STATISTICAL ANALYSIS PLAN

Clinical Protocol No. API-E004-CL-I

Study of Drug Exposure in Systemic Circulation of Primatene® Mist (0.25mg) by Oral Inhalation, versus Epinephrine Injection (0.30mg) by IM and ProAir® (0.18mg) by Oral Inhalation in Healthy Adults

(A Randomized, Safety Evaluator-blind, Three-Treatment, Crossover, Fasting Study)

AMPHASTAR PHARMACEUTICALS, INC.

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1. BACKGROUND

Epinephrine is an adrenal hormone and sympathetic neurotransmitter with both α- and β-adrenergic activities.

Armstrong Pharmaceuticals manufactured and marketed over-the-counter (OTC) Epinephrine CFC-MDI 220 mcg/inhalation in the U.S. for fifty (50) years, prior to discontinuation in the U.S. OTC market in 2011. The discontinuation is not due to safety, efficacy or quality issues, rather it is due to environmental consideration because of CFC propellant (Montreal Protocol).

By replacing the CFC propellant with HFA, Armstrong Pharmaceuticals is currently marketing Epinephrine HFA-MDI (internal code name "E004") 125 mcg/inhalation under the trade name of Primatene® MIST. E004 is the only FDA approved asthma inhaler indicated for the temporary relief of mild symptoms of intermittent asthma in adults and children 12 years of age and older in the U.S. OTC market. The FDA approved Primatene Mist in 2018 under NDA 205920.

Epinephrine administered through IV/IM/SC can result in a whole array of adrenergic responses, resembling those induced by activation of the sympathetic nervous system and the adrenal glands with common adverse effects including shakiness, anxiety, sweating, fast heart rate and high blood pressure, etc.

Clinical data obtained during E004 NDA development show that after E004 administrated by oral inhalation, the systematic exposure of epinephrine is much lower than that for direct injection of epinephrine. This clinical study API-E004-CL-I is designed for a direct comparison of systematic exposure in crossover subjects among treatments of

- Epinephrine 0.3 mg (EpiPen® by [redacted]) by IM;
- Epinephrine 0.25 mg (Primatene® Mist) by oral inhalation; and
- Albuterol 0.18 mg (ProAir® by [redacted]) by oral inhalation.

2. OBJECTIVES

This study is designed to assess the drug exposure profile in systemic circulation of Primatene® Mist (0.25mg) by oral inhalation, versus Epinephrine Injection (0.30mg) by IM and ProAir® (0.18mg) HFA by oral inhalation in healthy adults.

2.1 PRIMARY ENDPOINTS

- AUC_{0-t}, defined as area under the curve (AUC) concentration curve over time, from time 0 to the time when Epinephrine reduced to the baseline post-dose for exogenous Epinephrine;
- AUC_{0-24h}, defined AUC of plasma Albuterol concentration curve over time 0 to 24 hours post-dose;
- $AUC_{0-\infty}$, defined as AUC in the plot of plasma Albuterol, or exogenous Epinephrine versus time from time 0 to infinity; and
- C_{max}, defined as the maximum plasma concentration of Albuterol, or Epinephrine.

2.2 SECONDARY ENDPOINTS

- t_{max} of Albuterol, or Epinephrine, defined as the time, at which the C_{max} is observed; and
- $t_{½}$, terminal elimination half-life of each analyte.

3. STUDY DESIGN AND OUTCOMES

3.1 STUDY DESIGN

This study is a randomized, safety, evaluator-blinded, single dose, three-treatment, crossover, fasting study in healthy adult volunteers. The treatments and doses evaluated in this study are summarized in Table 1.

Table 1. Treatments and Dose

Items	Treatment-A	Treatment-B	Treatment-C
Study Drug Name	Primatene Mist, E004	Epinephrine Injection Auto-Injector (Generic of EpiPen®)	ProAir
Manufacturer	[redacted]		
API	Epinephrine	Epinephrine	Albuterol Sulfate
Dosage Form	Microcrystalline Suspension HFA MDI	Sterile Solution	Microcrystalline Suspension HFA MDI
Strength	0.125 mg/inh	0.3mg/0.3mL	0.09 mg/inh
Dose Regimen	2 inhalations, 0.25mg	IM Injection of 0.30 mg Epinephrine in 0.30 mL	2 inhalations, 0.180 mg
Route of Administration	Oral Inhalation	IM Injection	Oral Inhalation

The study is conducted in healthy male and female adult subjects at 18 to 50 years of age with a targeted total of 24 evaluable subjects at the completion of study.

