

OP109219\_JP-2266-101-FIH\_A (v.2.0)

Screening Event: Screening [SCR]

Page: Visit Date [SV]

VISIT DATE	
<b>▶</b> Date of Visit	



Trial: **OP109219\_JP-2266-101-FIH\_A (v.2.0)** 

Event: Screening [SCR]

Page: Informed Consent [ICF]

1	N	ΙE	O	R	N	1E	D	C	O	N	S	E	N	IT	۰

▶ Has the nature of the study been explained to the patient	Yes 🦳	No 🔘
and written informed consent has been obtained?		
▶ Date of Signed Informed Consent		



Trial: **OP109219\_JP-2266-101-FIH\_A (v.2.0)** 

Event: Screening [SCR]

Page: ICF Genomics [ICFEG]

INICODIACO	AANAENT FAR	EVALABATABY	OFNORMO.
INFORMED	CONSENT FOR	<b>EXPLORATORY</b>	GENUNIC

	• • • •		genomic informed			Voc.	No.	$\overline{}$
Has the	written	exploratory	genomic informed	consent has	been obtained?	169	INO [	

**▶** Date of Signed Informed Consent

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Trial: **OP109219\_JP-2266-101-FIH\_A (v.2.0)** 

Event: Screening [SCR]
Page: Demographics [DM]

DEMOGRAPH	IICS
<b>&gt;</b> Age	Years
<b>&gt;</b> Height	cm
<b>&gt;</b> Weight	kg
<b>≫</b> BMI	kg/m2



Trial: **OP109219\_JP-2266-101-FIH\_A (v.2.0)** 

Event: Screening [SCR]

Page: Medical/Surgical His [MEDICAL/SURGICAL\_HISTORY]

<b>MEDI</b>	CAL/	SUR	<b>GICAL</b>	HIST	ORY

▶Any relevant medical and/or surgical history?

C Yes C No

Seq. No. Medical/Surgical History Start Date Ongoing End Date



Trial: **OP109219\_JP-2266-101-FIH\_A (v.2.0)** 

Event: Screening [SCR]
Page: Physical Exam [PE]

PHYSICAL EXA	AMINATION		
Parameter Name	Assessment	Abnormal Finding	Clinically Significant
<b>≫</b> Skin and Mucous	Normal Abnorma	→	Yes No
<b>&gt;</b> Ears/Nose/Throat	Normal Abnorma	l <b>»</b>	➤ C Yes C No
<b>&gt;</b> Pulmonary	Normal Abnorma	l <b>»</b>	➤ C Yes C No
<b>&gt;&gt;</b> Cardiac	C Normal C Abnorma	l <b>»</b>	Yes No
→ Gastro - intestinal	Normal Abnorma	l <b>»</b>	Yes No
<b>&gt;</b> Neurological	C Normal C Abnorma	l <b>»</b>	→ ○ Yes ○ No



Trial: **OP109219\_JP-2266-101-FIH\_A (v.2.0)** 

Event: Screening [SCR]
Page: Hematology [LH]

HEMATOLOGY					
➤Sample Collected?					
▶If No,Specify					
<b>▶</b> Date of Collection					
<b>▶</b> Time of Collection					
Parameter Name	Result	Unit	LLN	ULN	Assessment
▶Red Blood Cells (RBC)				<b>&gt;</b>	Normal Abnormal NCS Abnormal CS Not Done
<b>&gt;&gt;</b> Hemoglobin				<b>&gt;&gt;</b>	Normal Abnormal NCS Abnormal CS Not Done
<b>&gt;&gt;</b> Hematocrit				<b>3</b> >	Normal Abnormal NCS Abnormal CS Not Done
➤ Mean Corpuscular Volume (MCV)				**	Normal Abnormal NCS Abnormal CS Not Done
➤ Mean Corpuscular Hemoglobin (MCH)				<b>&gt;&gt;</b>	Normal Abnormal NCS Abnormal CS Not Done
➤ Mean Corpuscular Hemoglobin Concentration (MCHC)				<b>&gt;&gt;</b>	Normal Abnormal NCS Abnormal CS Not Done
➤White Blood Cells (WBC)				**	Normal Abnormal NCS Abnormal CS Not Done
<b>▶</b> Neutrophils				<b>&gt;&gt;</b>	Normal Abnormal NCS Abnormal CS Not Done
<b>≫</b> Eosinophils				<b>&gt;&gt;</b>	Normal Abnormal NCS Abnormal CS Not Done

<b>&gt;&gt;</b> Basophils			Normal Abnormal NCS Abnormal CS Not Done
<b>&gt;&gt;</b> Lymphocytes		<b>3</b>	Normal Abnormal NCS Abnormal CS Not Done
<b>≫</b> Monocytes		<b>3</b>	Normal Abnormal NCS Abnormal CS Not Done
<b>≫</b> Platelet count		<b>&gt;&gt;</b>	Normal Abnormal NCS Abnormal CS Not Done
Comment			



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Trial: **OP109219\_JP-2266-101-FIH\_A (v.2.0)** 

Event: Screening [SCR]
Page: Coagulation [LT]

C Yes C No				
Result	Unit	LLN	ULN	Assessment
				Normal Abnormal NCS Abnormal CS Not Done
				Normal Abnormal NCS Abnormal CS Not Done
				Normal Abnormal NCS Abnormal CS Not Done



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Trial: **OP109219\_JP-2266-101-FIH\_A (v.2.0)** 

Event: Screening [SCR]
Page: Biochemistry [LC]

BIOCHEMISTRY					
■Sample Collected? C Yes C No					
▶If No,Specify					
▶Fasting State	vn				
Date of Collection					
<b>▶</b> Time of Collection					
Parameter Name Symbo	ol Results	Units	LLN	ULN	Assessment
Fasting Glucose	<b>&gt;&gt;</b>				Normal Abnormal NCS Abnormal CS Not Done
HbA1c	<b>&gt;&gt;</b>				Normal Abnormal NCS Abnormal CS Not Done
Creatinine	<b>&gt;&gt;</b>				Normal Abnormal NCS Abnormal CS Not Done
Urea	<b>&gt;&gt;</b>				Normal Abnormal NC: Abnormal CS Not Done
Blood Urea Nitrogen (BUN)	<b>&gt;&gt;</b>				Normal Abnormal NC: Abnormal CS Not Done
Creatinine clearance	<b>&gt;&gt;</b>				Normal Abnormal NC: Abnormal CS Not Done
Alanine Serine Transferase (AST)	<b>&gt;&gt;</b>				Normal Abnormal NCS Abnormal CS Not Done
Alanine Leucine Transferase (ALT)	<b>3</b>				Normal Abnormal NCS Abnormal CS Not Done
Gamma Glutamyl Transferase (GGT)	»				Normal Abnormal NCS Abnormal CS Not Done

Alkaline Phosphatases (ALP)		<b>3</b> >		<b>3</b>	Normal Abnormal NCS Abnormal CS Not Done
Lactate Dehydrogenase (LDH)		<b>3</b> >		21	Normal Abnormal NCS Abnormal CS Not Done
Creatine Phosphokinase (CPK)		<b>35</b>		) i	Normal Abnormal NCS Abnormal CS Not Done
Lipase		<b>35</b>			Normal Abnormal NCS Abnormal CS Not Done
Total Bilirubin	< <= >> >=	<b>3</b> >		) i	Normal Abnormal NCS Abnormal CS Not Done
Conjugated Bilirubin	< <= >> =	<b>&gt;&gt;</b>		) i	Normal Abnormal NCS Abnormal CS Not Done
Unconjugated Bilirubin	< <= >> =	<b>3</b> >		20	Normal Abnormal NCS Abnormal CS Not Done
Total Cholesterol		<b>»</b>		2)	Normal Abnormal NCS Abnormal CS Not Done
Triglycerides	< <= >> >=	<b>»</b>		2)	Normal Abnormal NCS Abnormal CS Not Done
Sodium		3>		<b>3</b> 1	Normal Abnormal NCS Abnormal CS Not Done
Potassium		»		<b>3</b> 4	Normal Abnormal NCS Abnormal CS Not Done
Chloride		<b>»</b>		31	Normal Abnormal NCS Abnormal CS Not Done

Calcium	<b>»</b>		•	Normal Abnormal NCS Abnormal CS Not Done
Phosphorus	3>		<b>&gt;&gt;</b>	Normal Abnormal NCS Abnormal CS Not Done
Total Protein	<b>3</b> >		<b>&gt;&gt;</b>	Normal Abnormal NCS Abnormal CS Not Done
Comment				



Trial: **OP109219\_JP-2266-101-FIH\_A (v.2.0)** 

Event: Screening [SCR]
Page: Urinalysis [UR]

URINALYSIS					
Sample Collected?	C Yes C	) No			
► If No, Specify					
▶ Date of Collection					
<b>≫</b> Time of Collection					
Parameter Name	Symbol	Results	LLN	ULN	Assessment
Glucose		Positive Negative		,	Normal Abnormal NCS Abnormal CS Not Done
Proteins		Positive Negative		,	Normal Abnormal NCS Abnormal CS Not Done
Ketones		Positive Negative		•	Normal Abnormal NCS Abnormal CS Not Done
Occult Blood		Positive Negative		•	Normal Abnormal NCS Abnormal CS Not Done
Bilirubin		Positive Negative		•	Normal Abnormal NCS Abnormal CS Not Done
Urobilinogen		Positive Negative		•	Normal Abnormal NCS Abnormal CS Not Done
рН		<b>3</b> >			Normal Abnormal NCS Abnormal CS Not Done
Nitrites		Positive Negative		•	Normal Abnormal NCS Abnormal CS Not Done
Specific Gravity	< <= > >=	»			Normal Abnormal NCS Abnormal CS Not Done

White Blood Cells	Positive Negative	Normal Abnormal NCS Abnormal CS Not Done
Comments		

MICROSCOPIC RES	ULTS				
Parameter Name	Results	Units	LLN	ULN	Assessment
<b>≫</b> Micr: Glucose					Normal Abnormal NCS Abnormal CS Not Done
<b>≫</b> Micr: Protein					Normal Abnormal NCS Abnormal CS Not Done
<b>≫</b> Micr: Red Blood Cells					Normal Abnormal NCS Abnormal CS Not Done
■Micr: White Blood Cells					Normal Abnormal NCS Abnormal CS Not Done
<b>≫</b> Micr: Crystals	Positive Negative				Normal Abnormal NCS Abnormal CS Not Done
<b>≫</b> Epithelial Cells	Positive Negative				Normal Abnormal NCS Abnormal CS Not Done
<b>≫</b> Epithelial Renal Cells	Positive Negative				Normal Abnormal NCS Abnormal CS Not Done
<b>≫</b> Bacteria	Positive Negative				Normal Abnormal NCS Abnormal CS Not Done
<b>≫</b> Casts	Positive Negative				Normal Abnormal NCS Abnormal CS Not Done

Comments			



Trial: **OP109219\_JP-2266-101-FIH\_A (v.2.0)** 

Event: Screening [SCR]

Page: Urine electro test [URE]

	LYTES TEST				
Sample Collected?			C Yes C No	_	
▶If No,Specify					
<b>▶</b> Date of Collection		Γ			
➡Time of Collection		Γ			
Parameter Name	Results	Units	LLN	ULN	Assessment
<b>≫</b> Calcium					Normal Abnormal NCS Abnormal CS Not Done
<b>≫</b> Phosphorus					Normal Abnormal NCS Abnormal CS Not Done
<b>≫</b> Sodium					Normal Abnormal NCS Abnormal CS Not Done
<b>≫</b> Potassium					Normal Abnormal NCS Abnormal CS Not Done
<b>≫</b> Chloride					Normal Abnormal NCS Abnormal CS Not Done



Trial: **OP109219\_JP-2266-101-FIH\_A (v.2.0)** 

Event: Screening [SCR]
Page: Serology [LS]

SEROLOGY	
➤ Sample Collected?	C Yes C No
Date of Collection	
⇒anti-HIV 1 and HIV 2 antibodies	C Positive C Negative
<b>&gt;</b> anti-HCV antibodies	Positive Negative
<b>&gt;</b> HBsAg	Positive Negative
Comments	



Trial: **OP109219\_JP-2266-101-FIH\_A (v.2.0)** 

Event: Screening [SCR]

Page: Urine Drug Screen [UDS]

URINE DRUG SCREEN	NING
<b>≫</b> Sample Collected?	○ Yes ○ No
<b>▶</b> Date of Collection	
<b>&gt;&gt;</b> Result	Positive Negative
▶If Positive, Specify the Positive Drug?	



Trial: **OP109219\_JP-2266-101-FIH\_A (v.2.0)** 

Event: Screening [SCR]

Page: Urinary cotinine [URC]

URINARY COTI	NINE
<b>▶</b> Sample Collected?	C Yes C No
<b>▶</b> Date of Collection	
<b>≫</b> Result	Positive Negative
Comments	



Trial: **OP109219\_JP-2266-101-FIH\_A (v.2.0)** 

Event: Screening [SCR]

Page: Alcohol Breath Test [ALC]

ALCOHOL BE	REATH TEST				
➤Test Performed?  Yes  No					
<b>≫</b> Date Performed					
<b>&gt;</b> Result	Positive Negative				
Comments					



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Trial: OP109219\_JP-2266-101-FIH\_A (v.2.0)

Event: Screening [SCR]
Page: Vital Signs [VS]

VITAL SIGNS	_
▶Vitals collected?	C Yes C No
▶If No,Specify	
<b>▶</b> Date of measurements	3
⇒Body Temperature (°C)	,
<b>≫</b> Result	O Normal O Abnorma
Clinically Significant	C Yes C No
Blood Pressure and	Heart Rate
After	Position
10 Mins	
2 Mins	
<b>≫</b> Result	Normal Abnormal
Clinically Significant	C Yes C No
г	
Abnormal Finding/	
Relevant Comments	



Trial: **OP109219\_JP-2266-101-FIH\_A (v.2.0)** 

Event: Screening [SCR]
Page: 12 Lead ECG [EG]

12 LEAD ECG	
<b>≫</b> ECG Performed?	C Yes C No
▶If No,Specify	
<b>▶</b> Date of ECG	
<b>≫</b> Time of ECG	
→ Heart Rate (Beats/min)	
▶PR (ms)	
⇒QRS (ms)	
<b>&gt;&gt;</b> QT (ms)	
<b>&gt;&gt;</b> QTcF (ms)	
Conclusion Result	Normal Abnormal
➤ Clinically Significant?	C Yes C No
Abnormality Finding / Relevant Comment	



Trial: **OP109219\_JP-2266-101-FIH\_A (v.2.0)** 

Event: Screening [SCR]

Page: Subject Eligibility [IE]

ELIGIBILITY OF SUBJECT	
▶Are all the inclusion criteria answered Yes? Yes ○ No	
▶If No, please report the inclusion criteria numbers answered as No	
Comment	
▶ Are all the Non Inclusion criteria answered No? Yes ○ No	
▶ If No, please report the Non Inclusion criteria numbers answered as Yes	
Comment	
▶ Is the subject eligible to participate in the study?	
Date of confirmation of eligibility	
Comments on eligibility/non-eligibility	



Trial: **OP109219\_JP-2266-101-FIH\_A (v.2.0)** 

D-2 Event: P1 D-2 [P1\_D-2]
Page: Visit Date [SV]

P1

VISIT DATE	E
<b>▶</b> Date of Visit	



Trial: **OP109219\_JP-2266-101-FIH\_A (v.2.0)** 

Event: **P1 D-2 [P1\_D-2]** 

Page: Urine Drug Screen [UDS]

URINE DRUG SCREEN	NING
<b>≫</b> Sample Collected?	O Yes O No
<b>▶</b> Date of Collection	
<b>≫</b> Result	Positive Negative
▶If Positive, Specify the Positive Drug?	



