Case Report Form

A Prospective, Double-Blind, Randomized, Placebo-Controlled, Parallel-Group, Proof-of-Concept Study to Investigate the Effect Effectiveness of KEFPEP® on Regulating Blood Pressure

Protocol No.: PHP1705H01

Screen No.: S ___ ___ ___

Subject Initials: ___ ___ ___

CRF Version: 1.0

Date: Jul-12-2017

Screen No.	Subject Initials	Screening Visit 1
S ___ ___ ___	___ ___ ___	Page 1

Date of visit: __ __/__ __ __/__ __ __ __ (dd/mmm/yyyy)

Informed Consent Signed

Informed consent was given for the patient's participation in this clinical study after the nature, scope and possible consequences of the study were explained to the person giving consent in an understandable manner as described in the study protocol.

IMPORTANT: Informed consent must be obtained from the patient BEFORE any trial procedures are started.

Date of informed consent signed: __ __/__ __ __/__ __ __ __ (dd/mmm/yyyy)

Demographics

Date of birth: __ __/__ __ __/__ __ __ __ (dd/mmm/yyyy)

Gender: ☐ Male ☐ Female

Race: ☐ Taiwanese ☐ Other, please specify _____

Height: __ __ __. __ cm Weight: __ __ __. __ kg BMI: __ __ __. __ kg/ m^2

Smoking habit: ☐ Yes ☐ No

Alcohol abuse*: ☐ Yes ☐ No

*: Alcohol abuse is classified as ≥ 8 units of alcoholic consumption per week within 1 month prior to study participation. The patient with alcohol abuse should be excluded from the study.

Pregnancy Test

Is pregnancy test performed: ☐ Yes

☐ No, reason: ☐ Male ☐ Postmenopause

☐ Hysterectomy ☐ Bilateral tubal Ligation

☐ Other, please specify _____

Date of assessment: __ __/__ __ __/__ __ __ __ (dd/mmm/yyyy)

Result: ☐ Positive ☐ Negative

Screen No.	Subject Initials	Screening Visit 1
S ___ ___ ___	___ ___ ___	Page 2-( )

Medical History

Is there any significant medical history*: ☐ Yes ☐ No

*: Record medical histories in the past 6 months prior to Screening visit/ICF date, while specific events (milk allergy and lactose intolerance) prior to Screening visit should be checked without time limitation.

No.	Medical history	Past or Active
H__ __ __		☐ Past ☐ Active
H__ __ __		☐ Past ☐ Active
H__ __ __		☐ Past ☐ Active
H__ __ __		☐ Past ☐ Active
H__ __ __		☐ Past ☐ Active
H__ __ __		☐ Past ☐ Active
H__ __ __		☐ Past ☐ Active
H__ __ __		☐ Past ☐ Active
H__ __ __		☐ Past ☐ Active
H__ __ __		☐ Past ☐ Active
H__ __ __		☐ Past ☐ Active
H__ __ __		☐ Past ☐ Active
H__ __ __		☐ Past ☐ Active
H__ __ __		☐ Past ☐ Active
H__ __ __		☐ Past ☐ Active
H__ __ __		☐ Past ☐ Active
H__ __ __		☐ Past ☐ Active
H__ __ __		☐ Past ☐ Active
H__ __ __		☐ Past ☐ Active
H__ __ __		☐ Past ☐ Active

Is this the last page used? ☐ Yes ☐ No

Physical Examinations

Is the examination performed: ☐ Yes ☐ No

Date of examination: __ __/__ __ __/__ __ __ __ (dd/mmm/yyyy)

Sites/System	Result		Specify if abnormal or not done
	Normal	Abnormal	
1 General appearance	☐	☐	
2 Head/ears/eyes/nose/throat	☐	☐	
3 Mouth	☐	☐	
4 Skin	☐	☐	
5 Neck (including thyroid)	☐	☐	
6 Lymph nodes	☐	☐	
7 Spine	☐	☐	
8 Cardiovascular system	☐	☐	
9 Respiratory system	☐	☐	
10 Gastro-intestinal system	☐	☐	
11 Nervous system	☐	☐	
12 Musculoskeletal system	☐	☐	
13 Blood and blood forming organs	☐	☐	
14 Mental status	☐	☐	
15 Other, specify: _____	☐	☐	

Vital Signs

Is the assessment performed: ☐ Yes ☐ No

Date of assessment: __ __/__ __ __/__ __ __ __ (dd/mmm/yyyy)

Body temperature: __ __ __.__℃

Pulse rate: __ __ __ bpm

Respiratory rate: __ __ __ times/ minute

Seated Office Blood Pressure

Is the assessment performed*: ☐ Yes ☐ No

*: the subject's office BP will be measured at an air-conditioned room after around 30 minutes of rest in the sitting position using an electronic sphygmomanometer

Date of assessment: __ __/__ __ __/__ __ __ __ (dd/mmm/yyyy)

Systolic Blood Pressure$: Right arm: __ __ __ mmHg Left arm: __ __ __ mmHg

$: The arm with higher SBP value will be used to verify the inclusion criteria #2.

