# 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<br>Reference<br>Placebo/vehicle | | |
| **Subjects:** | Number of subjects enrolled (#Males/#Females)<br>Mean age (min-max) | | |
| **Statistical Analysis** | **Test** | **Reference** | **Placebo/ vehicle** |
| **PP Population (N)** | | | |
| Least Squares Means (±Std Error) | | | |
| 90% Confidence Interval for Test/Reference (%) | | | |
| **mITT Population (N)** | | | |
| Least Squares Means (±Std Error) for Test vs Placebo | | | |
| p-value for Test vs Placebo | | | |
| Least Squares Means (±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<br>Reference<br>Placebo/vehicle | | |
| **Subjects:** | Number of subjects enrolled (#Males/#Females)<br>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 | | | | |
| **Sex (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? | ☐ Yes (please explain)<br>☐ 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? | ☐ Yes, Please explain<br>☐ 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? | ☐ Yes, Please explain<br>☐ No<br>☐ 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.