Trial: **OP109219\_JP-2266-101-FIH\_A (v.2.0)** 

Event: **P1 D-2 [P1\_D-2]** 

Page: Urinary cotinine [URC]

URINARY COTI	NINE
<b>≫</b> Sample Collected?	C Yes C No
<b>▶</b> Date of Collection	
<b>&gt;</b> Result	Positive Negative
Comments	



Trial: **OP109219\_JP-2266-101-FIH\_A (v.2.0)** 

Event: **P1 D-2 [P1\_D-2]** 

Page: Alcohol Breath Test [ALC]

ALCOHOL BE	REATH TEST
<b>&gt;&gt;</b> Test Performed?	C Yes C No
<b>&gt;&gt;</b> Date Performed	
<b>≫</b> Result	Positive Negative
Comments	



Trial: **OP109219\_JP-2266-101-FIH\_A (v.2.0)** 

D-1 Event: P1 D-1 [P1D-1]
Page: Visit Date [SV]

P1

VISIT DATE	<b>=</b>
<b>&gt;&gt;</b> Date of Visit	



Trial: **OP109219\_JP-2266-101-FIH\_A (v.2.0)** 

Event: P1 D-1 [P1D-1]
Page: PE (Predose) [PE]

PHYSICAL EXAMINATION (Predo	ose)
Time Point	Pre-dose
<b>▶</b> Did the Physical Examination performed?	C Yes C No
If No,specify	
<b>&gt;</b> Date Performed	
→Time performed	
<b>≫</b> Results	C Normal C Abnormal
<b>≫</b> Abnormal Physical Finding	
Clinically Significant?	C Yes C No



Trial: **OP109219\_JP-2266-101-FIH\_A (v.2.0)** 

Event: **P1 D-1 [P1D-1]** 

Page: Hematology(Predose) [LH]

HEMATOLOGY (PRE	DOSE)				
Time Point Pre-de	ose s ( No				
	S () NO				
▶If No,Specify ▶Date of Collection					
Time of Collection					
,					
Parameter Name		Result	Un	it	it LLN
Red Blood Cells (RBC)					
<b>≫</b> Hemoglobin					
<b>≫</b> Hematocrit					
<b>≫</b> Mean Corpuscular Volume (	MCV)				
<b>≫</b> Mean Corpuscular Hemoglo	bin (MCH)				
<b>≫</b> Mean Corpuscular Hemoglo	bin Concentration (MCH	C)			
➤ White Blood Cells (WBC)				]	
<b>≫</b> Neutrophils					
<b>≫</b> Eosinophils				]	

<b>≫</b> Basophils		<b>&gt;&gt;</b>	Normal Abnormal NCS Abnormal CS Not Done
<b>≫</b> Lymphocytes		35	Normal Abnormal NCS Abnormal CS Not Done
<b>≫</b> Monocytes		<b>3</b>	Normal Abnormal NCS Abnormal CS Not Done
▶Platelet count		3)	Normal Abnormal NCS Abnormal CS Not Done
Comment			



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Trial: **OP109219\_JP-2266-101-FIH\_A (v.2.0)** 

Event: **P1 D-1 [P1D-1**]

Page: Coagulation(Predose) [LT]

DOSE)				
Pre-dose				
C Yes C No				
m-yyyy)				
Result	Unit	LLN	ULN	Assessment
				Normal Abnormal NCS Abnormal CS Not Done
o (INR)				Normal Abnormal NCS Abnormal CS Not Done
				Normal Abnormal NCS Abnormal CS Not Done
	m-yyyy)	Result Unit	Result Unit LLN	Result Unit LLN ULN



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Trial: **OP109219\_JP-2266-101-FIH\_A (v.2.0)** 

Event: **P1 D-1 [P1D-1**]

Page: Biochemistry(Predose [LC]

BIOCHEMISTRY (PRE DOSE)						
Time Point Pre-dose						
▶Sample Collected?						
▶If No,Specify						
▶ Fasting State	Unknown					
<b>▶</b> Date of Collection						
<b>▶</b> Time of Collection						
Parameter Name	Symbol	Results	Units	LLN	ULN	Assessment
Fasting Glucose		2>				Normal Abnormal NCS Abnormal CS Not Done
Creatinine		<b>»</b>				Normal Abnormal NCS Abnormal CS Not Done
Urea		»				Normal Abnormal NCS Abnormal CS Not Done
Blood Urea Nitrogen (BUN)		»				Normal Abnormal NCS Abnormal CS Not Done
Creatinine clearance		20				Normal Abnormal NCS Abnormal CS Not Done
Alanine Serine Transferase (AST)		<b>3</b> >				Normal Abnormal NCS Abnormal CS Not Done
Alanine Leucine Transferase (ALT)		<b>3</b> >				Normal Abnormal NCS Abnormal CS Not Done
Gamma Glutamyl Transferase (GGT)	< <= >					Normal Abnormal NCS Abnormal CS Not Done

Alkaline Phosphatases (ALP)		<b>3</b> >		<b>3</b>	Normal Abnormal NCS Abnormal CS Not Done
Lactate Dehydrogenase (LDH)		<b>3</b> >		21	Normal Abnormal NCS Abnormal CS Not Done
Creatine Phosphokinase (CPK)		<b>35</b>		) i	Normal Abnormal NCS Abnormal CS Not Done
Lipase		<b>3</b> >		) i	Normal Abnormal NCS Abnormal CS Not Done
Total Bilirubin	< <= >> =	<b>3</b> >		) i	Normal Abnormal NCS Abnormal CS Not Done
Conjugated Bilirubin	< <= >> =	<b>»</b>		21	Normal Abnormal NCS Abnormal CS Not Done
Unconjugated Bilirubin	< <= >> =	<b>3</b> >		21	Normal Abnormal NCS Abnormal CS Not Done
Total Cholesterol		<b>»</b>		<b>3</b> 1	Normal Abnormal NCS Abnormal CS Not Done
Triglycerides	< <= >> >=	<b>3</b> >		<b>3</b> 1	Normal Abnormal NCS Abnormal CS Not Done
Sodium		3>		<b>3</b> 1	Normal Abnormal NCS Abnormal CS Not Done
Potassium		»		<b>3</b> 4	Normal Abnormal NCS Abnormal CS Not Done
Chloride		<b>»</b>		31	Normal Abnormal NCS Abnormal CS Not Done

Calcium	<b>3</b>		•	Normal Abnormal NCS Abnormal CS Not Done
Phosphorus	3)		<b>&gt;&gt;</b>	Normal Abnormal NCS Abnormal CS Not Done
Total Protein	<b>»</b>		<b>&gt;</b>	Normal Abnormal NCS Abnormal CS Not Done
Comment				



Trial: **OP109219\_JP-2266-101-FIH\_A (v.2.0)** 

Event: **P1 D-1 [P1D-1]** 

Page: Urinalysis(Predose) [UR]

URINALYSIS (F	PRE DOSE	<b>()</b>			
Time Point	Pre-dose				
<b>≫</b> Sample Collected?	C Yes C	No			
► If No, Specify					
▶ Date of Collection					
▶Time of Collection					
Parameter Name	Symbol	Results	LLN	ULN	Assessment
Glucose		Positive Negative		1	Normal Abnormal NCS Abnormal CS Not Done
Proteins		<ul><li>Positive</li><li>Negative</li></ul>		1	Normal Abnormal NCS Abnormal CS Not Done
Ketones		Positive Negative		1	Normal Abnormal NCS Abnormal CS Not Done
Occult Blood		<ul><li>Positive</li><li>Negative</li></ul>		1	Normal Abnormal NCS Abnormal CS Not Done
Bilirubin		Positive Negative		1	Normal Abnormal NCS Abnormal CS Not Done
Urobilinogen		Positive Negative		1	Normal Abnormal NCS Abnormal CS Not Done
рН		<b>3&gt;</b>		,	Normal Abnormal NCS Abnormal CS Not Done
Nitrites		Positive Negative		1	Normal Abnormal NCS Abnormal CS Not Done
Specific Gravity	< <= >> >=	<b>3</b> >		,	Normal Abnormal NCS Abnormal CS Not Done

White Blood Ce	➤ Positive Negative	Normal Abnormal NCS Abnormal CS Not Done	
Comments			

MICROSCOPIC RES	BULTS				
Parameter Name	Results	Units	LLN	ULN	Assessment
<b>≫</b> Micr: Glucose					Normal Abnormal NCS Abnormal CS Not Done
<b>≫</b> Micr: Protein					Normal Abnormal NCS Abnormal CS Not Done
<b>≫</b> Micr: Red Blood Cells					Normal Abnormal NCS Abnormal CS Not Done
➤ Micr: White Blood Cells					Normal Abnormal NCS Abnormal CS Not Done
<b>≫</b> Micr: Crystals	<ul><li>Positive</li><li>Negative</li></ul>				Normal Abnormal NCS Abnormal CS Not Done
<b>≫</b> Epithelial Cells	<ul><li>Positive</li><li>Negative</li></ul>				Normal Abnormal NCS Abnormal CS Not Done
<b>≫</b> Epithelial Renal Cells	Positive Negative				Normal Abnormal NCS Abnormal CS Not Done
<b>≫</b> Bacteria	Positive Negative				Normal Abnormal NCS Abnormal CS Not Done
<b>≫</b> Casts	Positive Negative				Normal Abnormal NCS Abnormal CS Not Done

Comments			



Event: P1 D-1 [P1D-1]

Page: Vital Signs(Predose) [VS]

VITAL SIGNS (PI	RE DOSE)					
Time Point	Pre-dose					
<b>≫</b> Vitals collected?	C Yes C No					
▶If No,Specify						
<b>▶</b> Date of measuremen	its					
Blood Pressure and	l Heart Rate					
After	Position	Actual Time Position (hh:mm)	Actual Time Measurement (hh:mm)	Systolic (mmHg)	Diastolic (mmHg)	Heart rate (bpm)
10 Mins		<b>3</b>	<b>&gt;&gt;</b>	<b>&gt;&gt;</b>	<b>&gt;&gt;</b>	<b>&gt;&gt;</b>
2 Mins		<b>3)</b>	<b>&gt;&gt;</b>	<b>&gt;&gt;</b>	<b>≫</b>	<b>3</b>
<b>≫</b> Result	C Normal C Abnormal					
Clinically Significant	C Yes C No					
Abnormal Finding/ Relevant Comments						



Trial: **OP109219\_JP-2266-101-FIH\_A (v.2.0)** 

Event: **P1 D-1 [P1D-1]** 

Page: 12 Lead ECG(Predose) [EG]

12 LEAD ECG (PRI	E DOSE)
Time Point	Pre-dose
<b>▶</b> ECG Performed?	C Yes C No
▶If No,Specify	
<b>▶</b> Date of ECG	
<b>▶</b> Time of ECG	
→ Heart Rate (Beats/min)	
▶PR (ms)	
<b>&gt;</b> QRS (ms)	
<b>&gt;</b> QT (ms)	
<b>&gt;</b> QTcF (ms)	
Conclusion Result	Normal Abnormal
Clinically Significant?	C Yes C No
Abnormality Finding / Relevant Comment	



Trial: **OP109219\_JP-2266-101-FIH\_A (v.2.0)** 

Event: **P1 D-1 [P1D-1]** 

Page: Subject Eligibility [IE]

ELIGIBILITY OF SUBJECT		
▶Are all the inclusion criteria answered Yes?	C Yes C No	
▶If No, please report the inclusion criteria numbers answered as No		
Comment		
➤Are all the Non Inclusion criteria answered No?	C Yes C No	
▶ If No, please report the Non Inclusion criteria numbers answered as Yes		
Comment		
▶Is the subject eligible to participate in the study?	C Yes C No	
Date of confirmation of eligibility		
Comments on eligibility/non-eligibility		



Trial: **OP109219\_JP-2266-101-FIH\_A (v.2.0)** 

Event: **P1 D-1 [P1D-1]** 

Page: Randomization [RD]

RANDOMIZATION		
■ Was the subject randomized?	C Yes	O No
▶ Date of Randomization		
▶Food effect cohort	C Yes	O No



Trial: **OP109219\_JP-2266-101-FIH\_A (v.2.0)** 

Event: **P1 D-1 [P1D-1]** 

Page: Placebo Administrati [EX1]

PLACEBO ADMINISTRATION	1
<b>▶</b> Date of Placebo Administration	
⇒Time of Placebo Administration	
→ Administered Dose (mg)	
➤ Has the Placebo administration been performed according to the protocol?	C Yes C No
▶If No, please comment	



P1 D1 Trial: OP109219\_JP-2266-101-FIH\_A (v.2.0)

Event: P1 D1 [P1D1]
Page: Visit Date [SV]

VISIT DATE	E
<b>▶</b> Date of Visit	



Trial: **OP109219\_JP-2266-101-FIH\_A (v.2.0)** 

Event: P1 D1 [P1D1]
Page: PE (Pre Dose) [PE]

PHYSICAL EXAMINATION (PRE L	DOSE)
Time Point	Pre-dose
<b>▶</b> Did the Physical Examination performed?	C Yes C No
If No,specify	
Date Performed	
→Time performed	
<b>≫</b> Results	C Normal C Abnormal
▶Abnormal Physical Finding	
➤ Clinically Significant?	C Yes C No



Trial: **OP109219\_JP-2266-101-FIH\_A (v.2.0)** 

Event: **P1 D1 [P1D1]** 

Page: Hematology(Pre Dose) [LH]

HEMATOLOGY (PRE DOSE)					
Time Point Pre-dose					
Sample Collected?					
▶If No,Specify					
<b>&gt;&gt;</b> Date of Collection					
<b>≫</b> Time of Collection					
Parameter Name	Result	Unit	LLN	ULN ,	Assessment
▶Red Blood Cells (RBC)				<b>&gt;&gt;</b>	Normal Abnormal NCS Abnormal CS Not Done
<b>&gt;&gt;</b> Hemoglobin				**	Normal Abnormal NCS Abnormal CS Not Done
<b>&gt;&gt;</b> Hematocrit				<b>&gt;&gt;</b>	Normal Abnormal NCS Abnormal CS Not Done
➤Mean Corpuscular Volume (MCV)				<b>&gt;&gt;</b>	Normal Abnormal NCS Abnormal CS Not Done
➤Mean Corpuscular Hemoglobin (MCH)				<b>&gt;&gt;</b>	Normal Abnormal NCS Abnormal CS Not Done
➤ Mean Corpuscular Hemoglobin Concentration (MCHC)				<b>&gt;&gt;</b>	Normal Abnormal NCS Abnormal CS Not Done
<b>&gt;&gt;</b> White Blood Cells (WBC)				<b>&gt;&gt;</b>	Normal Abnormal NCS Abnormal CS Not Done
<b>≫</b> Neutrophils				**	Normal Abnormal NCS Abnormal CS Not Done
<b>≫</b> Eosinophils				<b>&gt;&gt;</b>	Normal Abnormal NCS Abnormal CS Not Done

<b>&gt;&gt;</b> Basophils		<b>&gt;&gt;</b>	Normal Abnormal NCS Abnormal CS Not Done
<b>&gt;&gt;</b> Lymphocytes		<b>3</b>	Normal Abnormal NCS Abnormal CS Not Done
<b>≫</b> Monocytes		<b>&gt;&gt;</b>	Normal Abnormal NCS Abnormal CS Not Done
<b>≫</b> Platelet count		<b>3</b>	Normal Abnormal NCS Abnormal CS Not Done
Comment			



Trial: **OP109219\_JP-2266-101-FIH\_A (v.2.0)** 

Event: **P1 D1 [P1D1]** 

Page: Coagulation(Pre Dose [LT]

COAGULATION (PRE DOSE)					
Time Point	Pre-dose				
<b>≫</b> Sample Collected?	C Yes C No				
▶If No,Specify					
Date of Collection (dd-mmm-yyyy)					
▶Time of Collection (hh:mm)					
Parameter Name	Result	Unit	LLN	ULN	Assessment
▶Prothrombin time (PT)					Normal Abnormal NCS Abnormal CS Not Done
▶International normalized ratio (INR)					Normal Abnormal NCS Abnormal CS Not Done
<b>≫</b> aPTT(ratio)					Normal Abnormal NCS Abnormal CS Not Done



Trial: **OP109219\_JP-2266-101-FIH\_A (v.2.0)** 

Event: **P1 D1 [P1D1]** 

Page: Biochemistry(PreDose [LC]

BIOCHEMISTRY (PRE DOSE)						
Time Point Pre-dose						
➤ Sample Collected?						
▶If No,Specify						
▶ Fasting State	Unknown					
<b>▶</b> Date of Collection						
▶Time of Collection						
Parameter Name	Symbol	Results	Units	LLN	ULN	Assessment
Fasting Glucose		<b>&gt;&gt;</b>				Normal Abnormal NCS Abnormal CS Not Done
Creatinine		<b>»</b>			:	Normal Abnormal NCS Abnormal CS Not Done
Urea		<b>3</b>				Normal Abnormal NCS Abnormal CS Not Done
Blood Urea Nitrogen (BUN)		»				Normal Abnormal NCS Abnormal CS Not Done
Creatinine clearance		<b>3</b>				Normal Abnormal NCS Abnormal CS Not Done
Alanine Serine Transferase (AST)		<b>3</b>				Normal Abnormal NCS Abnormal CS Not Done
Alanine Leucine Transferase (ALT)		<b>3)</b>				Normal Abnormal NCS Abnormal CS Not Done
Gamma Glutamyl Transferase (GGT)	< <= > >=	<b>»</b>				Normal Abnormal NCS Abnormal CS Not Done