Diastolic Blood Pressure: Right arm: __ __ __ mmHg Left arm: __ __ __ mmHg

Electrocardiogram (ECG)

Is the examination performed: ☐ Yes ☐ No

Date of examination: __ __/__ __ __/__ __ __ __ (dd/mmm/yyyy)

Result: ☐ Normal ☐ Abnormal, NCS ☐ Abnormal, CS

Abnormal Findings:

Biochemistry Tests

Is the test performed: ☐ Yes ☐ No

Date of sample: ___/___/___ (dd/mmm/yyyy)

	Item	Value	Result	
			Normal	Abnormal
1	Total bilirubin		☐	☐CS ☐NCS
2	Aspartate transaminase (AST)		☐	☐CS ☐NCS
3	Alanine transaminase (ALT)		☐	☐CS ☐NCS
4	Alkaline phosphatase (ALP)		☐	☐CS ☐NCS
5	Serum creatinine		☐	☐CS ☐NCS
6	Blood urea nitrogen (BUN)		☐	☐CS ☐NCS
7	Uric acid		☐	☐CS ☐NCS
8	Triglyceride (TG)		☐	☐CS ☐NCS
9	Total cholesterol (T-Cho)		☐	☐CS ☐NCS
10	HDL-cholesterol (HDL-C)		☐	☐CS ☐NCS
11	LDL-cholesterol (LDL-C)		☐	☐CS ☐NCS
12	Glucose (A.C.)		☐	☐CS ☐NCS
13	Hba1c		☐	☐CS ☐NCS
14	Sodium (Na)		☐	☐CS ☐NCS
15	Potassium (K)		☐	☐CS ☐NCS
16	Chloride (Cl)		☐	☐CS ☐NCS

Hematology Tests

Is the test performed: ☐ Yes ☐ No

Date of sample: __ __/__ __ __/__ __ __ __ (dd/mmm/yyyy)

	Item	Value	Result	
			Normal	Abnormal
1	Hemoglobin		☐	☐CS ☐NCS
2	Platelet		☐	☐CS ☐NCS
3	RBC		☐	☐CS ☐NCS
4	WBC		☐	☐CS ☐NCS
5	Neurophils		☐	☐CS ☐NCS
6	Eosinophils		☐	☐CS ☐NCS
7	Lymphocyte		☐	☐CS ☐NCS
8	Monocytes		☐	☐CS ☐NCS
9	Basophils		☐	☐CS ☐NCS

Urinalysis Tests

Is the test performed: ☐ Yes ☐ No

Date of sample: __ __/__ __ __/__ __ __ __ (dd/mmm/yyyy)

	Item	Value	Result	
			Normal	Abnormal
1	WBC		☐	☐CS ☐NCS
2	RBC		☐	☐CS ☐NCS
3	PH		☐	☐CS ☐NCS
4	PROTEIN		☐	☐CS ☐NCS
5	SUGAR		☐	☐CS ☐NCS

Inclusion Criteria			
		Yes	No
1	Male or female patient ages 20 years or older.	☐	☐
2	Belong to either one of the following categories based on JNC 7 as measured by office BP at Screening visit: ➢ Prehypertension (SBP 120 – 139 mmHg or DBP 80 – 89 mmHg) ➢ Stage I hypertension (SBP 140 – 159 mmHg or DBP 90 – 99 mmHg)	☐	☐
3	Body weight ≤ 90 kg, and BMI ≥ 18.5 kg/m^2 or < 30 kg/m^2.	☐	☐
4	**NOT** on any antihypertensive treatment at the time of entry into the study.	☐	☐
5	Willing to comply with the study procedures and follow-ups.	☐	☐
6	A good understanding of the nature of the study and placed signature on the informed consent form.	☐	☐
Exclusion Criteria			
1	Patients with any of the following conditions within 6 months prior to study participation: ➢ Secondary hypertension ➢ Uncontrolled diabetes mellitus ➢ Renal disease based on the investigator's judgment ➢ Severe hepatic disease with Child-Pugh class C ➢ Severe anaemia ➢ Any malignant disease or serious disease	☐	☐
2	Patients with clinically significant abnormalities in the following laboratory parameters within 2 weeks prior to Screening visit or during the screening period: ➢ HbA1c > 9% ➢ AST or ALT ≥ 3*upper limit of normal (ULN) ➢ Estimated glomerular filtration rate (eGFR) < 50 ml/min/1.73 m^2 ➢ Serum creatinine ≥ 3*ULN ➢ Hemoglobin < 10 g/dL	☐	☐
3	History of milk allergy and/or lactose intolerance.	☐	☐
4	Alcohol abuse classified as ≥ 8 units of alcoholic consumption per week within 1 month prior to study participation.	☐	☐
5	Constant use of oral medication or supplements affecting blood pressure.	☐	☐
6	Female patients who are pregnant, planning to become pregnant, or lactating.	☐	☐
7	Male or female patients of child-bearing potential do not agree to use an effective method of contraception during the study period.	☐	☐
8	Currently participating in any other interventional clinical study within 30 days.	☐	☐
9	Patients who are considered not suitable for the study according to the investigator's judgment for the patient's best interest.	☐	☐

