

**SUMMARY TABLES FOR SUBMISSIONS CONTAINING COMPARATIVE
CLINICAL ENDPOINT BIOEQUIVALENCE STUDIES**

Table 1: Submission Summary

Drug Product Name	
Strength(s)	
Drug Class	
Reference Listed Drug (RLD) or Reference Standard (RS)	
RLD Applicant	
New Drug Application (NDA) #	
Date of RLD Approval	
Approved Indication(s)	

Table 2: Source of Comparative Clinical Endpoint Bioequivalence (BE) Study Data

Protocol Number	
Study Title	
Study Design	
Objectives	
Study Period	
Enrollment	# Subjects
National Clinical Trial (NCT) Identifier	
CRO	Name and Contact Information

Table 3: Protocol Review

Protocol Version	Protocol Date(s)	IRB Approval Date(s)	Changes from Previous Version
Original			
Additional versions or amendments			

Table 4: FDA Product-Specific Guidance Deviations (if applicable)

FDA Product-Specific Guidance (PSG) referenced for current study (link):			
Date of Recommendation:			
Last Revised:			
Element of PSG	Section of PSG	Deviation	Justification

Table 5: Summary of Comparative Clinical Endpoint BE Studies with Continuous Primary Endpoint (if applicable)

Study Number:			
Study Title:			
Study Design:	For example (e.g.), Placebo controlled parallel		
Primary endpoint(s):	Continuous Primary Endpoint e.g., Change from baseline at visit X (day)		
Treatment (dose, dosage form, dosing regimen, route, application site):	Test Reference Placebo/vehicle		
Subjects:	Number of subjects enrolled (#Males/#Females) Mean age (min-max)		
Statistical Analysis	Test	Reference	Placebo/ vehicle
<u>PP Population (N)</u>			
Least Squares Means (\pm Std Error)			
90% Confidence Interval for Test/Reference (%)			
<u>mITT Population (N)</u>			
Least Squares Means (\pm Std Error) for Test vs Placebo			
p-value for Test vs Placebo			
Least Squares Means (\pm Std Error) for Reference vs Placebo			
p-value for Reference vs Placebo			

Table 6: Summary of Comparative Clinical Endpoint BE Studies with Binary Primary Endpoint (if applicable)

Study Number:			
Study Title:			
Study Design:	For example (e.g.), Placebo controlled parallel		
Primary endpoint(s):	Binary Primary Endpoint e.g., Treatment success rate at visit X (day)		
Treatment (dose, dosage form, dosing regimen, route, application site):	Test Reference Placebo/vehicle		
Subjects:	Number of subjects enrolled (#Males/#Females) Mean age (min-max)		
Statistical Analysis	Test	Reference	Placebo/ vehicle
PP Population(N)			
Success/Cure Rate (%)			
90% Confidence Interval for Test-Reference (%)			

Table 7: Study Center Information

Site Number	Principal Investigator and Location	Subjects Enrolled (n)	Included in Safety Population (n)	Included in MITT Population (n)	Included in PP Population (n)
01					
02					
03					

Table 8: Study Inclusion/Exclusion Criteria

	Inclusion Criteria
1	
2	
3	

	Exclusion Criteria
1	
2	
3	

Table 9: Prohibited Concomitant Medication List

Drug Class, Type or Name	Examples (NOT comprehensive)	Washout Period (minimum)	Notes

Table 10: Product Information

Product	Test	Reference	Placebo/Vehicle
Treatment ID (if applicable)			
Product Name			
Manufacturer			
Batch/Lot #.			
Manufacture Date			
Expiration Date			
Strength			
Dosage Form			
Route of administration			
Dose administered			
Dosing regimen (e.g., BID, QD)			
Dosing duration			
Dosing timing			
Assignment Ratio			

Table 11: Study Schedule (for example)

Visit Number	Visit 1	Visit 2	Visit 3	
Visit Type	Baseline		End of Study/ Early Termination	Unscheduled Visit
Visit Day	Day 1	Day 4 (± 4 days)	Day 14 (± 4 days)	
Screening/Consent	X			
Demographics	X			
Medical History	X			
Physical Examination	X			
Urine Pregnancy Test	X			
Inclusion/Exclusion Criteria Review	X			
[Applicant to add additional items]				

Table 12: Subject Populations

	Test	Reference	Placebo/Vehicle	Total
Enrolled				
Enrolled in Period 1 (Placebo Run-in Period) – SPECIFIC FOR NASAL SPRAY PRODUCTS				
Randomized into Period 2 (Treatment Period) – SPECIFIC FOR NASAL SPRAY PRODUCTS				
Total exclusion from Period 2 (i.e., Placebo responder) – SPECIFIC FOR NASAL SPRAY PRODUCTS				
Total Safety population				
Total exclusion from Safety population				
Reason for exclusion from Safety				
Did Not Use Any Study Medication				
Total (M)ITT population				
Total exclusion from (M)ITT population				
Reason for exclusion from (M)ITT				
[Applicant to add additional items as needed]				
Total PP population				
Total Exclusion from PP population				
Reason for exclusion from PP				
Enrolled in error				
Lost To Follow-Up				
Non-compliant (diary, if applicable)				
Non-compliant (dosing)				
Outside visit window				
Randomized in Error				
Restricted Medication				
Adverse event				
Others				
[Applicant to add additional items]				