Alkaline Phosphatases (ALP)		<b>3</b> >		<b>3</b>	Normal Abnormal NCS Abnormal CS Not Done
Lactate Dehydrogenase (LDH)		<b>3</b> >		21	Normal Abnormal NCS Abnormal CS Not Done
Creatine Phosphokinase (CPK)		<b>35</b>		) i	Normal Abnormal NCS Abnormal CS Not Done
Lipase		<b>35</b>			Normal Abnormal NCS Abnormal CS Not Done
Total Bilirubin	< <= >> >=	<b>3</b> >		) i	Normal Abnormal NCS Abnormal CS Not Done
Conjugated Bilirubin	< <= >> =	<b>&gt;&gt;</b>		) i	Normal Abnormal NCS Abnormal CS Not Done
Unconjugated Bilirubin	< <= >> =	<b>3</b> >		20	Normal Abnormal NCS Abnormal CS Not Done
Total Cholesterol		<b>»</b>		2)	Normal Abnormal NCS Abnormal CS Not Done
Triglycerides	< <= >> >=	<b>»</b>		2)	Normal Abnormal NCS Abnormal CS Not Done
Sodium		3>		<b>3</b> 1	Normal Abnormal NCS Abnormal CS Not Done
Potassium		»		<b>3</b> 4	Normal Abnormal NCS Abnormal CS Not Done
Chloride		<b>»</b>		31	Normal Abnormal NCS Abnormal CS Not Done

Calcium	<b>»</b>		•	Normal Abnormal NCS Abnormal CS Not Done
Phosphorus	3>		<b>&gt;&gt;</b>	Normal Abnormal NCS Abnormal CS Not Done
Total Protein	<b>3</b> >		<b>&gt;&gt;</b>	Normal Abnormal NCS Abnormal CS Not Done
Comment				



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Trial: **OP109219\_JP-2266-101-FIH\_A (v.2.0)** 

Event: **P1 D1 [P1D1]** 

Page: Urinalysis(Pre Dose) [UR]

URINALYSIS (F	PRE DOSE	<b>()</b>			
Time Point	Pre-dose				
Sample Collected?	C Yes C	No			
► If No, Specify					
▶ Date of Collection					
▶Time of Collection					
Parameter Name	Symbol	Results	LLN	ULN	Assessment
Glucose		Positive Negative		1	Normal Abnormal NCS Abnormal CS Not Done
Proteins		<ul><li>Positive</li><li>Negative</li></ul>		1	Normal Abnormal NCS Abnormal CS Not Done
Ketones		Positive Negative		1	Normal Abnormal NCS Abnormal CS Not Done
Occult Blood		<ul><li>Positive</li><li>Negative</li></ul>		1	Normal Abnormal NCS Abnormal CS Not Done
Bilirubin		Positive Negative		1	Normal Abnormal NCS Abnormal CS Not Done
Urobilinogen		Positive Negative		1	Normal Abnormal NCS Abnormal CS Not Done
рН		»		,	Normal Abnormal NCS Abnormal CS Not Done
Nitrites		Positive Negative		1	Normal Abnormal NCS Abnormal CS Not Done
Specific Gravity	< <= >> >=	20		1	Normal Abnormal NCS Abnormal CS Not Done

White Blood Cells	Positive Negative	Normal Abnormal NCS Abnormal CS Not Done
Comments		

MICROSCOPIC RES	ULTS				
Parameter Name	Results	Units	LLN	ULN	Assessment
<b>≫</b> Micr: Glucose					Normal Abnormal NCS Abnormal CS Not Done
<b>≫</b> Micr: Protein					Normal Abnormal NCS Abnormal CS Not Done
<b>≫</b> Micr: Red Blood Cells					Normal Abnormal NCS Abnormal CS Not Done
■Micr: White Blood Cells					Normal Abnormal NCS Abnormal CS Not Done
<b>≫</b> Micr: Crystals	Positive Negative				Normal Abnormal NCS Abnormal CS Not Done
<b>≫</b> Epithelial Cells	Positive Negative				Normal Abnormal NCS Abnormal CS Not Done
<b>≫</b> Epithelial Renal Cells	Positive Negative				Normal Abnormal NCS Abnormal CS Not Done
<b>≫</b> Bacteria	Positive Negative				Normal Abnormal NCS Abnormal CS Not Done
<b>≫</b> Casts	Positive Negative				Normal Abnormal NCS Abnormal CS Not Done

Comments			



Trial: **OP109219\_JP-2266-101-FIH\_A (v.2.0)** 

Event: P1 D1 [P1D1]

Page: Urine electro(Predos [URE]

URINE ELECTR	OLYTES TEST (PR	RE DOSE)			
Time Point			Pre-dose		
Sample Collected?			C Yes C No		
►If No,Specify				-	
<b>&gt;&gt;</b> Date of Collection					
<b>≫</b> Time of Collection					
Parameter Name	Results	Units	LLN	ULN	Assessment
<b>≫</b> Calcium					Normal Abnormal NCS Abnormal CS Not Done
<b>&gt;&gt;</b> Phosphorus					Normal Abnormal NCS Abnormal CS Not Done
<b>≫</b> Sodium					Normal Abnormal NCS Abnormal CS Not Done
<b>≫</b> Potassium					Normal Abnormal NCS Abnormal CS Not Done
<b>▶</b> Chloride					Normal Abnormal NCS Abnormal CS Not Done
Comments					



Event: P1 D1 [P1D1]

Page: Vital Signs(Predose) [VS1]

VITAL SIGNS (PI	RE DOSE)					
Time Point	Pre-dose					
<b>≫</b> Vitals collected?	C Yes C No					
▶If No,Specify						
<b>▶</b> Date of measuremen	its					
Blood Pressure and	l Heart Rate					
After	Position	Actual Time Position (hh:mm)	Actual Time Measurement (hh:mm)	Systolic (mmHg)	Diastolic (mmHg)	Heart rate (bpm)
10 Mins		<b>3</b>	<b>&gt;&gt;</b>	<b>&gt;&gt;</b>	<b>&gt;&gt;</b>	<b>&gt;&gt;</b>
2 Mins		<b>3)</b>	<b>&gt;&gt;</b>	<b>&gt;&gt;</b>	<b>≫</b>	<b>3</b>
<b>≫</b> Result	C Normal C Abnormal					
Clinically Significant	C Yes C No					
Abnormal Finding/ Relevant Comments						



Trial: **OP109219\_JP-2266-101-FIH\_A (v.2.0)** 

Event: **P1 D1 [P1D1]** 

Page: Blood sampling EG [PKEG]

BLOOD SA	AMPLE FOR EXPLOR	RATORY GENOMIC	
<i>Time Point</i> Pre Dose	Sample Collected?  → Yes No	Actual Date & Actual Time	
Comment			



Trial: **OP109219\_JP-2266-101-FIH\_A (v.2.0)** 

Event: **P1 D1 [P1D1]** 

Page: Drug Administration [EX]

DRUG ADMINISTRATION	
<b>▶</b> Date of Study Drug Administration	
⇒Time of Study Drug Administration	
→ Administered Dose (mg)	
➤ Has the drug administration been performed according to the protocol?	C Yes C No
▶If No, please comment	



Event: **P1 D1 [P1D1]** 

Page: Vital Signs (T1h) [VS]

VITAL SIGNS (T	1 HOUR)					
Time Point	T1h					
➤ Vitals collected?	C Yes C No					
▶If No,Specify						
<b>▶</b> Date of measuremen	nts					
Blood Pressure and	d Heart Rate					
After	Position	Actual Time Position (hh:mm)	Actual Time Measurement (hh:mm)	t Systolic (mmHg)	Diastolic (mmHg)	Heart rate (bpm)
10 Mins			<b>&gt;</b>	<b>&gt;</b>	<b>&gt;&gt;</b>	<b>&gt;&gt;</b>
2 Mins		20-	<b>&gt;&gt;</b>	<b>»</b>	33)	<b>&gt;&gt;</b>
<b>≫</b> Result	C Normal C Abnormal					
Clinically Significant	C Yes C No					
Abnormal Finding/ Relevant Comments						



Event: **P1 D1 [P1D1]** 

Page: Vital Signs (T2h) [VS2]

VITAL SIGNS (T2	2 HOUR)					
Time Point	T2h					
➤ Vitals collected?	C Yes C No					
▶If No,Specify						
<b>≫</b> Date of measuremen	nts					
Blood Pressure and	d Heart Rate					
After	Position	Actual Time Position (hh:mm)	Actual Time Measuremen (hh:mm)	t Systolic (mmHg)	Diastolic (mmHg)	Heart (bpm
10 Mins			<b>*</b>	<b>&gt;&gt;</b>	<b>&gt;</b>	<b>&gt;&gt;</b>
2 Mins		<b>3</b>	•	2>	<b>&gt;&gt;</b>	<b>&gt;&gt;</b>
<b>≫</b> Result	C Normal C Abnormal					
Clinically Significant	C Yes C No					
Abnormal Finding/						
Relevant Comments						



Trial: **OP109219\_JP-2266-101-FIH\_A (v.2.0)** 

Event: **P1 D1 [P1D1]** 

Page: 12 Lead ECG (T2h) [EG]

12 LEAD ECG (T2 I	HOUR)
Time Point	T2h
<b>▶</b> ECG Performed?	C Yes C No
▶If No,Specify	
<b>▶</b> Date of ECG	
<b>≫</b> Time of ECG	
→ Heart Rate (Beats/min)	
▶PR (ms)	
<b>&gt;</b> QRS (ms)	
<b>&gt;</b> QT (ms)	
<b>&gt;</b> QTcF (ms)	
Conclusion Result	Normal Abnormal
Clinically Significant?	C Yes C No
Abnormality Finding / Relevant Comment	



Event: **P1 D1 [P1D1]** 

Page: Vital Signs (T4h) [VS3]

<b>▶</b> If No,Specify	T4h  Yes No					
<ul><li>➤Vitals collected?</li><li>➤If No,Specify</li><li>➤Date of measurements</li></ul>						
Date of measurements	3					
Blood Pressure and I	Heart Rate					
After	Position	Actual Time Position (hh:mm)	Actual Time Measurement (hh:mm)	t Systolic (mmHg)	Diastolic (mmHg)	Hea (bp
10 Mins		<b>&gt;</b>	<b>→</b>	<b>&gt;</b>	<b>&gt;&gt;</b>	<b>3)</b>
2 Mins		<b>3</b>	<b>3</b> +	<b>&gt;&gt;</b>	<b>&gt;&gt;</b>	<b>&gt;&gt;</b>
Result	Normal Abnormal					
Clinically Significant	C Yes C No					
Abnormal Finding/ Relevant Comments						



Trial: **OP109219\_JP-2266-101-FIH\_A (v.2.0)** 

Event: **P1 D1 [P1D1]** 

Page: 12 Lead ECG (T4h) [EG1]

12 LEAD ECG (T4 I	HOUR)
Time Point	T4h
<b>▶</b> ECG Performed?	C Yes C No
▶If No,Specify	
<b>▶</b> Date of ECG	
<b>≫</b> Time of ECG	
→ Heart Rate (Beats/min)	
▶PR (ms)	
<b>&gt;</b> QRS (ms)	
<b>&gt;</b> QT (ms)	
<b>→</b> QTcF (ms)	
Conclusion Result	Normal Abnormal
Clinically Significant?	C Yes C No
Abnormality Finding / Relevant Comment	



Event: **P1 D1 [P1D1]** 

Page: Blood Sample for PK [PK]

BLOOD S	AMPLE FOR PK						
Time Point	Sample Collected?	Schedule Date & Time	Actual Date & Ac	tual Time	Time windov (min)	Meal restriction respected?	
Pre Dose	Yes C No		34	33-	-60 Mins	Yes No Unknown	
T0h15min	Yes No		20-	<b>33</b>	+/- 1 Min		
T0h30min	➤ C Yes C No		20-	<b>3</b> >	+/- 1 Min		
T0h45min	Yes No		20-	<b>3</b>	+/- 1 Min		
T1h	Yes No		20-	200	+/- 5Mins		
T1h30min	Yes No		20-	<b>33</b>	+/- 5Mins		
T2h	➤ C Yes C No		20-	<b>3</b> >	+/- 5 Mins		
T2h30min	Yes No		20-	<b>33</b>	+/- 5 Mins		
T3h	Yes No		20-	<b>33)</b>	+/- 5 Mins		
T3h30 min	Yes No		20-	20	+/- 5 Mins		
T4h	Yes No		<b>3</b> >	20-	+/- 5 Mins	Yes No Unknown	
T6h	Yes No		20-	<b>20)</b>	+/- 5 Mins		
T8h	Yes No		20-	20-	+/- 5 Mins		
T10h	Yes No		20-	20-	+/- 5 Min		
T12h	Yes No		<b>3</b> >	20-	+/- 5 Mins	Yes No Unknown	
Comment							



Trial: **OP109219\_JP-2266-101-FIH\_A (v.2.0)** 

Event: P1 D1 [P1D1]

Page: Blood Sample for PD [PK1]

## **BLOOD SAMPLE FOR PD** Time window Time Point Sample Collected? Schedule Date & Time Actual Date & Actual Time (min) C Yes C No Pre Dose - 60 Mins T0h30min C Yes C No +/- 1 Min T1h C Yes C No +/- 5 Mins C Yes C No T1h30min +/- 5 Mins C Yes C No T2h +/- 5 Mins C Yes C No T3h +/- 5 Mins T4h C Yes C No +/- 5 Mins C Yes C No T6h +/- 5 Mins C Yes C No T8h +/- 5 Mins Yes No T12h +/- 5 Mins Comment



Event: P1 D1 [P1D1]

Page: Urine Sample PK & PD [URPK]

URINE SAMPLE FOR PK &	PD					
Time Interval	Sample Collected?	Start Date	Start Tim	e End Date	End Time	Urine vol(g) Urine vol(ml)
( D-1 pre-dose to D1 T0h) only PD	Yes No	<b>&gt;&gt;</b>	<b>&gt;&gt;</b>	200	>>	<b>&gt;&gt;</b>
Pre Dose (Only PK)	Yes No	<b>3</b> >	<b>»</b>			<b>&gt;&gt;</b>
]T0H-T4H]	Yes No	<b>&gt;&gt;</b>	<b>3</b>	30-	<b>3</b>	<b>3</b> >
]T4H-T8H]	Yes No	200	<b>»</b>	<b>&gt;&gt;</b>	<b>3</b>	<b>3</b>
]T8H-T12H]	Yes No	<b>3</b> >	<b>»</b>	<b>&gt;</b>	<b>&gt;&gt;</b>	<b>&gt;&gt;</b>
Comment						



OP109219\_JP-2266-101-FIH\_A (v.2.0) P1 D2 Event:

P1 D2 [P1D2] Page: Visit Date [SV]

VISIT DATE	
<b>≫</b> Date of Visit	



Trial: **OP109219\_JP-2266-101-FIH\_A (v.2.0)** 

Event: **P1 D2 [P1D2]** 

Page: Hematology (T24h) [LH]

HEMATOLOGY (T24 HOUR)				
Time Point T24h				
Sample Collected? Yes No	1			
If No,Specify				
Date of Collection  → Time of Collection				
Time of Collection				
Parameter Name	Result	Unit	L	LN
▶Red Blood Cells (RBC)				
<b>≫</b> Hemoglobin				
<b>≫</b> Hematocrit				
<b>≫</b> Mean Corpuscular Volume (MCV)				
<b>≫</b> Mean Corpuscular Hemoglobin (MCH)				
▶Mean Corpuscular Hemoglobin Concentration	on (MCHC)			
➤ White Blood Cells (WBC)				
<b>≫</b> Neutrophils				
<b>≫</b> Eosinophils				

<b>&gt;&gt;</b> Basophils			Normal Abnormal NCS Abnormal CS Not Done
<b>&gt;&gt;</b> Lymphocytes		<b>3</b>	Normal Abnormal NCS Abnormal CS Not Done
<b>≫</b> Monocytes		<b>3</b>	Normal Abnormal NCS Abnormal CS Not Done
<b>≫</b> Platelet count		<b>&gt;&gt;</b>	Normal Abnormal NCS Abnormal CS Not Done
Comment			



Trial: **OP109219\_JP-2266-101-FIH\_A (v.2.0)** 

Event: **P1 D2 [P1D2]** 

Page: Coagulation (T24h) [LT]

