Formatting of Bioequivalence Summary Tables

1. Please provide these tables as pdf files and in MSWord. Place the MSWord format of all the tables in Module 2.7 and the pdf files in the appropriate eCTD/CTD locations.

2. Margins for the paper should be 1" for the top and bottom and 1.25" for the left and right sides.

3. All text should be Times New Roman 10.

4. Please use the Default Table Style when creating the tables when they are created in Microsoft® Word. (Select Menu Table-Table Auto Format-Table Normal)

5. Table 1, Table 4, Table 7, Table 8, and Tables 10-16 should be in PORTRAIT orientation.

6. Table 2, Table 3, Table 5, Table 6, Table 9 should be in LANDSCAPE orientation.

Table 1 Submission Summary*

Drug Product Name	
Strength(s)	
Applicant Name	
Address	
Point of Contact **Name** **Address** **Telephone Number** **Fax Number**	

Or, please provide an electronic copy of Form 356H.

* This information is needed for a complete Bioequivalence review and, although required for the archival copy submitted to the Agency, it is frequently not readily available in the Bioequivalence Submission. The Division of Bioequivalence prefers that this information be submitted as a electronic Form 356H. If this is not possible, then please complete Table 1.

Table 2 Summary of Bioavailability Studies

Study Ref. No.	Study Objective	Study Design	Treatments (Dose, Dosage Form, Route) [Product ID]	Subjects (No. (M/F) Type Age: mean (Range)	Mean Parameters (+/-SD)						Study Report Location
					Cmax (units/mL)	Tmax (hr)	AUC0-t (units)	AUC∞ (units)	T½ (hr)	Kel (hr-1)	
Study #	Fasting study title	Randomized single-dose crossover	Test product strength Tab./Cap./Susp p.o. [Batch #] Ref. product strength Tab./Cap./Susp p.o. [Batch #]	# completing (#M/#F) Healthy subjects or patients mean age (range)	M (%CV) M (%CV)	Median (Range) Median (Range)	M (%CV) M (%CV)	M (%CV) M (%CV)	M (%CV) M (%CV)	M (%CV) M (%CV)	Vol.# p.#
Study #	Fed study title	Randomized single-dose crossover	Test product strength Tab./Cap./Susp p.o. [Batch #] Ref. product strength Tab./Cap./Susp p.o. [Batch #]	# completing (#M/#F) Healthy subjects or patients mean age (range)	M (%CV) M (%CV)	Median (Range) Median (Range)	M (%CV) M (%CV)	M (%CV) M (%CV)	M (%CV) M (%CV).	M (%CV) M (%CV)	Vol.# p.#

Table 3 Statistical Summary of the Comparative Bioavailability Data

Drug Dose (# x mg) Least Squares Geometric Means, Ratio of Means, and 90% Confidence Intervals				
Fasted Bioequivalence Study (Study No.)				
Parameter	**Test**	**Reference**	**Ratio**	**90% C.I.**
AUC0-t				
AUC∞				
Cmax				
Fed Bioequivalence Study (Study No.)				
Parameter	**Test**	**Reference**	**Ratio**	**90% C.I.**
AUC0-t				
AUC∞				
Cmax				

Table 4 Bioanalytical Method Validation

Information Requested	Data
Bioanalytical method validation report location	Provide the volume(s) and page(s)
Analyte	Provide the name(s) of the analyte(s)
Internal standard (IS)	Identify the internal standard used
Method description	Brief description of extraction method; analytical method
Limit of quantitation	LOQ, units
Average recovery of drug (%)	%
Average recovery of IS (%)	%
Standard curve concentrations (units/mL)	Standard curve range and appropriate concentration units
QC concentrations (units/mL)	List all the concentrations used
QC Intraday precision range (%)	Range or per QC
QC Intraday accuracy range (%)	Range or per QC
QC Interday precision range (%)	Range or per QC
QC Interday accuracy range (%)	Range or per QC
Bench-top stability (hrs)	hours @ room temperature
Stock stability (days)	days @ 4ºC
Processed stability (hrs)	hours @ room temperature; hours @ 4ºC
Freeze-thaw stability (cycles)	# cycles
Long-term storage stability (days)	17 days @ -20ºC (or other)
Dilution integrity	Concentration diluted X-fold
Selectivity	No interfering peaks noted in blank plasma samples

Please include table for each analyte.
Please submit all Method Validation SOPs.

Table 5 Summary of In Vitro Dissolution Studies

Dissolution Conditions	**Apparatus:**	
	Speed of Rotation:	
	Medium:	
	Volume:	
	Temperature:	
Firm's Proposed Specifications		
Dissolution Testing Site (Name, Address)		

Study Ref No.	**Testing Date**	**Product ID \ Batch No. (Test - Manufacture Date) (Reference – Expiration Date)**	**Dosage Strength & Form**	**No. of Dosage Units**		**Collection Times (minutes or hours)**					**Study Report Location**
Study Report #:		Test Product	mg Tablet Capsule	12	Mean						
					Range						
					%CV						
Study Report #:		Reference Product	mg Tablet Capsule	12	Mean						
					Range						
					%CV						

Provide dissolution data for all strengths (test and reference).