The design includes one screening visit, three (3) study visits and a follow-up phone evaluation. All subjects will be screened for enrollment before being randomly assigned to one of the six treatment sequences by 3 x 3 Latin Square method. According to the randomized treatment sequence, each qualified subject will be treated with one of the three (3) treatments at each study visit. At each study visit, 26 PK blood samples will be collected and plasma will be isolated for analyzing concentrations of albuterol and epinephrine. The three (3) study visits, and main study procedures, are outlined in Summary of Activities below (Table 2):

The three study visits, and main study procedures, are outlined in Study Schema:

Table 2. Summary of Activities in All Visits and EOS

Study Activities & Evaluations	Screen Visit	Dosing Visit-1	Dosing Visit-2 and 3	EOS[1]
Informed Consent / HIPAA	X			
Medical history / demographics	X			
Physical Exam (PE)	X			X
Lab: Urinalysis (UA)	X			X
Lab: CBC/Comp. metab. Panel	X			X
Lab: Thyroid Function	X			
Lab: HIV-Ab, HB-sAg, HCV-Ab	X			
Inclusion/Exclusion	X	X		
Confirmation of enrollment		X		
Assign subject ID		X		
Randomization		X		
Training/Dosing of MDI	X	X	X	
Concomitant Medicines	Record throughout study period			
Urine or serum pregnancy test	X	X	X	
Urine drug screen	X	X	X	
Alcohol screen (urine or breathalyzer)	X	X	X	
Food / beverage restrictions		X	X	
Meals served		X	X	
PK Baseline samples		X (1)	X (1)	
PK samples		X (25)	X (25)	
Vital signs	X	X (6)	X (6)	X[2]
12-lead ECG	X	X (4)	X (4)	X[2]
Serum potassium and glucose	X	X (4)	X (4)	X[2]
Adverse event reporting	Record throughout study period			

1. The fasting comprehensive metabolic panel (≥8 hours) for EOS will be taken at the Study Visit-3 or study termination
2. Vital signs, ECG and serum potassium and glucose at 24 ± 2h at Visit-3 can be used for EOS

3.2 OUTCOME MEASUREMENT

3.2.1 PK Measurements

In the three study visits, PK blood samples will be taken from each subject at 26 scheduled time points (Table 3).

PK samples will be analyzed with an established and validated test method at Amphastar R&D labs.

Table 3. PK Blood Sampling Schedule

Seq. #	Scheduling	Time window	Sample No.,"XX"	Seq. #	Scheduling	Time window	Sample No.,"XX"
1	Baseline	within 30 min pre-dosing	01	14	40 min	±5 min	14
2	1 min	± 0.5 min	02	15	50 min		15
3	2 min		03	16	60 min		16
4	3 min		04	17	70 min		17
5	5 min	±1 min	05	18	80 min		18
6	7 min		06	19	90 min		19
7	9 min		07	20	120 min	±10 min	20
8	12 min	±1 min	08	21	4 hrs		21
9	15 min		09	22	6 hrs	±15 min	22
10	18 min		10	23	8 hrs		23
11	21 min		11	24	12 hrs	±20 min	24
12	25 min	±2 min	12	25	18 hrs		25
13	30 min		13	26	24 hrs		26

3.2.2 Data for Safety Evaluation

The following safety parameters will be monitored, documented and summarized:

i). Vital signs, i.e., blood pressure (SBP/DBP) and heart rate (HR), at

- Screening;
- Pre-dose baseline, 5±2 min, 15±5 min, 60±5 min, 120±15 min and 24 ±2 hrs post-dose at dosing visits;

ii). 12-lead ECG (Routine and QT/QTc analysis), at

- Screening;
- at baseline, 20±5 min, 120±15 min and 24 ±2 hours post-dose at dosing visits;

iii). Serum glucose and potassium levels at

- Screening;
- at baseline, 10±2 min, 60±5 min and 24 ±2 hours post-dose at dosing visits;

iv). Results obtained from any clinically significant findings in physical examinations, CBC, metabolic panel and urinalysis (UA) for all subjects at

- Screening;
- End of study evaluation.

v). Concomitant medication record.