T24h				
C Yes C No				
Result	Unit	LLN	ULN	Assessment
				Normal Abnormal NCS Abnormal CS Not Done
				Normal Abnormal NCS Abnormal CS Not Done
				Normal Abnormal NCS Abnormal CS Not Done
	Result	Result Unit	Result Unit LLN	Result Unit LLN ULN



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Trial: OP109219\_JP-2266-101-FIH\_A (v.2.0)

Event: **P1 D2 [P1D2]** 

Page: Biochemistry (T24h) [LC]

BIOCHEMISTRY	(T24h)						
Time Point	Γ24h						
<b>≫</b> Sample Collected?	Yes 🦰 No						
▶If No,Specify							
▶ Fasting State	Yes O No O	Unknown					
<b>▶</b> Date of Collection							
<b>▶</b> Time of Collection							
Parameter Name		Symbol	Results	Units	LLN	ULN	Assessment
Fasting Glucose			36				Normal Abnormal NCS Abnormal CS Not Done
Creatinine			»			<b>&gt;&gt;</b>	Normal Abnormal NCS Abnormal CS Not Done
Urea			<b>»</b>			<b>3</b>	Normal Abnormal NCS Abnormal CS Not Done
Blood Urea Nitrogen (E	BUN)		3)			<b>3</b>	Normal Abnormal NCS Abnormal CS Not Done
Creatinine clearance			3>			<b>&gt;&gt;</b>	Normal Abnormal NCS Abnormal CS Not Done
Alanine Serine Transfe	rase (AST)		33)			<b>&gt;&gt;</b>	Normal Abnormal NCS Abnormal CS Not Done
Alanine Leucine Transi	ferase (ALT)		<b>»</b>			<b>3</b>	Normal Abnormal NCS Abnormal CS Not Done
Gamma Glutamyl Trar	nsferase (GGT)	< <= > >=	»			<b>&gt;&gt;</b>	Normal Abnormal NCS Abnormal CS Not Done

Alkaline Phosphatases (ALP)		<b>3</b> >		<b>3</b>	Normal Abnormal NCS Abnormal CS Not Done
Lactate Dehydrogenase (LDH)		<b>3</b> >		21	Normal Abnormal NCS Abnormal CS Not Done
Creatine Phosphokinase (CPK)		<b>35</b>		) i	Normal Abnormal NCS Abnormal CS Not Done
Lipase		<b>3</b> >		) i	Normal Abnormal NCS Abnormal CS Not Done
Total Bilirubin	< <= >> =	<b>3</b> >		) i	Normal Abnormal NCS Abnormal CS Not Done
Conjugated Bilirubin	< <= >> =	<b>»</b>		21	Normal Abnormal NCS Abnormal CS Not Done
Unconjugated Bilirubin	< <= >> =	<b>3</b> >		21	Normal Abnormal NCS Abnormal CS Not Done
Total Cholesterol		<b>»</b>		<b>3</b> 1	Normal Abnormal NCS Abnormal CS Not Done
Triglycerides	< <= >> >=	<b>3</b> >		<b>3</b> 1	Normal Abnormal NCS Abnormal CS Not Done
Sodium		3>		<b>3</b> 1	Normal Abnormal NCS Abnormal CS Not Done
Potassium		» .		<b>3</b> 4	Normal Abnormal NCS Abnormal CS Not Done
Chloride		<b>»</b>		31	Normal Abnormal NCS Abnormal CS Not Done

Calcium	36		•	Normal Abnormal NCS Abnormal CS Not Done
Phosphorus	<b>3</b> >		<b>&gt;&gt;</b>	Normal Abnormal NCS Abnormal CS Not Done
Total Protein	<b>3</b> >		<b>&gt;&gt;</b>	Normal Abnormal NCS Abnormal CS Not Done
Comment				



Trial: **OP109219\_JP-2266-101-FIH\_A (v.2.0)** 

Event: P1 D2 [P1D2]

Page: Urinalysis (T24h) [UR]

URINALYSIS (T	24h)				
Time Point	T24h				
➤ Sample Collected?	C Yes C	) No			
► If No, Specify					
▶ Date of Collection					
➤ Time of Collection					
Parameter Name	Symbol	Results	LLN	ULN	Assessment
Glucose		<ul><li>Positive</li><li>Negative</li></ul>			Normal Abnormal NCS Abnormal CS Not Done
Proteins		<ul><li>Positive</li><li>Negative</li></ul>		•	Normal Abnormal NCS Abnormal CS Not Done
Ketones		<ul><li>Positive</li><li>Negative</li></ul>		•	Normal Abnormal NCS Abnormal CS Not Done
Occult Blood		<ul><li>Positive</li><li>Negative</li></ul>		,	Normal Abnormal NCS Abnormal CS Not Done
Bilirubin		<ul><li>Positive</li><li>Negative</li></ul>		•	Normal Abnormal NCS Abnormal CS Not Done
Urobilinogen		Positive Negative			Normal Abnormal NCS Abnormal CS Not Done
рН		<b>3</b> >			Normal Abnormal NCS Abnormal CS Not Done
Nitrites		<ul><li>Positive</li><li>Negative</li></ul>		•	Normal Abnormal NCS Abnormal CS Not Done
Specific Gravity	< <= >> >=	<b>3</b> >			Normal Abnormal NCS Abnormal CS Not Done

White Blood Cells	Positive Negative	Normal Abnormal NCS Abnormal CS Not Done
Comments		

MICROSCOPIC RES	ULTS				
Parameter Name	Results	Units	LLN	ULN	Assessment
<b>≫</b> Micr: Glucose					Normal Abnormal NCS Abnormal CS Not Done
<b>≫</b> Micr: Protein					Normal Abnormal NCS Abnormal CS Not Done
<b>≫</b> Micr: Red Blood Cells					Normal Abnormal NCS Abnormal CS Not Done
<b>≫</b> Micr: White Blood Cells					Normal Abnormal NCS Abnormal CS Not Done
<b>≫</b> Micr: Crystals	<ul><li>Positive</li><li>Negative</li></ul>				Normal Abnormal NCS Abnormal CS Not Done
<b>≫</b> Epithelial Cells	Positive Negative				Normal Abnormal NCS Abnormal CS Not Done
<b>≫</b> Epithelial Renal Cells	Positive Negative				Normal Abnormal NCS Abnormal CS Not Done
<b>≫</b> Bacteria	Positive Negative				Normal Abnormal NCS Abnormal CS Not Done
<b>▶</b> Casts	C Positive				Normal Abnormal NCS Abnormal CS Not Done

Comments			



Trial: **OP109219\_JP-2266-101-FIH\_A (v.2.0)** 

Event: **P1 D2 [P1D2]** 

Page: Urine electrol(T24h) [URE]

URINE ELECTR	OLYTES TEST (T2	24h)			
Time Point			T24h		
<b>≫</b> Sample Collected?			C Yes C No		
► If No, Specify				_	
<b>▶</b> Date of Collection					
⇒Time of Collection					
Parameter Name	Results	Units	LLN	ULN	Assessment
<b>≫</b> Calcium					Normal Abnormal NCS Abnormal CS Not Done
<b>≫</b> Phosphorus					Normal Abnormal NCS Abnormal CS Not Done
<b>≫</b> Sodium					Normal Abnormal NCS Abnormal CS Not Done
<b>≫</b> Potassium					Normal Abnormal NCS Abnormal CS Not Done
<b>▶</b> Chloride					Normal Abnormal NCS Abnormal CS Not Done
Comments					



Event: P1 D2 [P1D2]

Page: Vital Signs (T24h) [VS]

VITAL SIGNS (T2	24 HOUR)					
Time Point	T24h					
▶Vitals collected?	C Yes C No					
▶If No,Specify						
<b>▶</b> Date of measuremen	ts					
Blood Pressure and	l Heart Rate					
After	Position	Actual Time Position (hh:mm)	Actual Time Measuremen (hh:mm)	t Systolic (mmHg)	Diastolic (mmHg)	Hear (bpr
10 Mins			<b>*</b>	<b>&gt;&gt;</b>	»	<b>&gt;&gt;</b>
2 Mins		<b>3</b> >	•	<b>&gt;&gt;</b>	>>	<b>&gt;&gt;</b>
<b>≫</b> Result	C Normal C Abnormal					
Clinically Significant	C Yes C No					
Abnormal Finding/						



Trial: **OP109219\_JP-2266-101-FIH\_A (v.2.0)** 

Event: **P1 D2 [P1D2]** 

Page: 12 Lead ECG (T24h) [EG]

12 LEAD ECG (T24	HOUR)
Time Point	T24h
<b>≫</b> ECG Performed?	C Yes C No
▶If No,Specify	
<b>▶</b> Date of ECG	
<b>≫</b> Time of ECG	
⇒ Heart Rate (Beats/min)	
⇒PR (ms)	
<b>⇒</b> QRS (ms)	
<b>≫</b> QT (ms)	
<b>⇒</b> QTcF (ms)	
➤ Conclusion Result	Normal Abnormal
Clinically Significant?	C Yes C No
Abnormality Finding / Relevant Comment	



Trial: **OP109219\_JP-2266-101-FIH\_A (v.2.0)** 

Event: **P1 D2 [P1D2]**Page: **PE (T36h) [PE]** 

PHYSICAL EXAMINATION (T36h)	
Time Point	T36h
<b>▶</b> Did the Physical Examination performed?	C Yes C No
If No,specify	
Date Performed	
→Time performed	
<b>≫</b> Results	C Normal C Abnormal
→ Abnormal Physical Finding	
➤ Clinically Significant?	○ Yes ○ No



Event: P1 D2 [P1D2]

Page: Blood Sample for PK [PK]

BLOOD SAMPLE FOR PK		
Time Point Sample Collected?	Schedule Date & Time Actual Date & Actual Time	Time window (min) Meal restriction respected?
T24h " 🦳 Yes 🦳 No	3b 3b	+/- 15 Mins >> C Yes C No C Unknown
T36h ➤ C Yes C No	35 D	+/- 15 Mins » C Yes C No C Unknown
Comment		



Trial: **OP109219\_JP-2266-101-FIH\_A (v.2.0)** 

Event: P1 D2 [P1D2]

Page: Blood Sample for PD [PD]

BLOOD SA	AMPLE FOR PD			
Time Point	Sample Collected?  → Yes No	Schedule Date & Time	Actual Date & Actual Time	Time window (min) +/- 15 Mins
Comment				



Trial: OP109219\_JP-2266-101-FIH\_A (v.2.0)

Event: **P1 D2 [P1D2]** 

Page: Urine Sample PK & PD [URPKPD]

URINE SAMPLE FOR PK & PD						
Time Interval Sample Collected?  JT12H-T24H] ➤ ↑ Yes ↑ No	Start Date	Start Time	End Date	End Time	Urine vol(g) Urine vol(ml	)
]T24H-T48H] <b>→</b> 🦳 Yes 🦳 No 🙀	•	<b>&gt;&gt;</b>	<b>&gt;&gt;</b>	<b>&gt;</b>		
Comment						



OP109219\_JP-2266-101-FIH\_A (v.2.0) P1 D3 Event:

P1 D3 [P1\_D3] Page: Visit Date [SV]

VISIT DATE	<b></b>
<b>▶</b> Date of Visit	



Event: P1 D3 [P1\_D3]

Page: Vital Signs (T48h) [VS]

VITAL SIGNS (T4	18 HOUR)					
Time Point	T48h					
▶Vitals collected?	C Yes C No					
▶If No,Specify						
▶Date of measuremen	ts					
Blood Pressure and	l Heart Rate					
After	Position	Actual Time Position (hh:mm)	Actual Time Measurement (hh:mm)	Systolic (mmHg)	Diastolic (mmHg)	Heart rate (bpm)
10 Mins		<b>&gt;&gt;</b>	<b>*</b>	<b>&gt;&gt;</b>	<b>&gt;&gt;</b>	<b>&gt;&gt;</b>
2 Mins		<b>3</b>	<b>&gt;</b>	<b>3</b>	<b>»</b>	<b>&gt;&gt;</b>
<b>≫</b> Result	C Normal C Abnormal					
Clinically Significant	C Yes C No					
Abnormal Finding/ Relevant Comments						



Event: P1 D3 [P1\_D3]

Page: Blood Sample for PK [PK]

BLOOD SAMPLE FOR PK		
Time Point Sample Collected?	Schedule Date & Time	Time window (min)  Meal restriction respected?
T48h → C Yes C No	3b 3b	+/- 15 Mins >> C Yes C No C Unknown
Comment		



Trial: **OP109219\_JP-2266-101-FIH\_A (v.2.0)** 

Event: P1 D3 [P1\_D3]

Page: Blood Sample for PD [PD]

BLOOD SA	AMPLE FOR PD		
Time Point	Sample Collected?  Yes No	Schedule Date & Time	Time window (min) +/- 15 Mins
Comment			



Trial: OP109219\_JP-2266-101-FIH\_A (v.2.0)

Event: P1 D3 [P1\_D3]

Page: Urine Sample PK & PD [URPKPD]

URINE SAMPLE FOR PK & PD		
Time Interval     Sample Collected?     Start Date       ]T48H-T72H]     ➤ ☐ Yes ☐ No     ➤	Start Time End Date	End Time Urine vol(g) Urine vol(ml)
Comment		



P1 D4 Trial: OP109219\_JP-2266-101-FIH\_A (v.2.0)

Event: P1 D4 [P1\_D4]
Page: Visit Date [SV]

VISIT DATI	Ε
<b>&gt;&gt;</b> Date of Visit	



Event: P1 D4 [P1\_D4]

Page: Vital Signs (T72h) [VS]

VITAL SIGNS (T	72 HOUR)					
Time Point	T72h					
▶Vitals collected?	C Yes C No					
▶If No,Specify						
<b>▶</b> Date of measuremen	its					
Blood Pressure and	l Heart Rate					
After	Position	Actual Time Position (hh:mm)	Actual Time Measuremen (hh:mm)	t Systolic (mmHg)	Diastolic (mmHg)	Heart rate (bpm)
10 Mins		<b>&gt;&gt;</b>	<b>&gt;&gt;</b>	<b>&gt;&gt;</b>	<b>&gt;&gt;</b>	<b>3</b>
2 Mins		<b>3</b>	<b>3</b>	<b>&gt;&gt;</b>	<b>&gt;&gt;</b>	<b>»</b>
<b>≫</b> Result	Normal  Abnormal					
▶Clinically Significant	C Yes C No					
Abnormal Finding/						
Relevant Comments						



Event: P1 D4 [P1\_D4]

Page: Blood Sample for PK [PK]

BLOOD SAMPLE FOR PK		
Time Point Sample Collected?	Schedule Date & Time Actual Date & Actual Time	Time window (min) Meal restriction respected?
T72h 🕨 🖰 Yes 🦰 No	35 35	+/- 15 Mins >> C Yes C No C Unknown
Comment		



Trial: **OP109219\_JP-2266-101-FIH\_A (v.2.0)** 

Event: P1 D4 [P1\_D4]

Page: Blood Sample for PD [PD]

BLOOD SA	AMPLE FOR PD		
Time Point	Sample Collected?	Schedule Date & Time	Time window (min)
T72h	➤ C Yes C No	<b>3</b>	+/- 15 Mins
Comment			



Event: P1 D4 [P1\_D4]

Page: Urine Sample PD [URPKPD]

URINE SAMPLE FOR PD		
Time Interval     Sample Collected?     Start Date       ]T72H-T96H]     ➤ ☐ Yes ☐ No     ➤	Start Time End Date	End Time Urine vol(g) Urine vol(ml)
Comment		



OP109219\_JP-2266-101-FIH\_A (v.2.0) P1 D5 Event:

P1 D5 [P1D5] Page: Visit Date [SV]

VISIT DATE	<b>=</b>
<b>≫</b> Date of Visit	



Trial: **OP109219\_JP-2266-101-FIH\_A (v.2.0)** 

Event: **P1 D5 [P1D5]**Page: **PE (T96h) [PE]** 

PHYSICAL EXAMINATION (T96h)	
Time Point	T96h
<b>▶</b> Did the Physical Examination performed?	C Yes C No
▶If No,specify	
Date Performed	
➤Time performed	
<b>&gt;</b> Results	C Normal C Abnormal
<b>▶</b> Abnormal Physical Finding	
➤ Clinically Significant?	○ Yes ○ No



Trial: **OP109219\_JP-2266-101-FIH\_A (v.2.0)** 

Event: **P1 D5 [P1D5]** 

Page: Hematology (T96h) [LH]