Date of visit: __ __/__ __ __/__ __ __ __ (dd/mmm/yyyy)

Investigational Product Administration
Is investigational product dispensed to subject: ☐ Yes* ☐ No *:All the eligible subjects will receive **PLACEBO** during the run-in period
Date of dispense: __ __/__ __ __/__ __ __ __ (dd/mmm/yyyy)
Number of dispensed: __ __ __ Pack

Date of visit: __ __/__ __ __/__ __ __ __ (dd/mmm/yyyy)

Physical Examinations

Is the examination performed: ☐ Yes ☐ No

Date of examination: __ __/__ __ __/__ __ __ __ (dd/mmm/yyyy)

	Sites/System	Result		Specify if abnormal or not done
		Normal	Abnormal	
1	General appearance	☐	☐	
2	Head/ears/eyes/nose/throat	☐	☐	
3	Mouth	☐	☐	
4	Skin	☐	☐	
5	Neck (including thyroid)	☐	☐	
6	Lymph nodes	☐	☐	
7	Spine	☐	☐	
8	Cardiovascular system	☐	☐	
9	Respiratory system	☐	☐	
10	Gastro-intestinal system	☐	☐	
11	Nervous system	☐	☐	
12	Musculoskeletal system	☐	☐	
13	Blood and blood forming organs	☐	☐	
14	Mental status	☐	☐	
15	Other, specify: _____	☐	☐	

Vital Signs

Is the assessment performed: ☐ Yes ☐ No

Date of assessment: __ __/__ __ __/__ __ __ __ (dd/mmm/yyyy)

Body temperature: __ __ __.__℃

Pulse rate: __ __ __ bpm

Respiratory rate: __ __ __ times/ minute

Seated Office Blood Pressure

Is the assessment performed*: ☐ Yes ☐ No

*: the subject's office BP will be measured at an air-conditioned room after around 30 minutes of rest in the sitting position using an electronic sphygmomanometer

Date of assessment: __ __/__ __ __/__ __ __ __ (dd/mmm/yyyy)

Systolic Blood Pressure:	Right arm: __ __ __ mmHg	Left arm: __ __ __ mmHg
Diastolic Blood Pressure:	Right arm: __ __ __ mmHg	Left arm: __ __ __ mmHg

Eligibility Confirmation and Randomization

Does subject meet the criteria*: ☐ Yes ☐ No

The arm with higher SBP value should be used to re-confirm the inclusion criteria #2.

Does subject enter randomization: ☐ Yes

Random No.: R ___ ___ ___

BP measurement arm[&]: ☐ Left arm ☐ Right arm

&: Blood pressure measurements (including office BP and 24-hour ABPM) in the following visits should be made on the same arm with the higher value at baseline.

☐ No, please fill in completion of study page.

Signature

Investigator's signature: _____ Date: _____

24-hour Ambulatory SBP/DBP

Is the assessment performed: ☐ Yes ☐ No

Date of assessment: ___/___ ___/___ ___ ___ (dd/mmm/yyyy)