Table 13: Summary of Protocol Deviations

Protocol Deviation Type	Test	Reference	Placebo/Vehicle	Total
Randomized in error	N, subject no.			
Non-Compliance				
Lost To Follow Up				
Outside Visit Window				
Restricted Medication				
[Applicant to add additional items]				

Table 14: Summary of Subject Discontinuation/Early Termination From the Study

Reason for Discontinuation	Test	Reference	Placebo/Vehicle	Total
Adverse Events	N, subject no.			
Insufficient Therapeutic Response/Treatment Failure				
Lost to follow-up				
Restricted Medication				
Withdrew Consent				
Non-Compliance				
Protocol violation				
Investigator decision				
[Applicant to add additional items]				

Table 15: Demographic Characteristics at Baseline for the Safety Population, (M)ITT Population, and Per-Protocol Population

Demographic		Test (N)	Reference (N)	Placebo/ Vehicle (N)	p value
Age (years)	Mean ± SD				
	Min-Max				
Gender (N and %)	Female				
	Male				
Ethnicity (N and %)	Hispanic/Latino				
	Not Hispanic/Latino				
Race (N and %)	White				
	Black/African American				
	Native Hawaiian/Other Pacific Islander				
	Asian				
	American Indian/Alaska Native				
	Other				

* Please see FDA Guidance for Industry, [Collection of Race and Ethnicity Data in Clinical Trials](#), for clarification of demographic data collection.

Table 16: Primary Endpoint Analysis Result for a Comparative Clinical Endpoint BE Study

Primary Endpoint (continuous endpoint)			
	Test	Reference	Placebo
PP Population			
N			
LS MEAN (±STD. ERROR)			
90% CI for Test and Reference for Mean Response (e.g., test/reference or test-reference), if applicable	(XX– XX)		
90% CI for Test and Reference for Median Response if data is not normally distributed (e.g., test/reference or test-reference), if applicable	(XX – XX)		
mITT Population			
N			
LS MEAN (±STD. ERROR)			
LS MEAN (±STD. ERROR)			
(Test or Reference) vs. Placebo (p-value)	p=XX	p=XX	

Primary Endpoint (dichotomized endpoint)			
	Test	Reference	Placebo
PP Population			
N			
Success/Cure rate	XX % (n/N)	XX% (n/N)	
90% confidence interval	(XX, XX)		
mITT population			
N			
Success/Cure rate	XX % (n/N)	XX % (n/N)	XX % (n/N)
(Test or Reference) vs. Placebo (p-value)	p=XX	p=XX	

Table 17: Summary of Adverse Events in Safety Population

Description	Test N(%)	Reference N(%)	Placebo N(%)	Total N(%)
Subjects in Safety Population				
Total number of AEs reported				
Number of subjects with at least one AE				
Number of subjects discontinued study drug due to above AE				
AEs reported				
Mild				
Moderate				
Severe				
Serious AEs (SAEs)				
Pregnancies				
Deaths				
[Applicant to add additional items]				

Table 18: Formulation

Ingredients	Function	Test Amount (mg, %) (e.g., % w/v, %w/w, mg/1 spray)			RLD/RS*	Placebo/Vehicle	IID limit
		%w/w	%w/v	%v/v			

*for RLD used in study; Add additional column if formulation is different than marketed product.

18a. For a waiver of bioequivalence study requirements or for a test product that requires qualitative and quantitative sameness to the RLD/RS (Reference Standard), if applicable

		Test			RLD/RS*	IID limit
Ingredient	Function	%w/w	%w/v	%v/v		

*for RLD used in study; Add additional column if formulation is different than marketed product.

Any differences in formulation (e.g. including overages, etc.) between test product used in comparative clinical endpoint BE study and proposed commercial/to-be-marketed product?	<input type="checkbox"/> Yes (please explain) <input type="checkbox"/> No
Any differences in any aspects of manufacturing (e.g. processes) of test product used in comparative clinical endpoint BE study and proposed commercial/to-be-marketed product?	<input type="checkbox"/> Yes, Please explain <input type="checkbox"/> No
Any differences in any aspects of device (including any components) used with test product used in comparative clinical endpoint BE study and proposed commercial/to-be-marketed device product?	<input type="checkbox"/> Yes, Please explain <input type="checkbox"/> No <input type="checkbox"/> Not applicable

*If answered “yes” to any of the above questions, provide list and description of information to justify any differences between drug-device product used in comparative clinical endpoint BE study and proposed commercial/to-be-marketed drug-device product.