HEMATOLOGY (T96 HOUR)				
ne Point T96h				
Sample Collected?	ſ			
If No,Specify				
Date of Collection				
Time of Collection				
Parameter Name	Result	Uni	it	it LLN
Red Blood Cells (RBC)				
·Hemoglobin			]	
·Hematocrit				
Mean Corpuscular Volume (MCV)				
Mean Corpuscular Hemoglobin (MCH)				
Mean Corpuscular Hemoglobin Concentration	n (MCHC)			
White Blood Cells (WBC)				
Neutrophils				
Eosinophils				

<b>&gt;&gt;</b> Basophils			Normal Abnormal NCS Abnormal CS Not Done
<b>&gt;&gt;</b> Lymphocytes		<b>3</b>	Normal Abnormal NCS Abnormal CS Not Done
<b>≫</b> Monocytes		<b>3</b>	Normal Abnormal NCS Abnormal CS Not Done
<b>≫</b> Platelet count		<b>&gt;&gt;</b>	Normal Abnormal NCS Abnormal CS Not Done
Comment			



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Trial: **OP109219\_JP-2266-101-FIH\_A (v.2.0)** 

Event: **P1 D5 [P1D5]** 

Page: Coagulation (T96h) [LT]

COAGULATION (T96h)						
Time Point	T96h					
<b>▶</b> Sample Collected?	C Yes C No					
▶If No,Specify						
<b>▶</b> Date of Collection (dd-mmm-yyyy)						
▶Time of Collection (hh:mm)						
Parameter Name	Result	Unit	LLN	ULN	4	Assessment
<b>≫</b> Prothrombin time (PT)						Normal Abnormal NC Abnormal CS Not Done
▶International normalized ratio (INR)						Normal Abnormal NC Abnormal CS Not Done
<b>▶</b> aPTT(ratio)					<b>3</b> >	Normal Abnormal NC Abnormal CS Not Done



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Trial: OP109219\_JP-2266-101-FIH\_A (v.2.0)

Event: **P1 D5 [P1D5]** 

Page: Biochemistry (T96h) [LC]

BIOCHEMISTR	Y (T96h)						
Time Point	T96h						
Sample Collected?	C Yes C No						
<b>▶</b> If No,Specify							
▶ Fasting State	C Yes C No	Unknown					
<b>▶</b> Date of Collection							
<b>▶</b> Time of Collection							
Parameter Name		Symbol	Results	Units	LLN	ULN	Assessment
Fasting Glucose			<b>»</b>				Normal Abnormal NCS Abnormal CS Not Done
Creatinine			<b>»</b>			•	Normal Abnormal NCS Abnormal CS Not Done
Urea			<b>3</b> >				Normal Abnormal NCS Abnormal CS Not Done
Blood Urea Nitrogen	(BUN)		20				Normal Abnormal NCS Abnormal CS Not Done
Creatinine clearance			<b>3</b> >				Normal Abnormal NCS Abnormal CS Not Done
Alanine Serine Trans	oferase (AST)		<b>3</b> )				Normal Abnormal NCS Abnormal CS Not Done
Alanine Leucine Trar	nsferase (ALT)		»				Normal Abnormal NCS Abnormal CS Not Done
Gamma Glutamyl Tr	ansferase (GGT)	< <= > >=	<b>30</b>				Normal Abnormal NCS Abnormal CS Not Done

Alkaline Phosphatases (ALP)		<b>»</b>			Normal Abnormal NCS Abnormal CS Not Done
Lactate Dehydrogenase (LDH)		<b>&gt;&gt;</b>			Normal Abnormal NCS Abnormal CS Not Done
Creatine Phosphokinase (CPK)		<b>&gt;&gt;</b>		,	Normal Abnormal NCS Abnormal CS Not Done
Lipase		<b>3</b> >			Normal Abnormal NCS Abnormal CS Not Done
Total Bilirubin	< <= >> >=	<b>&gt;&gt;</b>			Normal Abnormal NCS Abnormal CS Not Done
Conjugated Bilirubin	< <= > >=	<b>&gt;&gt;</b>			Normal Abnormal NCS Abnormal CS Not Done
Unconjugated Bilirubin	< <= > >=	<b>&gt;&gt;</b>			Normal Abnormal NCS Abnormal CS Not Done
Total Cholesterol		<b>&gt;&gt;</b>			Normal Abnormal NCS Abnormal CS Not Done
Triglycerides	< <= >> >=	<b>»</b>			Normal Abnormal NCS Abnormal CS Not Done
Sodium		<b>»</b>		,	Normal Abnormal NCS Abnormal CS Not Done
Potassium		<b>»</b>		,	Normal Abnormal NCS Abnormal CS Not Done
Chloride		<b>&gt;&gt;</b>			Normal Abnormal NCS Abnormal CS Not Done

Calcium	<b>»</b>		•	Normal Abnormal NCS Abnormal CS Not Done
Phosphorus	3>		<b>&gt;&gt;</b>	Normal Abnormal NCS Abnormal CS Not Done
Total Protein	<b>3</b> >		<b>&gt;&gt;</b>	Normal Abnormal NCS Abnormal CS Not Done
Comment				



Trial: **OP109219\_JP-2266-101-FIH\_A (v.2.0)** 

Event: **P1 D5 [P1D5]** 

Page: Urinalysis (T96h) [UR]

URINALYSIS (T	96h)				
Time Point	T96h				
<b>≫</b> Sample Collected?	C Yes C	No			
▶If No,Specify					
<b>▶</b> Date of Collection					
▶Time of Collection					
Parameter Name	Symbol	Results	LLN	ULN	Assessment
Glucose		Positive Negative		21	Normal Abnormal NCS Abnormal CS Not Done
Proteins		<ul><li>Positive</li><li>Negative</li></ul>		391	Normal Abnormal NCS Abnormal CS Not Done
Ketones		Positive Negative		31	Normal Abnormal NCS Abnormal CS Not Done
Occult Blood		Positive Negative		<b>)</b>	Normal Abnormal NCS Abnormal CS Not Done
Bilirubin		Positive Negative		ופ	Normal Abnormal NCS Abnormal CS Not Done
Urobilinogen		Positive Negative		21	Normal Abnormal NCS Abnormal CS Not Done
рН		<b>3</b> >		31	Normal Abnormal NCS Abnormal CS Not Done
Nitrites		<ul><li>Positive</li><li>Negative</li></ul>		ופ	Normal Abnormal NCS Abnormal CS Not Done
Specific Gravity	<	<b>33</b>		21	Normal Abnormal NCS Abnormal CS Not Done

White Blood Cells	➤ Positive Negative	Abnormal NCS Abnormal CS Not Done	
Comments			

MICROSCOPIC RES Parameter Name	Results	Units	LLN	ULN	Assessment
i arameter Name	Results	Omts	LLI	OLIV	Assessment
<b>≫</b> Micr: Glucose					Normal Abnormal NCS Abnormal CS Not Done
<b>≫</b> Micr: Protein					Normal Abnormal NCS Abnormal CS Not Done
<b>≫</b> Micr: Red Blood Cells					Normal Abnormal NCS Abnormal CS Not Done
<b>≫</b> Micr: White Blood Cells					Normal Abnormal NCS Abnormal CS Not Done
	Positive				Normal
<b>≫</b> Micr: Crystals	Negative				Abnormal NCS Abnormal CS Not Done
<b>≫</b> Epithelial Cells	Positive				Normal
	Negative				Abnormal NCS Abnormal CS Not Done
<b>≫</b> Epithelial Renal Cells	Positive				Normal
	Negative				Abnormal NCS Abnormal CS Not Done
<b>≫</b> Bacteria	Positive				Normal
	Negative				Abnormal NCS Abnormal CS Not Done
	Positive				Normal
<b>▶</b> Casts	Negative				Abnormal NCS Abnormal CS Not Done

Comments	
ı	



Trial: **OP109219\_JP-2266-101-FIH\_A (v.2.0)** 

Event: **P1 D5 [P1D5]** 

Page: Urine electrol(T96h) [URE]

J. WITE LELOTINGE	YTES TEST (T	<b>96h)</b>			
Time Point			T96h		
Sample Collected?			C Yes C No		
▶If No,Specify		Γ			
▶ Date of Collection					
▶Time of Collection		Γ			
Parameter Name	Results	Units	LLN	ULN	Assessment
<b>≫</b> Calcium					Normal Abnormal NCS Abnormal CS Not Done
<b>≫</b> Phosphorus					Normal Abnormal NCS Abnormal CS Not Done
<b>≫</b> Sodium					Normal Abnormal NCS Abnormal CS Not Done
<b>▶</b> Potassium					Normal Abnormal NCS Abnormal CS Not Done
<b>&gt;&gt;</b> Chloride					Normal Abnormal NCS Abnormal CS Not Done



Event: P1 D5 [P1D5]

Page: Vital Signs (T96h) [VS]

VITAL SIGNS (TS	96 HOUR)					
Time Point	T96h					
▶Vitals collected?	C Yes C No					
▶If No,Specify		]				
<b>▶</b> Date of measuremen	ıts					
Blood Pressure and	l Heart Rate					
After	Position	Actual Time Position (hh:mm)	Actual Time Measuremen (hh:mm)	t Systolic (mmHg)	Diastolic (mmHg)	Heart rate (bpm)
10 Mins			<b>*</b>	***	»	<b>&gt;&gt;</b>
2 Mins		20	<b>3</b> +	20-	<b>&gt;&gt;</b>	<b>»</b>
<b>≫</b> Result	O Normal O Abnormal					
Clinically Significant	C Yes C No					
Abnormal Finding/ Relevant Comments						



Trial: **OP109219\_JP-2266-101-FIH\_A (v.2.0)** 

Event: **P1 D5 [P1D5]** 

Page: 12 Lead ECG (T96h) [EG]

12 LEAD ECG (T96 HOUR)		
Time Point	T96h	
<b>≫</b> ECG Performed?	C Yes C No	
▶If No,Specify		
<b>▶</b> Date of ECG		
<b>≫</b> Time of ECG		
⇒ Heart Rate (Beats/min)		
⇒PR (ms)		
<b>⇒</b> QRS (ms)		
<b>≫</b> QT (ms)		
<b>⇒</b> QTcF (ms)		
➤ Conclusion Result	Normal Abnormal	
Clinically Significant?	C Yes C No	
Abnormality Finding / Relevant Comment		



P1

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OP109219\_JP-2266-101-FIH\_A (v.2.0)

D10 Event: **P1 D10 [P1D10]** Page: Visit Date [SV]

Trial:

VISIT DATE	<b>.</b>
<b>▶</b> Date of Visit	



Trial: **OP109219\_JP-2266-101-FIH\_A (v.2.0)** 

Event: **P1 D10 [P1D10]** 

Page: Physical Examination [PE]

PHYSICAL EXAMINATION	
<b>▶</b> Did the Physical Examination performed?	C Yes C No
▶If No,specify	
Date Performed	
<b>≫</b> Results	Normal Abnormal
→ Abnormal Physical Finding	
Clinically Significant?	C Yes C No
<b>&gt;</b> Weight	kg



Trial: **OP109219\_JP-2266-101-FIH\_A (v.2.0)** 

Event: P1 D10 [P1D10]
Page: Hematology [LH]

HEMATOLOGY					
➤Sample Collected?					
▶If No,Specify					
<b>▶</b> Date of Collection					
<b>▶</b> Time of Collection					
Parameter Name	Result	Unit	LLN	ULN	Assessment
▶Red Blood Cells (RBC)				<b>&gt;</b>	Normal Abnormal NCS Abnormal CS Not Done
<b>&gt;&gt;</b> Hemoglobin				3>	Normal Abnormal NCS Abnormal CS Not Done
<b>&gt;&gt;</b> Hematocrit				<b>3</b> >	Normal Abnormal NCS Abnormal CS Not Done
➤ Mean Corpuscular Volume (MCV)				<b>&gt;&gt;</b>	Normal Abnormal NCS Abnormal CS Not Done
➤Mean Corpuscular Hemoglobin (MCH)				<b>&gt;&gt;</b>	Normal Abnormal NCS Abnormal CS Not Done
▶Mean Corpuscular Hemoglobin Concentration (MCHC)				<b>&gt;&gt;</b>	Normal Abnormal NCS Abnormal CS Not Done
<b>&gt;&gt;</b> White Blood Cells (WBC)				**	Normal Abnormal NCS Abnormal CS Not Done
<b>▶</b> Neutrophils				<b>&gt;&gt;</b>	Normal Abnormal NCS Abnormal CS Not Done
<b>≫</b> Eosinophils				<b>&gt;&gt;</b>	Normal Abnormal NCS Abnormal CS Not Done

<b>&gt;&gt;</b> Basophils			Normal Abnormal NCS Abnormal CS Not Done
<b>&gt;&gt;</b> Lymphocytes		<b>3</b>	Normal Abnormal NCS Abnormal CS Not Done
<b>≫</b> Monocytes		<b>3</b>	Normal Abnormal NCS Abnormal CS Not Done
<b>≫</b> Platelet count		<b>&gt;&gt;</b>	Normal Abnormal NCS Abnormal CS Not Done
Comment			



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Trial: **OP109219\_JP-2266-101-FIH\_A (v.2.0)** 

Event: P1 D10 [P1D10]
Page: Coagulation [LT]

COACHI ATION					
COAGULATION	N				
➤Sample Collected?	C Yes C No				
▶If No,Specify					
Date of Collection (dd-mmm-yyyy) ☐					
<b>≫</b> Time of Collection (hh:mm)					
Parameter Name	Result	Unit	LLN	ULN	Assessment
▶Prothrombin time (PT)					Normal Abnormal NCS Abnormal CS Not Done
International normalized ratio (INR)					Normal Abnormal NCS Abnormal CS Not Done
<b>≫</b> aPTT(ratio)					Normal Abnormal NCS Abnormal CS Not Done



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Trial: OP109219\_JP-2266-101-FIH\_A (v.2.0)

Event: P1 D10 [P1D10]
Page: Biochemistry [LC]

BIOCHEMISTRY					
➤ Sample Collected?					
▶If No,Specify					
▶ Fasting State	wn				
<b>▶</b> Date of Collection					
<b>▶</b> Time of Collection					
Parameter Name Symb	ool Results	Units	LLN	ULN	Assessment
Fasting Glucose	330				Normal Abnormal NCS Abnormal CS Not Done
Creatinine	<b>3</b>				Normal Abnormal NCS Abnormal CS Not Done
Urea	3>				Normal Abnormal NCS Abnormal CS Not Done
Blood Urea Nitrogen (BUN)	3>				Normal Abnormal NCS Abnormal CS Not Done
Creatinine clearance	<b>33</b>				Normal Abnormal NCS Abnormal CS Not Done
Alanine Serine Transferase (AST)	3>				Normal Abnormal NCS Abnormal CS Not Done
Alanine Leucine Transferase (ALT)	<b>33</b>				Normal Abnormal NCS Abnormal CS Not Done
Gamma Glutamyl Transferase (GGT)	330				Normal Abnormal NCS Abnormal CS Not Done
Alkaline Phosphatases (ALP)	<b>3</b>				Normal Abnormal NCS Abnormal CS Not Done

Lactate Dehydrogenase (LDH)		<b>3</b>		1	Normal Abnormal NCS Abnormal CS Not Done
Creatine Phosphokinase (CPK)		<b>»</b>			Normal Abnormal NCS Abnormal CS Not Done
Lipase		<b>&gt;&gt;</b>			Normal Abnormal NCS Abnormal CS Not Done
Total Bilirubin	< <= >> >=	<b>&gt;&gt;</b>		1	Normal Abnormal NCS Abnormal CS Not Done
Conjugated Bilirubin	< <= >> >=	<b>&gt;&gt;</b>		1	Normal Abnormal NCS Abnormal CS Not Done
Unconjugated Bilirubin	< <= >> >=	<b>»</b>		1	Normal Abnormal NCS Abnormal CS Not Done
Total Cholesterol		<b>»</b>		1	Normal Abnormal NCS Abnormal CS Not Done
Triglycerides	< <= >>=	<b>»</b>			Normal Abnormal NCS Abnormal CS Not Done
Sodium		<b>33</b>		1	Normal Abnormal NCS Abnormal CS Not Done
Potassium		<b>&gt;&gt;</b>			Normal Abnormal NCS Abnormal CS Not Done
Chloride		<b>&gt;&gt;</b>		1	Normal Abnormal NCS Abnormal CS Not Done
Calcium		<b>»</b>			Normal Abnormal NCS Abnormal CS Not Done

Phosphorus	26			Normal Abnormal NCS Abnormal CS Not Done
Total Protein	36		<b>&gt;&gt;</b>	Normal Abnormal NCS Abnormal CS Not Done
Comment				



Trial: **OP109219\_JP-2266-101-FIH\_A (v.2.0)** 

Event: P1 D10 [P1D10]
Page: Urinalysis [UR]