All subjects will be queried for adverse events (AEs) and AEs must be recorded with all related information and reported as required.

4. CALCULATION OF RELATED STATISTICAL QUANTITIES

4.1 PK/PD PARAMETERS

4.1.1 Primary Endpoints

(1) C_{max}, in units of pg/mL, is defined as the maximum of experimental data points of epinephrine or albuterol concentration for a given subject and given treatment:

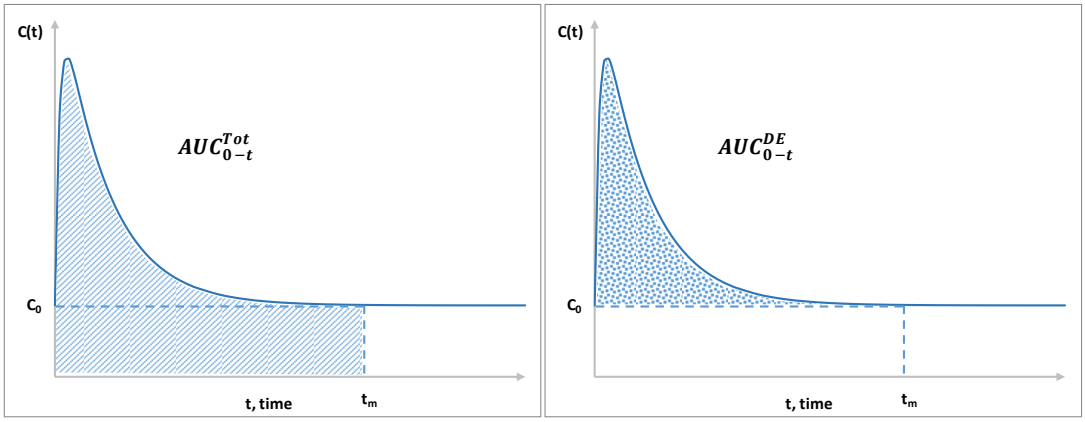
$$C_{\max} = \max\left(C_1 \cdots C_i \cdots C_n\right) \quad i = 1, 2, 3 \cdots n \tag{1}$$

where C_i is the observed plasma concentration of albuterol or epinephrine at the time t_i; which is the sampling point time;
t_1 is the baseline, and n is the number of available PK measurements.

(2) $AUC_{0-t_m}^{Tot}$ for Total API,

As is demonstrated in the left plot of **Figure 1**, the AUC is for total API, including both exogenous and endogenous, if the endogenous active ingredient exists, such as epinephrine for Treatments A and B.

Figure 1 AUC for Total Active Ingredient (left) and Drug Exposure (right)



$AUC_{0-t_m}^{Tot}$ is reported in units of pg/mL*hr, can be calculated per the trapezoidal rule as given the Eq. (2):

$$AUC_{0-t_m}^{Tot} = \sum_{i=1}^{m-1} \frac{C_i + C_{i+1}}{2}\left(t_{i+1} - t_i\right) \quad (2)$$

where

- t_m is the time of the first PK point for the subject and the treatment, after C_{max}, that is reduced to the same day baseline (C_0), if C_0 is detectable, such as for epinephrine, (see **Fig. 1**, left plot); and
- $t_m > t_{max}$, and is the smallest time point that meets

$$C(t_m) \le C_0 + \frac{1}{2}QL \quad (3)$$

- t_m=*24 hrs* for albuterol, or m is the number of available PK measurements until t_m.

(3) The AUC for Drug Exposure $AUC_{0-t_m}^{DE}$

The AUC for the drug exposure, as is demonstrated in the right plot of **Figure 1**, is the AUC for exogenous API, if the endogenous active ingredient exist such as epinephrine for Treatments A and B.

$AUC_{0-t_m}^{DE}$ is reported in units of pg/mL*hr, and is calculated as follows:

$$AUC_{0-t_m}^{DE} = AUC_{0-t_m}^{Tot} - C_0\, t_m \quad (4)$$

where $AUC_{0-t_m}^{Tot}$ and t_m is obtained based on Eqs. (2) and (3).