Time	SBP (mmHg)	DBP (mmHg)	Time	SBP (mmHg)	DBP (mmHg)
06 : 00	___ ___ ___	___ ___ ___	16 : 00	___ ___ ___	___ ___ ___
06 : 30	___ ___ ___	___ ___ ___	16 : 30	___ ___ ___	___ ___ ___
07 : 00	___ ___ ___	___ ___ ___	17 : 00	___ ___ ___	___ ___ ___
07 : 30	___ ___ ___	___ ___ ___	17 : 30	___ ___ ___	___ ___ ___
08 : 00	___ ___ ___	___ ___ ___	18 : 00	___ ___ ___	___ ___ ___
08 : 30	___ ___ ___	___ ___ ___	18 : 30	___ ___ ___	___ ___ ___
09 : 00	___ ___ ___	___ ___ ___	19 : 00	___ ___ ___	___ ___ ___
09 : 30	___ ___ ___	___ ___ ___	19 : 30	___ ___ ___	___ ___ ___
10 : 00	___ ___ ___	___ ___ ___	20 : 00	___ ___ ___	___ ___ ___
10 : 30	___ ___ ___	___ ___ ___	20 : 30	___ ___ ___	___ ___ ___
11 : 00	___ ___ ___	___ ___ ___	21 : 00	___ ___ ___	___ ___ ___
11 : 30	___ ___ ___	___ ___ ___	21 : 30	___ ___ ___	___ ___ ___
12 : 00	___ ___ ___	___ ___ ___	22 : 00	___ ___ ___	___ ___ ___
12 : 30	___ ___ ___	___ ___ ___	23 : 00	___ ___ ___	___ ___ ___
13 : 00	___ ___ ___	___ ___ ___	24 : 00	___ ___ ___	___ ___ ___
13 : 30	___ ___ ___	___ ___ ___	01 : 00	___ ___ ___	___ ___ ___
14 : 00	___ ___ ___	___ ___ ___	02 : 00	___ ___ ___	___ ___ ___
14 : 30	___ ___ ___	___ ___ ___	03 : 00	___ ___ ___	___ ___ ___
15 : 00	___ ___ ___	___ ___ ___	04 : 00	___ ___ ___	___ ___ ___
15 : 30	___ ___ ___	___ ___ ___	05 : 00	___ ___ ___	___ ___ ___

Biochemistry Tests

Is the test performed: ☐ Yes ☐ No

Date of sample: __ __/__ __ __/__ __ __ __ (dd/mmm/yyyy)

	Item	Value	Result	
			Normal	Abnormal
1	Total bilirubin		☐	☐CS ☐NCS
2	Aspartate transaminase (AST)		☐	☐CS ☐NCS
3	Alanine transaminase (ALT)		☐	☐CS ☐NCS
4	Alkaline phosphatase (ALP)		☐	☐CS ☐NCS
5	Serum creatinine		☐	☐CS ☐NCS
6	Blood urea nitrogen (BUN)		☐	☐CS ☐NCS
7	Uric acid		☐	☐CS ☐NCS
8	Triglyceride (TG)		☐	☐CS ☐NCS
9	Total cholesterol (T-Cho)		☐	☐CS ☐NCS
10	HDL-cholesterol (HDL-C)		☐	☐CS ☐NCS
11	LDL-cholesterol (LDL-C)		☐	☐CS ☐NCS
12	Glucose (A.C.)		☐	☐CS ☐NCS
13	Hba1c		☐	☐CS ☐NCS
14	Sodium (Na)		☐	☐CS ☐NCS
15	Potassium (K)		☐	☐CS ☐NCS
16	Chloride (Cl)		☐	☐CS ☐NCS

Hematology Tests

Is the test performed: ☐ Yes ☐ No

Date of sample: __ __/__ __ __/__ __ __ __ (dd/mmm/yyyy)

Item		Value	Result	
			Normal	Abnormal
1	Hemoglobin		☐	☐CS ☐NCS
2	Platelet		☐	☐CS ☐NCS
3	RBC		☐	☐CS ☐NCS
4	WBC		☐	☐CS ☐NCS
5	Neurophils		☐	☐CS ☐NCS
6	Eosinophils		☐	☐CS ☐NCS
7	Lymphocyte		☐	☐CS ☐NCS
8	Monocytes		☐	☐CS ☐NCS
9	Basophils		☐	☐CS ☐NCS

Urinalysis Tests

Is the test performed: ☐ Yes ☐ No

Date of sample: __ __/__ __ __/__ __ __ __ (dd/mmm/yyyy)

Item		Value	Result	
			Normal	Abnormal
1	WBC		☐	☐CS ☐NCS
2	RBC		☐	☐CS ☐NCS
3	PH		☐	☐CS ☐NCS
4	PROTEIN		☐	☐CS ☐NCS
5	SUGAR		☐	☐CS ☐NCS

Biomarkers for Blood Vessel Inflammation or Damage

Is the test performed: ☐ Yes ☐ No

Date of sample: __ __/__ __ __/__ __ __ __ (dd/mmm/yyyy)

	Item	Result
1	high sensitivity C-reactive protein (hsCRP)	
2	creatine kinase (CK/CPK)	

Electrocardiogram (ECG)

Is the examination performed: ☐ Yes ☐ No

Date of examination: __ __/__ __ __/__ __ __ __ (dd/mmm/yyyy)

Result: ☐ Normal ☐ Abnormal, NCS ☐ Abnormal, CS

Abnormal Findings:

Investigational Product Administration

Is investigational product **dispensed** to subject: ☐ Yes ☐ No

Date of dispense: __ __/__ __ __/__ __ __ __ (dd/mmm/yyyy)

Number of dispensed: __ __ __ Pack

Is investigational product **retrieved** from subject: ☐ Yes ☐ No

Date of retrieved: __ __/__ __ __/__ __ __ __ (dd/mmm/yyyy)

Number of retrieved: __ __ __ Pack

Number of lost: __ __ __ Pack

Number of taken: __ __ __ Pack

Date of visit: __ __/__ __ __/__ __ __ __ (dd/mmm/yyyy)

Physical Examinations

Is the examination performed: ☐ Yes ☐ No

Date of examination: __ __/__ __ __/__ __ __ __ (dd/mmm/yyyy)

Sites/System	Result		Specify if abnormal or not done
	Normal	Abnormal	
1 General appearance	☐	☐	
2 Head/ears/eyes/nose/throat	☐	☐	
3 Mouth	☐	☐	
4 Skin	☐	☐	
5 Neck (including thyroid)	☐	☐	
6 Lymph nodes	☐	☐	
7 Spine	☐	☐	
8 Cardiovascular system	☐	☐	
9 Respiratory system	☐	☐	
10 Gastro-intestinal system	☐	☐	
11 Nervous system	☐	☐	
12 Musculoskeletal system	☐	☐	
13 Blood and blood forming organs	☐	☐	
14 Mental status	☐	☐	
15 Other, specify: _____	☐	☐	

Vital Signs

Is the assessment performed: ☐ Yes ☐ No

Date of assessment: __ __/__ __ __/__ __ __ __ (dd/mmm/yyyy)

Body temperature: __ __ __.__℃

Pulse rate: __ __ __ bpm

Respiratory rate: __ __ __ times/ minute

Seated Office Blood Pressure

Is the assessment performed*: ☐ Yes ☐ No

*: the subject's office BP will be measured at an air-conditioned room after around 30 minutes of rest in the sitting position using an electronic sphygmomanometer. All measurements have to be made on the same arm and the same equipment

Date of assessment: __ __/__ __ __/__ __ __ __ (dd/mmm/yyyy)

Systolic Blood Pressure : __ __ __mmHg

Diastolic Blood Pressure: __ __ __ mmHg

Investigational Product Administration

Is investigational product **dispensed** to subject: ☐ Yes ☐ No

Date of dispense: __ __/__ __ __/__ __ __ __ (dd/mmm/yyyy)

Number of dispensed: __ __ __ Pack

Is investigational product **retrieved** from subject: ☐ Yes ☐ No

Date of retrieved: __ __/__ __ __/__ __ __ __ (dd/mmm/yyyy)

Number of retrieved: __ __ __ Pack

Number of lost: __ __ __ Pack

Number of taken: __ __ __ Pack

Date of visit: __ __/__ __ __/__ __ __ __ (dd/mmm/yyyy)

Physical Examinations

Is the examination performed: ☐ Yes ☐ No

Date of examination: __ __/__ __ __/__ __ __ __ (dd/mmm/yyyy)

Sites/System	Result		Specify if abnormal or not done
	Normal	Abnormal	
1 General appearance	☐	☐	
2 Head/ears/eyes/nose/throat	☐	☐	
3 Mouth	☐	☐	
4 Skin	☐	☐	
5 Neck (including thyroid)	☐	☐	
6 Lymph nodes	☐	☐	
7 Spine	☐	☐	
8 Cardiovascular system	☐	☐	
9 Respiratory system	☐	☐	
10 Gastro-intestinal system	☐	☐	
11 Nervous system	☐	☐	
12 Musculoskeletal system	☐	☐	
13 Blood and blood forming organs	☐	☐	
14 Mental status	☐	☐	
15 Other, specify: _____	☐	☐	

Vital Signs

Is the assessment performed: ☐ Yes ☐ No

Date of assessment: __ __/__ __ __/__ __ __ __ (dd/mmm/yyyy)

Body temperature: __ __ __.__℃

Pulse rate: __ __ __ bpm

Respiratory rate: __ __ __ times/ minute

Seated Office Blood Pressure

Is the assessment performed*: ☐ Yes ☐ No

*: the subject's office BP will be measured at an air-conditioned room after around 30 minutes of rest in the sitting position using an electronic sphygmomanometer. All measurements have to be made on the same arm and the same equipment

Date of assessment: __ __/__ __ __/__ __ __ __ (dd/mmm/yyyy)

Systolic Blood Pressure : __ __ __ mmHg

Diastolic Blood Pressure: __ __ __ mmHg

Investigational Product Administration

Is investigational product **dispensed** to subject: ☐ Yes ☐ No

Date of dispense: __ __/__ __ __/__ __ __ __ (dd/mmm/yyyy)