URINALYSIS					
➤ Sample Collected?	C Yes C	No			
▶If No,Specify					
<b>≫</b> Date of Collection					
➡Time of Collection					
Parameter Name	Symbol	Results	LLN	ULN	Assessment
Glucose	1	Positive Negative		<b>&gt;&gt;</b>	Normal Abnormal NCS Abnormal CS Not Done
Proteins	1	Positive Negative		<b>&gt;&gt;</b>	Normal Abnormal NCS Abnormal CS Not Done
Ketones	1	Positive Negative		<b>&gt;&gt;</b>	Normal Abnormal NCS Abnormal CS Not Done
Occult Blood	1	Positive Negative		<b>&gt;&gt;</b>	Normal Abnormal NCS Abnormal CS Not Done
Bilirubin	1	Positive Negative		<b>&gt;&gt;</b>	Normal Abnormal NCS Abnormal CS Not Done
Urobilinogen	1	Positive Negative		<b>3</b> >	Normal Abnormal NCS Abnormal CS Not Done
рН	1	<b>»</b>		<b>&gt;&gt;</b>	Normal Abnormal NCS Abnormal CS Not Done
Nitrites		Positive Negative		<b>3</b>	Normal Abnormal NCS Abnormal CS Not Done
Specific Gravity	<	<b>»</b>		<b>&gt;&gt;</b>	Normal Abnormal NCS Abnormal CS Not Done

White Blood C	Positive  Cells  Negative	Abnormal NCS Abnormal CS Not Done
Comments		

MICROSCOPIC RES	Results	Units	LLN	ULN	Assessment
<b>≫</b> Micr: Glucose					Normal Abnormal NCS Abnormal CS Not Done
<b>≫</b> Micr: Protein					Normal Abnormal NCS Abnormal CS Not Done
➤Micr: Red Blood Cells					Normal Abnormal NCS Abnormal CS Not Done
<b>≫</b> Micr: White Blood Cells					Normal Abnormal NCS Abnormal CS Not Done
<b>≫</b> Micr: Crystals	<ul><li>Positive</li><li>Negative</li></ul>				Normal Abnormal NCS Abnormal CS Not Done
<b>≫</b> Epithelial Cells	<ul><li>Positive</li><li>Negative</li></ul>				Normal Abnormal NCS Abnormal CS Not Done
<b>≫</b> Epithelial Renal Cells	Positive Negative				Normal Abnormal NCS Abnormal CS Not Done
<b>≫</b> Bacteria	Positive Negative				Normal Abnormal NCS Abnormal CS Not Done
<b>≫</b> Casts	Positive Negative				Normal Abnormal NCS Abnormal CS Not Done

Comments	



Trial: **OP109219\_JP-2266-101-FIH\_A (v.2.0)** 

Event: **P1 D10 [P1D10]** 

Page: Urine electro test [URE]

URINE ELECTROL	YTES TEST				
<b>≫</b> Sample Collected?			C Yes C No		
► If No,Specify		Γ			
▶ Date of Collection					
<b>≫</b> Time of Collection		Γ			
Parameter Name	Results	Units	LLN	ULN	Assessment
<b>≫</b> Calcium					Normal Abnormal NCS Abnormal CS Not Done
<b>≫</b> Phosphorus					Normal Abnormal NCS Abnormal CS Not Done
<b>≫</b> Sodium					Normal Abnormal NCS Abnormal CS Not Done
<b>≫</b> Potassium					Normal Abnormal NCS Abnormal CS Not Done
<b>&gt;&gt;</b> Chloride					Normal Abnormal NCS Abnormal CS Not Done



Trial: **OP109219\_JP-2266-101-FIH\_A (v.2.0)** 

Event: P1 D10 [P1D10]
Page: Vital Signs [VS]

VITAL SIGNS	
➤ Vitals collected?	C Yes C No
▶If No,Specify	
<b>▶</b> Date of measurements	
<b>≫</b> Body Temperature (°C)	
<b>≫</b> Result	C Normal C Abnorm
Clinically Significant	C Yes C No
Blood Pressure and F	leart Rate
After	Position
10 Mins	
2 Mins	
<b>&gt;</b> Result (	Normal Abnormal
➤ Clinically Significant	⊃ Yes ┌ No
- Onlinearly Organicant	
Abnormal Finding/	
Relevant Comments	



Trial: **OP109219\_JP-2266-101-FIH\_A (v.2.0)** 

Event: **P1 D10 [P1D10]**Page: **12 Lead ECG [EG]** 

12 LEAD ECG	
▶ECG Performed?	C Yes C No
▶If No,Specify	
<b>▶</b> Date of ECG	
<b>▶</b> Time of ECG	
→ Heart Rate (Beats/min)	
▶PR (ms)	
<b>&gt;</b> QRS (ms)	
<b>&gt;</b> QT (ms)	
<b>▶</b> QTcF (ms)	
Conclusion Result	Normal Abnormal
Clinically Significant?	C Yes C No
Abnormality Finding / Relevant Comment	



Trial: **OP109219\_JP-2266-101-FIH\_A (v.2.0)** 

Event: **P1 D10 [P1D10]** 

Page: Study Restriction [SR]

STUDY RESTRICTIONS
▶ Did the subject respect the study restrictions throughout the course of the study?
▶If no, Please Clarify



Trial: **OP109219\_JP-2266-101-FIH\_A (v.2.0)** 

Event: **P1 D10 [P1D10]** 

Page: Study Comments [CO]



Trial: **OP109219\_JP-2266-101-FIH\_A (v.2.0)** 

Event: **P1 D10 [P1D10]** 

Page: Study Completion [DS]

STUDY COMPLETION	
<b>▶</b> Completion/Discontinuation Date	
<b>⇒</b> Status	Completed
	Adverse Event
	C Lost to Follow-Up
	Withdrawal by Subject
	Physician Decision
	Death
	Protocol Violation
	Study Terminated by Sponsor
	Other
▶If Other Specify	



Trial: **OP109219\_JP-2266-101-FIH\_A (v.2.0)** 

D-2 Event: P2 D-2 [P2\_D-2]
Page: Visit Date [SV]

P2

VISIT DATI	<b>=</b>
<b>≫</b> Date of Visit	



Trial: **OP109219\_JP-2266-101-FIH\_A (v.2.0)** 

Event: **P2 D-2 [P2\_D-2]** 

Page: Urine Drug Screen [UDS]

URINE DRUG SCREENING				
<b>≫</b> Sample Collected?	O Yes O No			
<b>▶</b> Date of Collection				
<b>≫</b> Result	Positive Negative			
▶If Positive, Specify the Positive Drug?				



Trial: **OP109219\_JP-2266-101-FIH\_A (v.2.0)** 

Event: **P2 D-2 [P2\_D-2]** 

Page: Urinary cotinine [URC]

URINARY COTI	NINE
<b>≫</b> Sample Collected?	C Yes C No
<b>▶</b> Date of Collection	
<b>≫</b> Result	Positive Negative
Comments	



Trial: **OP109219\_JP-2266-101-FIH\_A (v.2.0)** 

Event: **P2 D-2 [P2\_D-2]** 

Page: Alcohol Breath Test [ALC]

ALCOHOL BI	REATH TEST
➤ Test Performed?	C Yes C No
<b>&gt;&gt;</b> Date Performed	
<b>&gt;</b> Result	Positive Negative
Comments	



Trial: **OP109219\_JP-2266-101-FIH\_A (v.2.0)** 

D-1 Event: P2 D-1 [P2D-1]

P2

Page: Visit Date [SV]

VISIT DATI	<b>=</b>
<b>▶</b> Date of Visit	



Trial: **OP109219\_JP-2266-101-FIH\_A (v.2.0)** 

Event: P2 D-1 [P2D-1]
Page: PE (Predose) [PE]

PHYSICAL EXAMINATION (Predo	ose)
Time Point	Pre-dose
<b>▶</b> Did the Physical Examination performed?	C Yes C No
If No,specify	
Date Performed	
→Time performed	
<b>≫</b> Results	C Normal C Abnormal
<b>≫</b> Abnormal Physical Finding	
Clinically Significant?	○ Yes ○ No



 ${\bf Sponsor:}~ {\bf JEIL~Pharmaceutical~Co.,~Ltd.}$ 

Trial: **OP109219\_JP-2266-101-FIH\_A (v.2.0)** 

Event: **P2 D-1 [P2D-1]** 

Page: Hematology(Predose) [LH]

HEMATOLOGY (PRE	DOSE)				
Time Point Pre-de	ose s ( No				
	S () NO				
▶If No,Specify ▶Date of Collection					
Time of Collection					
,					
Parameter Name		Result	Un	it	it LLN
Red Blood Cells (RBC)					
<b>≫</b> Hemoglobin					
<b>≫</b> Hematocrit					
<b>≫</b> Mean Corpuscular Volume (	MCV)				
<b>≫</b> Mean Corpuscular Hemoglo	bin (MCH)				
<b>≫</b> Mean Corpuscular Hemoglo	bin Concentration (MCH	C)			
➤ White Blood Cells (WBC)				]	
<b>≫</b> Neutrophils					
<b>≫</b> Eosinophils				]	

<b>&gt;&gt;</b> Basophils			Normal Abnormal NCS Abnormal CS Not Done
<b>≫</b> Lymphocytes		3>	Normal Abnormal NCS Abnormal CS Not Done
<b>≫</b> Monocytes		**	Normal Abnormal NCS Abnormal CS Not Done
▶Platelet count		3)	Normal Abnormal NCS Abnormal CS Not Done
Comment			



Trial: **OP109219\_JP-2266-101-FIH\_A (v.2.0)** 

Event: **P2 D-1 [P2D-1]** 

Page: Coagulation(Predose) [LT]

<b>=</b> )				
Pre-dose				
C Yes C No				
Result	Unit	LLN	ULN	Assessment
				Normal Abnormal NCS Abnormal CS Not Done
				Normal Abnormal NCS Abnormal CS Not Done
				Normal Abnormal NCS Abnormal CS Not Done
	C Yes C No	Pre-dose  Yes No	Pre-dose  Yes No	Pre-dose  Yes No



 ${\bf Sponsor:}~ {\bf JEIL~Pharmaceutical~Co.,~Ltd.}$ 

Trial: **OP109219\_JP-2266-101-FIH\_A (v.2.0)** 

Event: **P2 D-1 [P2D-1]** 

Page: Biochemistry(Predose [LC]

BIOCHEMISTR	Y (PRE DOSE)					
Time Point	Pre-dose					
Sample Collected?	C Yes C No	_				
▶If No,Specify						
▶ Fasting State	O Yes O No	Unknown				
▶ Date of Collection						
▶Time of Collection						
Parameter Name		Symbol	Results	Units	LLN	
Fasting Glucose			<b>&gt;&gt;</b>			
Creatinine			<b>3</b> >			
Urea			20			
Blood Urea Nitroger	າ (BUN)		»			
Creatinine clearance	Э		»			
Alanine Serine Trans	sferase (AST)		<b>3)</b>			
Alanine Leucine Tra	nsferase (ALT)		<b>3)</b>			
Gamma Glutamyl Ti	ransferase (GGT)	< <= >	<b>3</b>			

Alkaline Phosphatases (ALP)		<b>»</b>			Normal Abnormal NCS Abnormal CS Not Done
Lactate Dehydrogenase (LDH)		<b>&gt;&gt;</b>			Normal Abnormal NCS Abnormal CS Not Done
Creatine Phosphokinase (CPK)		<b>&gt;&gt;</b>		,	Normal Abnormal NCS Abnormal CS Not Done
Lipase		<b>3</b> >			Normal Abnormal NCS Abnormal CS Not Done
Total Bilirubin	< <= >> >=	<b>&gt;&gt;</b>			Normal Abnormal NCS Abnormal CS Not Done
Conjugated Bilirubin	< <= > >=	<b>&gt;&gt;</b>			Normal Abnormal NCS Abnormal CS Not Done
Unconjugated Bilirubin	< <= > >=	<b>&gt;&gt;</b>			Normal Abnormal NCS Abnormal CS Not Done
Total Cholesterol		<b>&gt;&gt;</b>			Normal Abnormal NCS Abnormal CS Not Done
Triglycerides	< <= >> >=	<b>»</b>			Normal Abnormal NCS Abnormal CS Not Done
Sodium		<b>»</b>		,	Normal Abnormal NCS Abnormal CS Not Done
Potassium		<b>»</b>			Normal Abnormal NCS Abnormal CS Not Done
Chloride		<b>&gt;&gt;</b>			Normal Abnormal NCS Abnormal CS Not Done

Calcium	36		•	Normal Abnormal NCS Abnormal CS Not Done
Phosphorus	<b>3</b> >		<b>&gt;&gt;</b>	Normal Abnormal NCS Abnormal CS Not Done
Total Protein	<b>3</b> >		<b>&gt;&gt;</b>	Normal Abnormal NCS Abnormal CS Not Done
Comment				



Trial: **OP109219\_JP-2266-101-FIH\_A (v.2.0)** 

Event: **P2 D-1 [P2D-1]** 

Page: Urinalysis(Predose) [UR]

URINALYSIS (F	PRE DOSE	<b>()</b>			
Time Point	Pre-dose				
<b>≫</b> Sample Collected?	C Yes C	No			
► If No, Specify					
▶ Date of Collection					
▶Time of Collection					
Parameter Name	Symbol	Results	LLN	ULN	Assessment
Glucose		Positive Negative		1	Normal Abnormal NCS Abnormal CS Not Done
Proteins		<ul><li>Positive</li><li>Negative</li></ul>		1	Normal Abnormal NCS Abnormal CS Not Done
Ketones		Positive Negative		1	Normal Abnormal NCS Abnormal CS Not Done
Occult Blood		<ul><li>Positive</li><li>Negative</li></ul>		1	Normal Abnormal NCS Abnormal CS Not Done
Bilirubin		Positive Negative		1	Normal Abnormal NCS Abnormal CS Not Done
Urobilinogen		Positive Negative		1	Normal Abnormal NCS Abnormal CS Not Done
рН		»		,	Normal Abnormal NCS Abnormal CS Not Done
Nitrites		Positive Negative		1	Normal Abnormal NCS Abnormal CS Not Done
Specific Gravity	< <= >> >=	20		1	Normal Abnormal NCS Abnormal CS Not Done

White Blood Cells	➤ Positive Negative	Abnormal NCS Abnormal CS Not Done	
Comments			

MICROSCOPIC RES	Results	Units	LLN	ULN	Assessment
<b>≫</b> Micr: Glucose					Normal Abnormal NCS Abnormal CS Not Done
<b>≫</b> Micr: Protein					Normal Abnormal NCS Abnormal CS Not Done
➤Micr: Red Blood Cells					Normal Abnormal NCS Abnormal CS Not Done
<b>≫</b> Micr: White Blood Cells					Normal Abnormal NCS Abnormal CS Not Done
<b>≫</b> Micr: Crystals	<ul><li>Positive</li><li>Negative</li></ul>				Normal Abnormal NCS Abnormal CS Not Done
<b>≫</b> Epithelial Cells	<ul><li>Positive</li><li>Negative</li></ul>				Normal Abnormal NCS Abnormal CS Not Done
<b>≫</b> Epithelial Renal Cells	Positive Negative				Normal Abnormal NCS Abnormal CS Not Done
<b>≫</b> Bacteria	Positive Negative				Normal Abnormal NCS Abnormal CS Not Done
<b>≫</b> Casts	Positive Negative				Normal Abnormal NCS Abnormal CS Not Done

Comments	
ı	



Sponsor: **JEIL Pharmaceutical Co., Ltd.**Trial: **OP109219\_JP-2266-101-FIH\_A (v.2.0)** 

Event: **P2 D-1 [P2D-1]** 

Page: Vital Signs(Predose) [VS]

VITAL SIGNS (PI	RE DOSE)					
Time Point	Pre-dose					
<b>≫</b> Vitals collected?	C Yes C No					
▶If No,Specify						
<b>▶</b> Date of measuremen	its					
Blood Pressure and	l Heart Rate					
After	Position	Actual Time Position (hh:mm)	Actual Time Measurement (hh:mm)	Systolic (mmHg)	Diastolic (mmHg)	Heart rate (bpm)
10 Mins		<b>3</b>	<b>≫</b>	<b>&gt;&gt;</b>	<b>&gt;&gt;</b>	<b>&gt;&gt;</b>
2 Mins		<b>3)</b>	<b>&gt;&gt;</b>	<b>&gt;&gt;</b>	<b>≫</b>	<b>3</b>
<b>≫</b> Result	C Normal C Abnormal					
Clinically Significant	C Yes C No					
Abnormal Finding/ Relevant Comments						