(4) ***Drug Exposure $AUC_{0-\infty}$*** (in units of pg/mL*min) is defined as below

$$\begin{cases} AUC_{0-\infty} = AUC_{0-t_m}^{DE} & if\ t_m < 24\ hrs \\ AUC_{0-\infty} = AUC_{0-t_m}^{DE} + AUC_{t_m-\infty}^{DE} & if\ t_m = 24\ hrs \end{cases} \quad (5)$$

$AUC_{t-\infty}$ can be obtained per the extrapolation method as given in the Eqs. (6) –(7) below, based on the time is long enough so that

$$C(t) \approx Be^{-k_e t}, \quad (6)$$

thus

$$AUC_{t-\infty} = \int_{t_n}^{\infty} C(t)dt \approx -\frac{1}{K_e} Be^{-k_e t}\Big|_{t_n}^{\infty} = \frac{C_n}{K_e} \quad (7)$$

where $C_n = C(t_m)$ is the last available PK measurement for plasma Epinephrine or albuterol concentration, with data results greater than the analytical method's quantitation limit (QL);

K_e is the rate constant of elimination; and

B is a constant, irrelevant to time.

(5) **The Elimination Rate Constant**, K_e

The elimination rate constant, K_e, will be obtained using WinNonlin software.

If K_e cannot be obtained per WinNonlin (occasionally the software may not allow convergence to be achieved), or the obtained $AUC_{t-\infty}$ is 30% larger than AUC_{0-t}, then K_e for C_1=0 (Treatment C), will be calculated based on the least squares model from the logarithm of the last three (3) or more (m=3, 4, 5, 6) available PK measurements of the treatment for the subject, per the following linear equation:

$$Ln\ [C(t)] = a - K_e t \quad (8)$$

where $-K_e$ is the slope, and a is the intercept irrelevant to time. Then, $\boldsymbol{AUC_{t-\infty}}$ will be calculated with Eq. (5).

If the baseline is greater than QL (Treatments A and B), Eq. (8) will be modified to

$$Ln\ [C(t) - C(0)] = a + pt \quad (9)$$

where baseline $C_1 = C(0) > 0$, the slope $p = -K_e$ can be obtained from last m data points of the given subject that are greater than the quantitative limit of the test method with least square method; where m=3, 4, 5 or 6, and the obtained slope is denoted as p_m.

A consistent p_m can be accepted as the final p, for which the coefficient of variance (CV) of p_m and p_{m+1} is not more than 20%.

When m is up to 6 and CV ≤ 20% is not achieved, the p_m with lowest CV with p_{m+1} will be used as the final p.

Here, m is the number of plasma samples used to calculate K_e, where $K_e = -p$.

4.1.2 Secondary Endpoints

(1) t_{max} is an observed value, and is represented in units of "min",

(2) $t_{½}$, terminal elimination half-life of each analyte will be reported in this study. The half-life of elimination can be calculated using K_e:

$$t_{½} = \frac{\ln(2)}{K_e} \tag{10}$$

4.1.3 Other PK Parameters

The elimination rate constant, K_e, and half-life of elimination, epinephrine or albuterol will be reported in this study.

4.2 Safety-Related Statistical Quantities

The safety evaluations will be performed based on the safety data captured directly from the electronic CRF (eCRF) or Lab report.

5. STATISTICAL DESIGN AND ANALYSIS

5.1 STUDY POPULATION

5.1.1 Per Protocol Population (PPP)

The "Per Protocol" population is defined as all subjects who have received all study medications during the study and are evaluable for all treatments. The primary analyses will be performed based on "Per Protocol" population (PPP).