Number of dispensed: __ __ __ Pack

Is investigational product **retrieved** from subject: ☐ Yes ☐ No

Date of retrieved: __ __/__ __ __/__ __ __ __ (dd/mmm/yyyy)

Number of retrieved: __ __ __ Pack

Number of lost: __ __ __ Pack

Number of taken: __ __ __ Pack

Date of visit: __ __/__ __ __/__ __ __ __ (dd/mmm/yyyy)

Physical Examinations

Is the examination performed: ☐ Yes ☐ No

Date of examination: __ __/__ __ __/__ __ __ __ (dd/mmm/yyyy)

	Sites/System	Result		Specify if abnormal or not done
		Normal	Abnormal	
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5	Neck (including thyroid)	☐	☐	
6	Lymph nodes	☐	☐	
7	Spine	☐	☐	
8	Cardiovascular system	☐	☐	
9	Respiratory system	☐	☐	
10	Gastro-intestinal system	☐	☐	
11	Nervous system	☐	☐	
12	Musculoskeletal system	☐	☐	
13	Blood and blood forming organs	☐	☐	
14	Mental status	☐	☐	
15	Other, specify: _____	☐	☐	

Vital Signs

Is the assessment performed*: ☐ Yes ☐ No

Date of assessment: __ __/__ __ __/__ __ __ __ (dd/mmm/yyyy)

Body temperature: __ __ __.__℃

Pulse rate: __ __ __ bpm

Respiratory rate: __ __ __ times/ minute

Seated Office Blood Pressure

Is the assessment performed*: ☐ Yes ☐ No

*: the subject's office BP will be measured at an air-conditioned room after around 30 minutes of rest in the sitting position using an electronic sphygmomanometer. All measurements have to be made on the same arm and the same equipment

Date of assessment: __ __/__ __ __/__ __ __ __ (dd/mmm/yyyy)

Systolic Blood Pressure : __ __ __ mmHg

Diastolic Blood Pressure: __ __ __ mmHg

24-hour Ambulatory SBP/DBP

Is the assessment performed: ☐ Yes ☐ No

Date of assessment: __ __/__ __ __/__ __ __ __ (dd/mmm/yyyy)

Time	SBP (mmHg)	DBP (mmHg)	Time	SBP (mmHg)	DBP (mmHg)
06 : 00	___ ___ ___	___ ___ ___	16 : 00	___ ___ ___	___ ___ ___
06 : 30	___ ___ ___	___ ___ ___	16 : 30	___ ___ ___	___ ___ ___
07 : 00	___ ___ ___	___ ___ ___	17 : 00	___ ___ ___	___ ___ ___
07 : 30	___ ___ ___	___ ___ ___	17 : 30	___ ___ ___	___ ___ ___
08 : 00	___ ___ ___	___ ___ ___	18 : 00	___ ___ ___	___ ___ ___
08 : 30	___ ___ ___	___ ___ ___	18 : 30	___ ___ ___	___ ___ ___
09 : 00	___ ___ ___	___ ___ ___	19 : 00	___ ___ ___	___ ___ ___
09 : 30	___ ___ ___	___ ___ ___	19 : 30	___ ___ ___	___ ___ ___
10 : 00	___ ___ ___	___ ___ ___	20 : 00	___ ___ ___	___ ___ ___
10 : 30	___ ___ ___	___ ___ ___	20 : 30	___ ___ ___	___ ___ ___
11 : 00	___ ___ ___	___ ___ ___	21 : 00	___ ___ ___	___ ___ ___
11 : 30	___ ___ ___	___ ___ ___	21 : 30	___ ___ ___	___ ___ ___
12 : 00	___ ___ ___	___ ___ ___	22 : 00	___ ___ ___	___ ___ ___
12 : 30	___ ___ ___	___ ___ ___	23 : 00	___ ___ ___	___ ___ ___
13 : 00	___ ___ ___	___ ___ ___	24 : 00	___ ___ ___	___ ___ ___
13 : 30	___ ___ ___	___ ___ ___	01 : 00	___ ___ ___	___ ___ ___
14 : 00	___ ___ ___	___ ___ ___	02 : 00	___ ___ ___	___ ___ ___
14 : 30	___ ___ ___	___ ___ ___	03 : 00	___ ___ ___	___ ___ ___
15 : 00	___ ___ ___	___ ___ ___	04 : 00	___ ___ ___	___ ___ ___
15 : 30	___ ___ ___	___ ___ ___	05 : 00	___ ___ ___	___ ___ ___

Biochemistry Tests

Is the test performed: ☐ Yes ☐ No

Date of sample: __ __/__ __ __/__ __ __ __ (dd/mmm/yyyy)

