used for testing (e.g. apple juice).

Table 7.2 Comparative Recovery Study at Exit of Feeding Tube (Arithmetic mean)

Testing Date	pH of water*	Formulation	Strength /Batch #	No. of Dosage Units		Soaking Time	
						(e.g., 0 min)	(e.g., 15 min)
		Test		12	Mean		
					Min		
					Max		
					%CV		
		Reference		12	Mean		
					Min		
					Max		
					%CV		

* Please add recovery data at the exit of feeding tube in water with various pHs and soaking times for each strength of the test and reference products as needed. If it is not water, please indicate the medium used for testing (e.g. apple juice).

Table 8.1 Acid Resistance Stability Data after Delivery Through the Syringe

(Only required if the labeling indicates that product can be administered via oral syringe in addition to via the feeding tube)

Dissolution Conditions	**Apparatus:**	
	Speed of Rotation (rpm):	
	Medium:	
	Volume (mL):	
	Temperature (°C):	
	Firm's Proposed Specifications	

Water pH*	**Soaking Time (min)**	**No. of Dosage Units**		**% released in the acid medium**			
				Strength		**Strength**	
				Test (Batch #)	**RLD (Batch #)**	**Test (Batch #)**	**RLD (Batch #)**
		12	Mean (%)				
			Range (%)				
			%CV				

* Please add acid resistance stability data after delivery through syringe in water with various pHs and soaking times for each strength of the test and reference products as needed. If it is not water, please indicate the medium used for testing (e.g. apple juice).

Table 8.2 Acid Resistance Stability Data after Delivery Through the Feeding Tube

Dissolution Conditions	**Apparatus:**	
	Speed of Rotation (rpm):	
	Medium:	
	Volume (mL):	
	Temperature(°C)::	
	Firm's Proposed Specifications	

Water pH*	**Soaking Time (min)**	**No. of Dosage Units**		**% released in the acid medium**			
				Strength		**Strength**	
				Test (Batch #)	**RLD (Batch #)**	**Test (Batch #)**	**RLD (Batch #)**
		12	Mean (%)				
			Range (%)				
			%CV				

* Please add acid resistance stability data after delivery through feeding tube in water with various pHs and soaking times for each strength of the test and reference products as needed. If it is not water, please indicate the medium used for testing (e.g. apple juice).

Table 9. SAS Transport Formatted Tables for Submission of Data from In-Vitro Feeding Tube Studies

A. Particle Size Distribution Data:

Strength	pH of water*	Delivery method	Soaking Time (min)	Formulation (Test or RLD)	Lot#	**No. of Dosage Units**	D10 (µm)	D50 (µm)	D90 (µm)	D-span**

*If it is not water, please indicate the medium used for testing (e.g. apple juice).
**Span = (D90-D10)/D50

B. Recovery Study:

Strength	pH of water*	Delivery method	Formulation	Lot#	Unit	%Recovery –T1	%Recovery –T2	%Recovery –T3

*If it is not water, please indicate the medium used for testing (e.g. apple juice).

Definition Table for SAS Transport Dataset of NG/G/J Tube Study

Variable Name	Variable Label	Data Type	Notes
Strength	The strength (s) used in this testing	Character	e.g. 15 mg and 30 mg
Delivery method	Syringe only or syringe/or feeding tube	Character	Before (syringe only) and after delivery through a combination of syringe and feeding tube
Formulation	Test or Reference	Character	
T (Soaking Time)	Time Point	Character/Numeric	T1, T2 and T3 : Different soaking time
% Recovery	Percentage of drug substance recovered at the tube exit/initial dose and/or recovered at the syringe exit/ initial dose	Numeric	Percentage of recovery (e.g. 96.67%)
Unit	12 units of individual data for the test and reference product	Numeric	
pH	Testing Medium pH	Numeric	Testing Medium pH
D	Particle Size	Numeric	D10, D50, D90, and span; Span = (D90-D10)/D50; Unit = µm
Lot	Lot Number	Character/Numeric	Product Lot Number