An evaluable subject for primary analyses of this study must meet all of the following ten (10) items for both treatments:

(1) Correct dose and administration;
(2) Nineteen (19) or more of 25 post-dose PK data points (>75%) are available;
(3) There are no more than four (4) consecutive missing PK data points;
(4) The baseline PK data point is available;
(5) For Treatment-A, at least four (4) of the five (5) PK data points at 1, 2, 3, 5, and 7 minutes post-dose are available;
(6) For Treatment-B, at least four (4) of the five (5) PK data points at 9, 12, 15, 18, and 21 minutes post-dose are available;
(7) For Treatment-C, at least four (4) of the five (5) PK data points at 25, 30, 40, 50, and 60 minutes post-dose are available;
(8) For Treatment-A, at least three (3) of the PK data points at 25, 30, 40, and 50 minutes post-dose are available.
(9) For Treatment-B, at least three (3) of the PK data points at 80, 90, 120 minutes and 4 hours post-dose are available; and
(10) For Treatment-C, at least three (3) of the PK data points at 6, 8, 12 and 18 hours post-dose are available.

5.1.2 Treated Population (TP)

The "treated" population is defined as all subjects who have been randomized and treated with any dose of the study drugs.

The safety evaluation will be performed base on treated population (TP).

Safety analyses will be performed based on the treated population. The treated population will also be analyzed for the PK parameters, as supportive evidence to the PK profiles.

5.1.3 Intent-to-treat Population (ITT)

The "Intent-to-Treat" population is defined as all subjects who have been randomized.

5.2 MISSING DATA HANDLING

A table of all missing samples, with explanations, will be provided. Objective criteria for re-assay of samples considered as "pharmacokinetic anomalies" as defined in the Amphastar SOP will be observed. Re-assay analyses and data handling and reporting will be performed according to the approved SOP. Some re-assayed data may be considered as "final" data, where appropriate. Data for all populations and all Study Arms will be analyzed using both original as well as final values.

5.2.1 Missing Data Handling for Evaluable Subjects

For an evaluable subject that was defined in Section 5.1.1, only a small portion of PK measurements, if any, are allowed to be missed, and the interpolation method will be used for imputation.

5.2.2 Missing Data Handling for Non-Evaluable Subjects

Non-Evaluable Subjects will be excluded from PK evaluation.

5.3 STATISTICAL ANALYSIS

5.3.1 Demographic Data

Demographic data including, but not limited to age, race, gender and ethnicity and baseline characteristics such as medical history, vital signs, ECG will be reported for each subject. For all subjects as one group, continuous variables will be summarized with n, mean, standard deviation, while frequency counts and percentage of subjects within each category will be provided for categorical data.

5.3.2 PK Analysis

5.3.2.1 Concentration-time Profile

The concentration-time profile is constructed based on the plasma epinephrine concentration measurements. All concentration-time curves will be plotted for each subject for all treatment arms, and all mean concentration-time curves of all subjects will also be plotted for each treatment arm.

5.3.2.2 PK Parameters

For PK curve, the following main PK parameters will be obtained:

- ***Drug Exposure*** $AUC_{0-t_m}^{DE}$ for exogenous substance (t=t_m for Treatment-A and B, t=*24hrs* for Treatment-C),
- ***Drug Exposure*** for exogenous substance $\boldsymbol{AUC_{0-\infty}}$ and C_{max}, the peak concentration from the PK curve;
- t_{max}, time corresponding to C_{max}.
- $t_{½}$, terminal elimination half-life of each analyte.

PK curves will be fitted with the most suitable PK model by the standard PK analysis software, WinNonlin. The fitted PK parameters will be summarized in tables for all arms. The results will be listed for each subject in each treatment arm. The mean of each treatment arm will also be calculated.

5.3.2.3 Relative Bioavailability (*RBA*)

The relative bioavailability of Treatment-A (E004 Inhalation) over Treatment-B (IM) can be defined as follows:

$$\mathrm{RBA} = \frac{\mathrm{AUC}_{0-\infty}^{\mathrm{A}}}{\mathrm{AUC}_{0-\infty}^{\mathrm{B}}} \qquad (11)$$

RBA data for each subject of are to be calculated and tabulated. The mean RBA of Treatment-A over Treatment-B of all subjects will be calculated and summarized for comparison.

5.3.3 Safety Assessment

Safety will be assessed by tabulation of Adverse Events and will be presented with descriptive statistics at Baseline and each treatment arm. Adverse events will be summarized by treatment group. Treatment groups will be compared with respect to the incidence of each type of adverse event observed.

The n, mean and standard deviation of serum potassium and glucose, SBP/DBP, HR and ECG readings will be summarized per treatment arm by time of testing. The frequency count and percentage of whether any significant changes in physical exam, ECG and Lab results since screening visit will be reported at the end of study.