Table 6 Formulation Data

Ingredient	Amount (mg) / Tablet		Amount (%) / Tablet	
	Strength 1	Strength 2	Strength 1	Strength 2
Cores				
Coating				
Total			**100.00**	**100.0**

Please include the formulation of all strengths.

Table 7 Demographic Profile of Subjects Completing the Bioequivalence Study

Study No.			
		Treatment Groups	
		Test Product N =	**Reference Product N =**
Age (years)	Mean ± SD	50 ± 15	
	Range	21 - 64	
Age Groups	< 18	N(%)	N(%)
	18 – 40	N(%)	N(%)
	40 – 64	N(%)	N(%)
	65 – 75	N(%)	N(%)
	> 75	N(%)	N(%)
Sex	Male	N(%)	N(%)
	Female	N(%)	N(%)
Race	Asian	N(%)	N(%)
	Black	N(%)	N(%)
	Caucasian	N(%)	N(%)
	Hispanic	N(%)	N(%)
	Other	N(%)	N(%)
BMI	Mean ± SD		
	Range		
Other Factors			

Please provide a separate table for each Bioequivalence Study

Table 8 Incidence of Adverse Events in Individual Studies

Body System / Adverse Event	Reported Incidence by Treatment Groups	
	Fasted/Fed Bioequivalence Study Study No.	
	Test	Reference
Body as a whole		
Dizziness	N (%)	N (%)
Etc.	N (%)	N (%)
Cardiovascular		
Hypotension		
Etc.		
Gastrointestinal		
Constipation		
Etc.		
Other organ sys.		
Total	N (%)	N (%)

Provide separate table for each Bioequivalence Study

Table 9 Reanalysis of Study Samples

Study No. Additional information in Volume(s), Page(s)								
Reason why assay was repeated	**Number of samples reanalyzed**				**Number of recalculated values used after reanalysis**			
	Actual number		**% of total assays**		**Actual number**		**% of total assays**	
	T	**R**	**T**	**R**	**T**	**R**	**T**	**R**
Pharmacokinetic[1]								
Reason A (e.g. below LOQ)								
Reason B								
Reason C								
Etc.								
Total								

1 - If no repeats were performed for pharmacokinetic reasons, insert "0.0."

Please provide a separate table for each analyte measured for each in-vivo study.

Table 10 Study Information

Study Number	
Study Title	
Clinical Site (Name, Address, Phone #)	
Principal Investigator	
Dosing Dates	
Analytical Site (Name, Address, Phone #)	
Analysis Dates	
Analytical Director	
Storage Period of Biostudy Samples (no. of days from the first day of sample collection to the last day of sample analysis)	

Please provide separate table for each Bioequivalence Study

Table 11 Product Information

Product	Test	Reference
Treatment ID		
Product Name		
Manufacturer		
Batch/Lot No.		
Manufacture Date		N/A
Expiration Date	N/A	
Strength		
Dosage Form		
Bio-batch Size		N/A
Production Batch Size		N/A
Potency		
Content Uniformity (mean, %CV)		N/A
Dose Administered		
Route of Administration		

Table 12 Dropout Information

Study No.				
Subject No	**Reason for dropout/replacement***	**Period**	**Replaced?**	**Replaced with**

Please provide separate table for each Bioequivalence Study

* Please provide time, treatment (test or reference), and cause of dropout, if reason of dropout is other than "personal reasons".

Table 13 Protocol Deviations

Study No.		
Type	**Subject #s (Test)**	**Subject #s (Ref.)**

Please provide a separate table for each Bioequivalence Study

Table 14 Summary of Standard Curve and QC Data for Bioequivalence Sample Analyses*

Bioequivalence Study No. Analyte Name							
Parameter	**Standard Curve Samples**						
Concentration (ng, mcg/mL)							
Inter day Precision (%CV)							
Inter day Accuracy (%Actual)							
Linearity	(Range of R^2 values)						
Linearity Range (ng, mcg/mL)							
Sensitivity/LOQ (ng, mcg/mL)							

Bioequivalence Study No. Analyte Name				
Parameter	**Quality Control Samples**			
Concentration (ng, mcg/mL)				
Inter day Precision (%CV)				
Inter day Accuracy (%Actual)				

* If applicable, please provide separate tables for the parent drug and metabolite(s)

Table 15 SOP's Dealing with Bioanalytical Repeats of Study Samples*

SOP No.	Effective Date of SOP	SOP Title

* Please include the SOP for Bioanalytical Repeats in your submission.

Table 16 Composition of Meal Used in Fed Bioequivalence Study*

Composition of Meal Used in Fed Bioequivalence Study		
Composition	**Percent of total Kcal**	**Kcal**
Fat		
Carbohydrate		
Protein		
Total		

* If the standard meal referenced in the CDER Guidance for Industry Food-Effect Bioavailability and Fed Bioequivalence Studies is used, then it is not necessary to complete the table. In that case, please add a statement in the fed bioequivalence study report indicated that the "FDA standard meal" was used. If an alternative meal is used, then please complete the above summary table.