	Item	Value	Result	
			Normal	Abnormal
1	Total bilirubin		☐	☐CS ☐NCS
2	Aspartate transaminase (AST)		☐	☐CS ☐NCS
3	Alanine transaminase (ALT)		☐	☐CS ☐NCS
4	Alkaline phosphatase (ALP)		☐	☐CS ☐NCS
5	Serum creatinine		☐	☐CS ☐NCS
6	Blood urea nitrogen (BUN)		☐	☐CS ☐NCS
7	Uric acid		☐	☐CS ☐NCS
8	Triglyceride (TG)		☐	☐CS ☐NCS
9	Total cholesterol (T-Cho)		☐	☐CS ☐NCS
10	HDL-cholesterol (HDL-C)		☐	☐CS ☐NCS
11	LDL-cholesterol (LDL-C)		☐	☐CS ☐NCS
12	Glucose (A.C.)		☐	☐CS ☐NCS
13	Hba1c		☐	☐CS ☐NCS
14	Sodium (Na)		☐	☐CS ☐NCS
15	Potassium (K)		☐	☐CS ☐NCS
16	Chloride (Cl)		☐	☐CS ☐NCS

Hematology Tests

Is the test performed: ☐ Yes ☐ No

Date of sample: __ __/__ __ __/__ __ __ __ (dd/mmm/yyyy)

Item		Value	Result	
			Normal	Abnormal
1	Hemoglobin		☐	☐CS ☐NCS
2	Platelet		☐	☐CS ☐NCS
3	RBC		☐	☐CS ☐NCS
4	WBC		☐	☐CS ☐NCS
5	Neurophils		☐	☐CS ☐NCS
6	Eosinophils		☐	☐CS ☐NCS
7	Lymphocyte		☐	☐CS ☐NCS
8	Monocytes		☐	☐CS ☐NCS
9	Basophils		☐	☐CS ☐NCS

Urinalysis Tests

Is the test performed: ☐ Yes ☐ No

Date of sample: __ __/__ __ __/__ __ __ __ (dd/mmm/yyyy)

Item		Value	Result	
			Normal	Abnormal
1	WBC		☐	☐CS ☐NCS
2	RBC		☐	☐CS ☐NCS
3	PH		☐	☐CS ☐NCS
4	PROTEIN		☐	☐CS ☐NCS
5	SUGAR		☐	☐CS ☐NCS

Biomarkers for Blood Vessel Inflammation or Damage

Is the test performed: ☐ Yes ☐ No

Date of sample: __ __/__ __ __/__ __ __ __ (dd/mmm/yyyy)

	Item	Result
1	high sensitivity C-reactive protein (hsCRP)	
2	creatine kinase (CK/CPK)	

Electrocardiogram (ECG)

Is the examination performed: ☐ Yes ☐ No

Date of examination: __ __/__ __ __/__ __ __ __ (dd/mmm/yyyy)

Result: ☐ Normal ☐ Abnormal, NCS ☐ Abnormal, CS

Abnormal Findings: _____

Investigational Product Administration

Is investigational product **retrieved** from subject: ☐ Yes ☐ No

Date of retrieved: __ __/__ __ __/__ __ __ __ (dd/mmm/yyyy)

Number of retrieved: __ __ __ Pack

Number of lost: __ __ __ Pack

Number of taken: __ __ __ Pack

Date of visit: ___/___ ___/___ ___ ___ ___ (dd/mmm/yyyy)

Physical Examinations

Is the examination performed: ☐ Yes ☐ No

Date of examination: ___/___ ___/___ ___ ___ ___ (dd/mmm/yyyy)

Sites/System	Result		Specify if abnormal or not done
	Normal	Abnormal	
1 General appearance	☐	☐	
2 Head/ears/eyes/nose/throat	☐	☐	
3 Mouth	☐	☐	
4 Skin	☐	☐	
5 Neck (including thyroid)	☐	☐	
6 Lymph nodes	☐	☐	
7 Spine	☐	☐	
8 Cardiovascular system	☐	☐	
9 Respiratory system	☐	☐	
10 Gastro-intestinal system	☐	☐	
11 Nervous system	☐	☐	
12 Musculoskeletal system	☐	☐	
13 Blood and blood forming organs	☐	☐	
14 Mental status	☐	☐	
15 Other, specify: _____	☐	☐	

Vital Signs
Is the assessment performed: ☐ Yes ☐ No
Date of assessment: __ __/__ __ __/__ __ __ __ (dd/mmm/yyyy)
Body temperature: __ __ __.__℃
Pulse rate: __ __ __ bpm
Respiratory rate: __ __ __ times/ minute

Seated Office Blood Pressure
Is the assessment performed*: ☐ Yes ☐ No *: the subject's office BP will be measured at an air-conditioned room after around 30 minutes of rest in the sitting position using an electronic sphygmomanometer. All measurements have to be made on the same arm and the same equipment
Date of assessment: __ __/__ __ __/__ __ __ __ (dd/mmm/yyyy)
Systolic Blood Pressure : __ __ __ mmHg
Diastolic Blood Pressure: __ __ __ mmHg

Adverse Event

Is there any adverse event: ☐ Yes ☐ No

Note: All the adverse events occurring from Baseline (Visit 3) to study completion (Visit 7)/withdrawal should be recorded.