Trial: **OP109219\_JP-2266-101-FIH\_A (v.2.0)** 

Event: **P2 D-1 [P2D-1]** 

Page: 12 Lead ECG(Predose) [EG]

12 LEAD ECG (PR	E DOSE)
Time Point	Pre-dose
<b>▶</b> ECG Performed?	C Yes C No
▶If No,Specify	
<b>▶</b> Date of ECG	
<b>≫</b> Time of ECG	
→ Heart Rate (Beats/min)	
▶PR (ms)	
<b>⇒</b> QRS (ms)	
<b>⇒</b> QT (ms)	
<b>⇒</b> QTcF (ms)	
Conclusion Result	Normal Abnormal
Clinically Significant?	C Yes C No
Abnormality Finding / Relevant Comment	



Trial: **OP109219\_JP-2266-101-FIH\_A (v.2.0)** 

Event: **P2 D-1 [P2D-1]** 

Page: Placebo Administrati [EX1]

PLACEBO ADMINISTRATION	
Date of Placebo Administration	
▶Time of Placebo Administration	
➤ Administered Dose (mg)	
➤ Has the Placebo administration been performed according to the protocol?	C Yes C No
▶If No, please comment	



P2 D1 Trial: OP109219\_JP-2266-101-FIH\_A (v.2.0)

Event: P2 D1 [P2D1]
Page: Visit Date [SV]

VISIT DATE	
<b>≫</b> Date of Visit	



Trial: **OP109219\_JP-2266-101-FIH\_A (v.2.0)** 

Event: P2 D1 [P2D1]
Page: PE (Pre Dose) [PE]

PHYSICAL EXAMINATION (PRE DOSE)	
Time Point	Pre-dose
<b>▶</b> Did the Physical Examination performed?	C Yes C No
▶If No,specify	
Date Performed	
→Time performed	
<b>≫</b> Results	C Normal C Abnormal
➤ Abnormal Physical Finding	
➤ Clinically Significant?	C Yes C No



Trial: **OP109219\_JP-2266-101-FIH\_A (v.2.0)** 

Event: **P2 D1 [P2D1]** 

Page: Hematology(Pre Dose) [LH]

HEMATOLOGY (PRE	DOSE)				
Time Point Pre-de	ose s ( No				
	S () NO				
▶If No,Specify ▶Date of Collection					
Time of Collection					
,					
Parameter Name		Result	Un	it	it LLN
Red Blood Cells (RBC)					
<b>≫</b> Hemoglobin					
<b>≫</b> Hematocrit					
<b>≫</b> Mean Corpuscular Volume (	MCV)				
<b>≫</b> Mean Corpuscular Hemoglo	bin (MCH)				
<b>≫</b> Mean Corpuscular Hemoglo	bin Concentration (MCH	C)			
➤ White Blood Cells (WBC)				]	
<b>≫</b> Neutrophils					
<b>≫</b> Eosinophils				]	

<b>≫</b> Basophils			Normal Abnormal NCS Abnormal CS Not Done
<b>≫</b> Lymphocytes		<b>3</b>	Normal Abnormal NCS Abnormal CS Not Done
<b>≫</b> Monocytes		<b>3</b>	Normal Abnormal NCS Abnormal CS Not Done
▶Platelet count		3>	Normal Abnormal NCS Abnormal CS Not Done
Comment			



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Trial: **OP109219\_JP-2266-101-FIH\_A (v.2.0)** 

Event: **P2 D1 [P2D1]** 

Page: Coagulation(Pre Dose [LT]

E)				
Pre-dose				
C Yes C No				
y)				
Result	Unit	LLN	ULN	Assessment
				Normal Abnormal NCS Abnormal CS Not Done
				Normal Abnormal NCS Abnormal CS Not Done
				Normal Abnormal NCS Abnormal CS Not Done
	Yes No	( Yes ( No	Yes No  Result Unit LLN	Yes No  (Yes



 ${\bf Sponsor:}~ {\bf JEIL~Pharmaceutical~Co.,~Ltd.}$ 

Trial: **OP109219\_JP-2266-101-FIH\_A (v.2.0)** 

Event: **P2 D1 [P2D1]** 

Page: Biochemistry(PreDose [LC]

BIOCHEMISTRY (PRE DOSE)						
Time Point Pre-dose						
➤ Sample Collected?						
▶If No,Specify						
▶ Fasting State	Unknown					
<b>▶</b> Date of Collection						
▶Time of Collection						
Parameter Name	Symbol	Results	Units	LLN	ULN	Assessment
Fasting Glucose		<b>&gt;&gt;</b>				Normal Abnormal NCS Abnormal CS Not Done
Creatinine		<b>»</b>				Normal Abnormal NCS Abnormal CS Not Done
Urea		<b>3</b>				Normal Abnormal NCS Abnormal CS Not Done
Blood Urea Nitrogen (BUN)		»				Normal Abnormal NCS Abnormal CS Not Done
Creatinine clearance		<b>3</b>				Normal Abnormal NCS Abnormal CS Not Done
Alanine Serine Transferase (AST)		<b>3</b>				Normal Abnormal NCS Abnormal CS Not Done
Alanine Leucine Transferase (ALT)		<b>3)</b>				Normal Abnormal NCS Abnormal CS Not Done
Gamma Glutamyl Transferase (GGT)	< <= > >=	<b>»</b>				Normal Abnormal NCS Abnormal CS Not Done

Alkaline Phosphatases (ALP)		<b>»</b>			Normal Abnormal NCS Abnormal CS Not Done
Lactate Dehydrogenase (LDH)		<b>&gt;&gt;</b>			Normal Abnormal NCS Abnormal CS Not Done
Creatine Phosphokinase (CPK)		<b>&gt;&gt;</b>		,	Normal Abnormal NCS Abnormal CS Not Done
Lipase		<b>3</b> >			Normal Abnormal NCS Abnormal CS Not Done
Total Bilirubin	< <= >> >=	<b>&gt;&gt;</b>			Normal Abnormal NCS Abnormal CS Not Done
Conjugated Bilirubin	< <= > >=	<b>&gt;&gt;</b>			Normal Abnormal NCS Abnormal CS Not Done
Unconjugated Bilirubin	< <= > >=	<b>&gt;&gt;</b>			Normal Abnormal NCS Abnormal CS Not Done
Total Cholesterol		<b>&gt;&gt;</b>			Normal Abnormal NCS Abnormal CS Not Done
Triglycerides	< <= >> >=	<b>»</b>			Normal Abnormal NCS Abnormal CS Not Done
Sodium		<b>»</b>		,	Normal Abnormal NCS Abnormal CS Not Done
Potassium		<b>»</b>		,	Normal Abnormal NCS Abnormal CS Not Done
Chloride		<b>&gt;&gt;</b>			Normal Abnormal NCS Abnormal CS Not Done

Calcium	36		•	Normal Abnormal NCS Abnormal CS Not Done
Phosphorus	<b>3</b> >		<b>&gt;&gt;</b>	Normal Abnormal NCS Abnormal CS Not Done
Total Protein	<b>3</b> >		<b>&gt;&gt;</b>	Normal Abnormal NCS Abnormal CS Not Done
Comment				



Trial: **OP109219\_JP-2266-101-FIH\_A (v.2.0)** 

Event: **P2 D1 [P2D1]** 

Page: Urinalysis(Pre Dose) [UR]

URINALYSIS (PI	RE DOSE	)			
Time Point	Pre-dose				
➤ Sample Collected?	C Yes C	No No			
▶If No,Specify					
<b>▶</b> Date of Collection					
<b>▶</b> Time of Collection					
Parameter Name	Symbol	Results	LLN	ULN	Assessment
Glucose		<ul><li>Positive</li><li>Negative</li></ul>			Normal Abnormal NCS Abnormal CS Not Done
Proteins		<ul><li>Positive</li><li>Negative</li></ul>		•	Normal Abnormal NCS Abnormal CS Not Done
Ketones		<ul><li>Positive</li><li>Negative</li></ul>		,	Normal Abnormal NCS Abnormal CS Not Done
Occult Blood		<ul><li>Positive</li><li>Negative</li></ul>		,	Normal Abnormal NCS Abnormal CS Not Done
Bilirubin		<ul><li>Positive</li><li>Negative</li></ul>		,	Normal Abnormal NCS Abnormal CS Not Done
Urobilinogen		<ul><li>Positive</li><li>Negative</li></ul>		•	Normal Abnormal NCS Abnormal CS Not Done
рН		<b>»</b>			Normal Abnormal NCS Abnormal CS Not Done
Nitrites	_	<ul><li>Positive</li><li>Negative</li></ul>		•	Normal Abnormal NCS Abnormal CS Not Done
Specific Gravity	< <= > >=	<b>3</b> >			Normal Abnormal NCS Abnormal CS Not Done

White Blood	Cells	<ul><li>Positive</li><li>Negative</li></ul>	Abnormal NCS Abnormal CS Not Done	
Comments				

MICROSCOPIC RES	Results	Units	LLN	ULN	Assessment
<b>≫</b> Micr: Glucose					Normal Abnormal NCS Abnormal CS Not Done
<b>≫</b> Micr: Protein					Normal Abnormal NCS Abnormal CS Not Done
➤Micr: Red Blood Cells					Normal Abnormal NCS Abnormal CS Not Done
<b>≫</b> Micr: White Blood Cells					Normal Abnormal NCS Abnormal CS Not Done
<b>≫</b> Micr: Crystals	<ul><li>Positive</li><li>Negative</li></ul>				Normal Abnormal NCS Abnormal CS Not Done
<b>≫</b> Epithelial Cells	<ul><li>Positive</li><li>Negative</li></ul>				Normal Abnormal NCS Abnormal CS Not Done
<b>≫</b> Epithelial Renal Cells	Positive Negative				Normal Abnormal NCS Abnormal CS Not Done
<b>≫</b> Bacteria	Positive Negative				Normal Abnormal NCS Abnormal CS Not Done
<b>≫</b> Casts	Positive Negative				Normal Abnormal NCS Abnormal CS Not Done

Comments	
ı	



Trial: **OP109219\_JP-2266-101-FIH\_A (v.2.0)** 

Event: **P2 D1 [P2D1]** 

Page: Urine electro(Predos [URE]

URINE ELECTRO	OLYTES TEST (PI	RE DOSE)			
Time Point			Pre-dose		
Sample Collected?			C Yes C No		
▶If No,Specify				_	
<b>▶</b> Date of Collection					
▶Time of Collection					
Parameter Name	Results	Units	LLN	ULN	Assessment
<b>≫</b> Calcium					Normal Abnormal NCS Abnormal CS Not Done
<b>≫</b> Phosphorus					Normal Abnormal NCS Abnormal CS Not Done
<b>≫</b> Sodium					Normal Abnormal NCS Abnormal CS Not Done
<b>≫</b> Potassium					Normal Abnormal NCS Abnormal CS Not Done
<b>▶</b> Chloride					Normal Abnormal NCS Abnormal CS Not Done
Comments					



Event: **P2 D1 [P2D1]** 

Page: Vital Signs(Predose) [VS1]

VITAL SIGNS (PI	RE DOSE)					
Time Point	Pre-dose					
<b>≫</b> Vitals collected?	C Yes C No					
▶If No,Specify						
<b>▶</b> Date of measuremen	its					
Blood Pressure and	l Heart Rate					
After	Position	Actual Time Position (hh:mm)	Actual Time Measurement (hh:mm)	Systolic (mmHg)	Diastolic (mmHg)	Heart rate (bpm)
10 Mins		<b>3</b>	<b>&gt;&gt;</b>	<b>&gt;&gt;</b>	<b>&gt;&gt;</b>	<b>&gt;&gt;</b>
2 Mins		<b>3)</b>	<b>&gt;&gt;</b>	<b>&gt;&gt;</b>	<b>≫</b>	<b>3</b>
<b>≫</b> Result	C Normal C Abnormal					
Clinically Significant	C Yes C No					
Abnormal Finding/ Relevant Comments						



Trial: **OP109219\_JP-2266-101-FIH\_A (v.2.0)** 

Event: **P2 D1 [P2D1]** 

Page: Drug Administration [EX]

DRUG ADMINISTRATION	
▶Date of Study Drug Administration	
▶Time of Study Drug Administration	
→ Administered Dose (mg)	
➤ Has the drug administration been performed according to the protocol?	C Yes C No
▶If No, please comment	



Event: **P2 D1 [P2D1]** 

Page: Vital Signs (T1h) [VS]

VITAL SIGNS (T	HOUR)
Time Point	T1h
➤ Vitals collected?	C Yes C No
■If No,Specify	
<b>▶</b> Date of measuremen	ts
Blood Pressure and	l Heart Rate
After	Position
10 Mins	
2 Mins	
<b>&gt;</b> Result	C Normal C Abnormal
Clinically Significant	C Yes C No
Abnormal Finding/	
Relevant Comments	



Event: **P2 D1 [P2D1]** 

Page: Vital Signs (T2h) [VS2]

VITAL SIGNS (T2 Time Point  ▶ Vitals collected?	T2h No					
▶If No,Specify						
<b>≫</b> Date of measuremen	nts					
Blood Pressure and	d Heart Rate					
After	Position	Actual Time Position (hh:mm)	Actual Time Measurement (hh:mm)	Systolic (mmHg)	Diastolic (mmHg)	Heart rate (bpm)
10 Mins			<b>&gt;</b>	<b>&gt;&gt;</b>	<b>&gt;&gt;</b>	<b>&gt;&gt;</b>
2 Mins		<b>36</b>	<b>3</b>	<b>3</b>	<b>≫</b>	<b>3</b>
<b>≫</b> Result	C Normal C Abnormal					
Clinically Significant	C Yes C No					



Trial: **OP109219\_JP-2266-101-FIH\_A (v.2.0)** 

Event: **P2 D1 [P2D1]** 

Page: 12 Lead ECG (T2h) [EG]

12 LEAD ECG (T2	HOUR)
Time Point	T2h
<b>▶</b> ECG Performed?	C Yes C No
▶If No,Specify	
<b>▶</b> Date of ECG	
<b>≫</b> Time of ECG	
▶ Heart Rate (Beats/min)	
▶PR (ms)	
<b>≫</b> QRS (ms)	
<b>≫</b> QT (ms)	
<b>&gt;</b> QTcF (ms)	
➤ Conclusion Result	Normal Abnormal
Clinically Significant?	C Yes C No
Abnormality Finding / Relevant Comment	



Event: **P2 D1 [P2D1]** 

Page: Vital Signs (T4h) [VS3]

VITAL SIGNS (T	4 HOUR)					
Time Point	T4h					
▶Vitals collected?	C Yes C No					
▶If No,Specify						
<b>▶</b> Date of measuremen	nts					
Blood Pressure and	d Heart Rate					
After	Position	Actual Time Position (hh:mm)	Actual Time Measuremen (hh:mm)	t Systolic (mmHg)	Diastolic (mmHg)	Heart rate (bpm)
10 Mins			<b>&gt;</b>	<b>&gt;&gt;</b>	<b>&gt;&gt;</b>	<b>&gt;&gt;</b>
2 Mins		20	<b>&gt;&gt;</b>	<b>&gt;&gt;</b>	>>	<b>3</b> +
<b>≫</b> Result	C Normal C Abnormal					
Clinically Significant	C Yes C No					
Abnormal Finding/ Relevant Comments						



Trial: **OP109219\_JP-2266-101-FIH\_A (v.2.0)** 

Event: **P2 D1 [P2D1]** 

Page: 12 Lead ECG (T4h) [EG1]

12 LEAD ECG (T4	HOUR)
Time Point	T4h
<b>≫</b> ECG Performed?	C Yes C No
▶If No,Specify	
<b>▶</b> Date of ECG	
<b>≫</b> Time of ECG	
⇒ Heart Rate (Beats/min)	
⇒PR (ms)	
⇒QRS (ms)	
<b>≫</b> QT (ms)	
<b>⇒</b> QTcF (ms)	
➤ Conclusion Result	Normal Abnormal
Clinically Significant?	C Yes C No
Abnormality Finding / Relevant Comment	



Event: **P2 D1 [P2D1]** 

Page: Blood Sample for PK [PK]