Any early termination will be listed with primary reasons per treatment arm as part of the safety assessment.

5.4 INTERIM ANALYSES

No interim analyses are planned for this study.

5.5 DATA QUALITY ASSURANCE

5.5.1 Data Input

Study data is entered into e-CRF (Electronic Case Report Form) by the site personnel. The e-CRF data management system is a web based application that is used to manage study data. The e-CRF data management system is validated to comply with FDA 21 CFR Part 11.

5.5.2 Data Quality Assurance and Monitoring

The trial will be monitored according to current Amphastar Standard Operating Procedures (SOPs).

The sponsor site monitors will monitor investigational activities for the purpose of subject safety, study compliance to applicable regulatory guidelines, and study source data for quality and integrity.

The review of the e-CRF study data entries is also conducted by the sponsor site monitors, to ensure that CRF data is accurate and traceable to the reliable study source. The Investigators will permit Amphastar authorized monitors to access the subject source documents, clinical supplies dispensing and storage area and study documentation as frequently as necessary and agrees to assist the site monitors with their activities. In addition, the e-CRF data is also reviewed remotely by authorized personnel (Data Manager and safety Monitors) for data completeness and format. The Investigator will review the eCRF; provide missing or corrected data and e-sign the eCRF at the close out of the study. Personal or subject identifying information will be treated as confidential and will NOT be publicly accessible. The trial information may be reviewed by regulatory authorities or independent QA auditors. The study site may be inspected during or after completion of the study. The Investigators agree to allow inspectors from regulatory agencies to have access to all study records, including subject source documents and eCRF study data. By participating in this study, the

Investigators agree to these requirements and will assist the inspectors in their duties.

5.5.3 PK Samples Collected Out of the Sampling Window Defined by the Protocol

Being out of the pre-specified sampling window is one of the commonly existing protocol deviations. This type of protocol deviation may be flagged or excluded, as discussed below.

Assuming three (3) PK sampling time points are t_{j-1}, t_j, and t_{j+1} respectively, as demonstrated in Figure 2 below.

The time gap between PK sampling time points *j-1* & *j,* denoted as g_{j-1}, is:

$$g_{j-1} = t_j - t_{j-1} \qquad (12)$$

The time gap between PK sampling time points *j* & *j+1,* denoted as g_j, is

$$g_j = t_{j+1} - t_j \qquad (13)$$

The PK sampling window defined in protocol for sampling point t_j is $t_j \pm w_j$. In case a PK sample at the time point *j* was collected out of the window, a "flag-allowance" for the PK sample, denoted as θ_j (%), can be assigned to determine to flag or to exclude the corresponding PK sample, i.e.

- If the actual PK sample is within $t_j \pm w_j\ (1+\theta)$, flag the PK sample;
- If the actual PK sample is out of $t_j \pm w_j\ (1+\theta)$, the PK sample will be excluded and treated as a missing data point.