AE no. Adverse Event	Onset Date End date or Ongoing (dd/mmm/yyyy)	Severity 1=Mild, 2=Moderate, 3=Severe	SAE 1=Yes, 2=No,	Relationship to Study Drug 1=Certain, 2=Probable/Likely, 3=Possible, 4=Unlikely, 5=unrelated, 6=Unknown	Action Taken 1=IP$ not changed, , 2=IP interrupted, 3=IP withdrawn,	Treatment Required 1=No, 2=Medication 3=Non-drug therapy, 4=Medication and non-drug therapy	Outcome 1=Resolved 2=Persisting 3=Death* 4=Unknown
A___ ___ ___	__/__ __ __/__ __ __ __ __/__ __ __/__ __ __ __ or ☐	—	—	—	—	—	—
A___ ___ ___	__/__ __ __/__ __ __ __ __/__ __ __/__ __ __ __ or ☐	—	—	—	—	—	—
A___ ___ ___	__/__ __ __/__ __ __ __ __/__ __ __/__ __ __ __ or ☐	—	—	—	—	—	—
A___ ___ ___	__/__ __ __/__ __ __ __ __/__ __ __/__ __ __ __ or ☐	—	—	—	—	—	—

$: Investigational product; *: An AE that the outcome is death should be considered as a SAE

Is this the last page used? ☐ Yes ☐ No

Concomitant Medication

Is there any concomitant medication: ☐ Yes ☐ No

Note: Antihypertensive medication or supplements that the subjects took within 3 months prior to ICF date will be recorded. All the concomitant medication used from screening visit (Visit 1) to the end of the study (Visit 7)/early termination will also be recorded.

Medication no. Medication	Single dose	Unit [a]	Route [b]	Frequency [c],	Indication [d]	Start Date End date or Ongoing (dd/mmm/yyyy)
M___ ___ ___						__/__ ___/____ ____ __/__ ___/____ ____ or ☐
M___ ___ ___						__/__ ___/____ ____ __/__ ___/____ ____ or ☐
M___ ___ ___						__/__ ___/____ ____ __/__ ___/____ ____ or ☐
M___ ___ ___						__/__ ___/____ ____ __/__ ___/____ ____ or ☐

a: MG, ML, G, MCG, UG, TABLET, CAPSULE, DROPS…
b: 1=ORAL, 2=TOPICAL, 3=NASAL, 4=SUBLINGUAL, 5=INTRAVENOUS, 6=INTRAMUSCULAR, 7=INHALED, 8=SUBCUTANEOUS, 9=TRANSDERMAL, 10=OTHERS…
c: Q.I.D, T.I.D, B.I.D, Q12H, QD, HS, PRN, STAT…
d: Please use the event code according to the AE page (A001~), Medical history page (H001~), or Prophylaxis/ routine (P000)

Is this the last page used? ☐ Yes ☐ No

End of Study/ Early Termination

Date of the subject was taken off the study: __ __/__ __ __/__ __ __ __ (dd/mmm/yyyy)

Did the subject complete the study : ☐ Yes ☐ No (If No, please record the primary reason)

Primary reason for early termination

- ☐ Subject withdraw consent
- ☐ Lost to follow up
- ☐ Subjects who use prohibited medications, or any other medications/therapies/supplements that could affect blood pressure
- ☐ Subjects stop taking investigational product, or temporarily interrupt taking investigational product over 1 week
- ☐ Protocol violation
- ☐ Pregnancy or lactating
- ☐ Subject with two value of blood pressure over the upper limit of stage I hypertension within one week, SBP ≧160 mmHg or DBP ≧100 mmHg
- ☐ Adverse event(s):_____ _____
- ☐ Patients who are considered not suitable for the study according to the investigator's judgment for the patient's best interest
- ☐ Death, date of death: __ __/__ __ __/__ __ __ __ (dd/mmm/yyyy)
- ☐ Other, please specify: _____

Comments: _____

Signature

All data in this case report form have been entered under my authority and to the best of my knowledge are accurate and complete.

Investigator's signature: _____ Date: _____