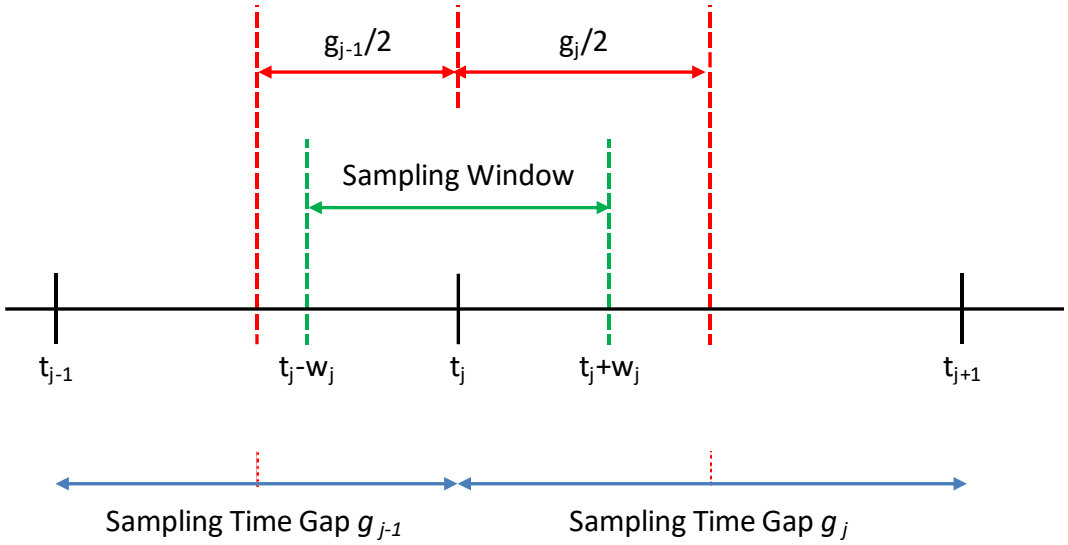


Figure 2 Sampling Points, Window and Flag-Allowance

As a minimum requirement, sample at t_j should have no possibility to overlap with samples at t_{j-1} (the previous sample) or t_{j+1} (the next sample), thus the flag-allowance θ_j must meet the below two equations simultaneously:

$$w_j(1+\theta_j) \le \frac{g_{j-1}}{2} \tag{14}$$

$$w_j(1+\theta_j) \le \frac{g_j}{2} \tag{15}$$

From Eqs (14) & (15), one has the maximum flag-allowance will be

$$\theta_j \le Min\left[\frac{g_{j-1}}{2w_j}-1,\quad \frac{g_j}{2w_j}-1\right] \tag{16}$$

The maximum allowed flag range, denoted as F_j can be obtained as:

$$\pm F_j = \pm\theta_j w_j \tag{17}$$

The safety coefficient, denoted as S_j, for an actually assigned flag-allowance, denoted f_j, can be obtained as:

$$S_j = \frac{F_j}{f_j} \times 100\% \qquad (18)$$

It is expected that $S_j \geq 100\%$.

The suggested flag-allowances of out-of-sampling-window for PK samples in this study are listed in **Table 4** below.

Table 4 Flag-Allowances of Out-of-Sampling-Window for PK Samples

#	Sampling Plan				Calculation				Evaluation for out of window		
	Description	Time Gap g_j	w_j	in	$g_j/(2w_j)-1$	θ_j	maximum Flag-Allowed $F_j=\theta_j w_j$		proposed f_j NMT 25%wj	Safety Coefficient Sj	Comments for f_j
0	C1: Baseline				-						
1	C2-C4 (Min. 1,2,3): 1 ± 0.5	1	0.5	min	0%	0%	0	min	0	-	no flag allowance
2	C5-C7 (Min. 5,7,9): 2 ± 1	2	1	min	0%	0%	0	min	0	-	ibid
3	C8-C11 (Min. 12, 15, 18, 21): 3 ± 1	3	1	min	50%	0%	0	min	0	-	ibid
4	C12-C13 (Min. 25,30): 5 ± 2	5	2	min	25%	25%	0.5	min	0.5	100%	
5	C14-C19 (Min. 40, 50, …80, 90): 10 ± 5	10	5	min	0%	0%	0	min	0	-	no flag allowance
6	C20-C21 (hr. 2): 120 ± 10	30	10	min	50%	0%	0	min	0		ibid
7	C20-C21 (hr. 4): 120 ± 10	120	10	min	500%	50%	5	min	30	17%	
8	C22-C23 (hr. 6,8): 120 ± 15	120	15	min	300%	300%	45	min	45	100%	
9	C24-C26 (hr. 12, 18,24): 360 ± 20	360	20	min	800%	300%	60	min	40	150%	

5.5.4 Database and Computer Programs for Statistical Analysis

A specialized trial-specific database is designed to capture data in such a way that it facilitates reporting and analysis, i.e. minimal data manipulation and programming to complete the analysis.

The data capture and report system is fully tested and validated. The system is demonstrated to be accurate, reproducible and secure.

The computer programs used for statistical analysis will be validated.

6. REFERENCES

[1] *Epinephrine Inhalation Aerosol USP, an HFA-MDI (E004)* Clinical Study I Protocol, Protocol No.: API-E004-CL-I, Ver. 1.1, (11/08/2019)

Attachment:

Template of Statistical Analysis Output for Clinical Study Protocol No. API-E004-CL-I (Available Upon Request)