BLOOD S	SAMPLE FOR PK				
Time Point	Sample Collected?	Schedule Date & Time	Actual Date & Actual Time	Time window (min)	Meal restriction respected?
Pre Dose	Yes No		3)	- 60 Mins	
T0h15min	➤ C Yes C No		» »	+/- 1 Min	
T0h30min	➤ C Yes C No		3 <b>)</b>	+/- 1 Min	
T0h45min	Yes No		» »	+/- 1 Min	
T1h	Yes No		» »	+/- 5Mins	
T1h30min	Yes ○ No		» »	+/- 5Mins	
T2h	Yes ○ No		» »	+/- 5 Mins	
T2h30min	Yes No		3b 3b	+/- 5 Mins	
T3h	Yes No		» »	+/- 5 Mins	
T3h30 min	Yes ○ No		» »	+/- 5 Mins	
T4h	Yes ○ No		» »	+/- 5 Mins	Yes No Unknown
T6h	Yes No		» »	+/- 5 Mins	
T8h	Yes No		» »	+/- 5 Mins	
T10h	Yes No		» »	+/- 5 Min	
T12h	Yes ○ No		» »	+/- 5 Mins	Yes No Unknown
Comment					
L					



Trial: **OP109219\_JP-2266-101-FIH\_A (v.2.0)** 

Event: **P2 D1 [P2D1]** 

Page: Blood Sample for PD [PK1]

## **BLOOD SAMPLE FOR PD** Time window Time Point Sample Collected? Schedule Date & Time Actual Date & Actual Time (min) C Yes C No Pre Dose - 60 Mins T0h30min C Yes C No +/- 1 Min C Yes C No T1h +/- 5 Mins C Yes C No T1h30min +/- 5 Mins C Yes C No +/- 5 Mins T2h C Yes C No T3h +/- 5 Mins T4h C Yes C No +/- 5 Mins C Yes C No +/- 5 Mins T6h C Yes C No T8h +/- 5 Mins Yes No T12h +/- 5 Mins Comment



Event: P2 D1 [P2D1]

Page: Urine Sample PK & PD [URPK]

URINE SAMPLE FOR PK & PD								
Time Interval	Sample Collected?	Start Date	Start Time	End Date	End Time	Urine vol(g) Urine vol(ml)		
( D-1 pre-dose to D1 T0h) only PD	Yes No	>>	<b>3</b>	<b>≫</b>	<b>≫</b>	<b>&gt;&gt;</b>		
Pre Dose (Only PK)	Yes No	<b>&gt;&gt;</b>	30-			25		
]T0H-T4H]	Yes No	<b>&gt;&gt;</b>	<b>3</b>	<b>&gt;&gt;</b>	20-	20		
]T4H-T8H]	Yes No	<b>&gt;&gt;</b>	<b>&gt;&gt;</b>	<b>&gt;&gt;</b>	30	<b>&gt;&gt;</b>		
]T8H-T12H]	Yes No	<b>&gt;&gt;</b>	<b>3</b>	<b>&gt;&gt;</b>	30	<b>3</b>		
Comment								



Trial: **OP109219\_JP-2266-101-FIH\_A (v.2.0)** 

Event: P2 D1 [P2D1]
Page: Meals [ML]

MEALS		
Meals date		
▶Breakfast taken?	C Yes	O No
⇒Breakfast start time		
<b>≫</b> Breakfast end time		
<b>&gt;&gt;</b> Lunch taken?	C Yes	O No
<b>≫</b> Lunch start time		
Dinner taken?	Yes	◯ No
<b>▶</b> Dinner start time		
Comments		



OP109219\_JP-2266-101-FIH\_A (v.2.0) P2 D2 Event: P2 D2 [P2D2]

Page: Visit Date [SV]

VISIT DATE	
<b>▶</b> Date of Visit	



Trial: **OP109219\_JP-2266-101-FIH\_A (v.2.0)** 

Event: **P2 D2 [P2D2]** 

Page: Hematology (T24h) [LH]

HEMATOLOGY (T24 HOUR)				
Time Point T24h				
Sample Collected? Yes No	1			
If No,Specify				
Date of Collection  → Time of Collection				
Time of Collection				
Parameter Name	Result	Unit	L	LN
▶Red Blood Cells (RBC)				
<b>≫</b> Hemoglobin				
<b>≫</b> Hematocrit				
<b>≫</b> Mean Corpuscular Volume (MCV)				
<b>≫</b> Mean Corpuscular Hemoglobin (MCH)				
▶Mean Corpuscular Hemoglobin Concentration	on (MCHC)			
➤ White Blood Cells (WBC)				
<b>≫</b> Neutrophils				
<b>≫</b> Eosinophils				

<b>&gt;&gt;</b> Basophils			Normal Abnormal NCS Abnormal CS Not Done
<b>▶</b> Lymphocytes		<b>&gt;</b>	Normal Abnormal NCS Abnormal CS Not Done
<b>≫</b> Monocytes		<b>&gt;&gt;</b>	Normal Abnormal NCS Abnormal CS Not Done
▶Platelet count		<b>3</b>	Normal Abnormal NCS Abnormal CS Not Done
Comment			



Trial: **OP109219\_JP-2266-101-FIH\_A (v.2.0)** 

Event: **P2 D2 [P2D2]** 

Page: Coagulation (T24h) [LT]

OACHLATION (TOAK)					
COAGULATION (T24h) Time Point	T24h				
Sample Collected?	C Yes C No				
If No,Specify					
Date of Collection (dd-mmm-yyyy)					
Time of Collection (hh:mm)					
Parameter Name	Result	Unit	LLN	ULN	Assessment
Prothrombin time (PT)					Normal Abnormal NCS Abnormal CS Not Done
International normalized ratio (INR)					Normal Abnormal NCS Abnormal CS Not Done
●aPTT(ratio)					Normal Abnormal NCS Abnormal CS Not Done



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Trial: **OP109219\_JP-2266-101-FIH\_A (v.2.0)** 

Event: **P2 D2 [P2D2]** 

Page: Biochemistry (T24h) [LC]

BIOCHEMISTRY (T24h) Time Point T24h  Sample Collected? Yes No  If No, Specify  Fasting State Yes No Unknown  Date of Collection  Time of Collection  Fasting Glucose  Creatinine  Urea  Blood Urea Nitrogen (BUN)  Creatinine clearance  Alanine Serine Transferase (AST)  Alanine Leucine Transferase (ALT)  Gamma Glutamyl Transferase (GGT)							
Sample Collected? Yes No  If No, Specify Fasting State Yes No Unknown  Date of Collection  Time of Collection  Parameter Name Symbol Results Units LLN  Fasting Glucose  Creatinine  Urea  Blood Urea Nitrogen (BUN)  Creatinine clearance  Alanine Serine Transferase (AST)  Alanine Leucine Transferase (ALT)		•					
In the specify  Fasting State  Yes No Unknown  Date of Collection  Time of Collection  Fasting Glucose  Creatinine  Urea  Blood Urea Nitrogen (BUN)  Creatinine clearance  Alanine Serine Transferase (AST)  Alanine Leucine Transferase (ALT)  Gamma Glutamyl Transferase (GGT)							
Fasting State  Parameter Name  Symbol Results  Units  LLN  Fasting Glucose  Creatinine  Urea  Blood Urea Nitrogen (BUN)  Creatinine clearance  Alanine Serine Transferase (AST)  Alanine Leucine Transferase (ALT)		O les O No					
Date of Collection  Parameter Name Symbol Results Units LLN  Fasting Glucose  Creatinine  Urea  Blood Urea Nitrogen (BUN)  Creatinine clearance  Alanine Serine Transferase (AST)  Alanine Leucine Transferase (ALT)  Gamma Glutamyl Transferase (GGT)	► If No,Specify						
Parameter Name Symbol Results Units LLN  Fasting Glucose  Creatinine  Urea  Blood Urea Nitrogen (BUN)  Creatinine clearance  Alanine Serine Transferase (AST)  Alanine Leucine Transferase (ALT)	▶ Fasting State	C Yes C No (	Unknown				
Parameter Name  Symbol Results Units LLN  Fasting Glucose  Creatinine  Urea  Blood Urea Nitrogen (BUN)  Creatinine clearance  Alanine Serine Transferase (AST)  Alanine Leucine Transferase (ALT)	Date of Collection						
Fasting Glucose  Creatinine  Urea  Blood Urea Nitrogen (BUN)  Creatinine clearance  Alanine Serine Transferase (AST)  Alanine Leucine Transferase (ALT)  Gamma Glutamyl Transferase (GGT)	⇒Time of Collection						
Fasting Glucose  Creatinine  Urea  Blood Urea Nitrogen (BUN)  Creatinine clearance  Alanine Serine Transferase (AST)  Alanine Leucine Transferase (ALT)  Gamma Glutamyl Transferase (GGT)							
Creatinine  Urea  Blood Urea Nitrogen (BUN)  Creatinine clearance  Alanine Serine Transferase (AST)  Alanine Leucine Transferase (ALT)  Gamma Glutamyl Transferase (GGT)	Parameter Name		Symbol	Results	Units	LLN	
Creatinine  Urea  Blood Urea Nitrogen (BUN)  Creatinine clearance  Alanine Serine Transferase (AST)  Alanine Leucine Transferase (ALT)  Gamma Glutamyl Transferase (GGT)							
Creatinine  Urea  Blood Urea Nitrogen (BUN)  Creatinine clearance  Alanine Serine Transferase (AST)  Alanine Leucine Transferase (ALT)  Gamma Glutamyl Transferase (GGT)	Fasting Glucose			<b>&gt;&gt;</b>			
Urea  Blood Urea Nitrogen (BUN)  Creatinine clearance  Alanine Serine Transferase (AST)  Alanine Leucine Transferase (ALT)  Gamma Glutamyl Transferase (GGT)	S .						
Urea  Blood Urea Nitrogen (BUN)  Creatinine clearance  Alanine Serine Transferase (AST)  Alanine Leucine Transferase (ALT)  Gamma Glutamyl Transferase (GGT)							
Urea  Blood Urea Nitrogen (BUN)  Creatinine clearance  Alanine Serine Transferase (AST)  Alanine Leucine Transferase (ALT)  Gamma Glutamyl Transferase (GGT)							
Blood Urea Nitrogen (BUN)  Creatinine clearance  Alanine Serine Transferase (AST)  Alanine Leucine Transferase (ALT)  Gamma Glutamyl Transferase (GGT)	Creatinine			<b>≫</b>			
Blood Urea Nitrogen (BUN)  Creatinine clearance  Alanine Serine Transferase (AST)  Alanine Leucine Transferase (ALT)  Gamma Glutamyl Transferase (GGT)							
Blood Urea Nitrogen (BUN)  Creatinine clearance  Alanine Serine Transferase (AST)  Alanine Leucine Transferase (ALT)  Gamma Glutamyl Transferase (GGT)							
Blood Urea Nitrogen (BUN)  Creatinine clearance  Alanine Serine Transferase (AST)  Alanine Leucine Transferase (ALT)  Gamma Glutamyl Transferase (GGT)							
Creatinine clearance  Alanine Serine Transferase (AST)  Alanine Leucine Transferase (ALT)  Gamma Glutamyl Transferase (GGT)	Urea			<b>&gt;&gt;</b>			
Creatinine clearance  Alanine Serine Transferase (AST)  Alanine Leucine Transferase (ALT)  Gamma Glutamyl Transferase (GGT)							
Creatinine clearance  Alanine Serine Transferase (AST)  Alanine Leucine Transferase (ALT)  Gamma Glutamyl Transferase (GGT)							
Creatinine clearance  Alanine Serine Transferase (AST)  Alanine Leucine Transferase (ALT)  Gamma Glutamyl Transferase (GGT)	DI III NE	(DIIN)					1
Alanine Serine Transferase (AST)  Alanine Leucine Transferase (ALT)  Gamma Glutamyl Transferase (GGT)	Blood Urea Nitrogen	(BUN)		<b>37</b>			
Alanine Serine Transferase (AST)  Alanine Leucine Transferase (ALT)  Gamma Glutamyl Transferase (GGT)							
Alanine Serine Transferase (AST)  Alanine Leucine Transferase (ALT)  Gamma Glutamyl Transferase (GGT)							
Alanine Serine Transferase (AST)  Alanine Leucine Transferase (ALT)  Gamma Glutamyl Transferase (GGT)	Creatinine clearance			3>			
Alanine Leucine Transferase (ALT)  Samma Glutamyl Transferase (GGT)							J
Alanine Leucine Transferase (ALT)  Samma Glutamyl Transferase (GGT)							
Alanine Leucine Transferase (ALT)  Gamma Glutamyl Transferase (GGT)							
Gamma Glutamyl Transferase (GGT)	Alanine Serine Trans	ferase (AST)		<b>→</b>			
Gamma Glutamyl Transferase (GGT)							
Gamma Glutamyl Transferase (GGT)							
Gamma Glutamyl Transferase (GGT)							
Gamma Glutamyl Transferase (GGT)	Alanine Leucine Tran	nsferase (ALT)		<b>3</b>			
Gamma Glutamyl Transferase (GGT)							
Gamma Glutamyl Transferase (GGT)							
Samina Glutarnyi Transierase (GGT)	Commo Oliviani T	anafarass (COT)					
	Gamma Giutamyi Tr	ansterase (GGT)		-			

Alkaline Phosphatases (ALP)		<b>»</b>			Normal Abnormal NCS Abnormal CS Not Done
Lactate Dehydrogenase (LDH)		<b>&gt;&gt;</b>			Normal Abnormal NCS Abnormal CS Not Done
Creatine Phosphokinase (CPK)		<b>&gt;&gt;</b>		,	Normal Abnormal NCS Abnormal CS Not Done
Lipase		<b>3</b> >			Normal Abnormal NCS Abnormal CS Not Done
Total Bilirubin	< <= >> >=	<b>&gt;&gt;</b>			Normal Abnormal NCS Abnormal CS Not Done
Conjugated Bilirubin	< <= > >=	<b>&gt;&gt;</b>			Normal Abnormal NCS Abnormal CS Not Done
Unconjugated Bilirubin	< <= > >=	<b>&gt;&gt;</b>			Normal Abnormal NCS Abnormal CS Not Done
Total Cholesterol		<b>&gt;&gt;</b>			Normal Abnormal NCS Abnormal CS Not Done
Triglycerides	< <= >> >=	<b>»</b>			Normal Abnormal NCS Abnormal CS Not Done
Sodium		<b>»</b>		,	Normal Abnormal NCS Abnormal CS Not Done
Potassium		<b>»</b>		,	Normal Abnormal NCS Abnormal CS Not Done
Chloride		<b>&gt;&gt;</b>			Normal Abnormal NCS Abnormal CS Not Done

Calcium	<b>»</b>		•	Normal Abnormal NCS Abnormal CS Not Done
Phosphorus	3>		<b>&gt;&gt;</b>	Normal Abnormal NCS Abnormal CS Not Done
Total Protein	<b>3</b> >		<b>&gt;&gt;</b>	Normal Abnormal NCS Abnormal CS Not Done
Comment				



Trial: **OP109219\_JP-2266-101-FIH\_A (v.2.0)** 

Event: **P2 D2 [P2D2]** 

Page: Urinalysis (T24h) [UR]

URINALYSIS (T	24h)				
Time Point	T24h				
Sample Collected?	C Yes C	No			
▶If No,Specify					
<b>▶</b> Date of Collection					
<b>▶</b> Time of Collection					
Parameter Name	Symbol	Results	LLN		Assessment
Glucose	:	Positive Negative		3>	Normal Abnormal NCS Abnormal CS Not Done
Proteins		Positive Negative		**	Normal Abnormal NCS Abnormal CS Not Done
Ketones	:	Positive Negative		3>	Normal Abnormal NCS Abnormal CS Not Done
Occult Blood	:	Positive Negative		3>	Normal Abnormal NCS Abnormal CS Not Done
Bilirubin	:	Positive Negative		3>	Normal Abnormal NCS Abnormal CS Not Done
Urobilinogen	:	Positive Negative		**	Normal Abnormal NCS Abnormal CS Not Done
рН	:	<b>&gt;&gt;</b>		<b>&gt;&gt;</b>	Normal Abnormal NCS Abnormal CS Not Done
Nitrites		Positive Negative		<b>»</b>	Normal Abnormal NCS Abnormal CS Not Done
Specific Gravity	< <= >> >=	<b>&gt;&gt;</b>		<b>&gt;&gt;</b>	Normal Abnormal NCS Abnormal CS Not Done

White Blood C	Positive  Cells  Negative	Abnormal NCS Abnormal CS Not Done
Comments		

MICROSCOPIC RES	Results	Units	LLN	ULN	Assessment
<b>≫</b> Micr: Glucose					Normal Abnormal NCS Abnormal CS Not Done
<b>≫</b> Micr: Protein					Normal Abnormal NCS Abnormal CS Not Done
➤Micr: Red Blood Cells					Normal Abnormal NCS Abnormal CS Not Done
<b>≫</b> Micr: White Blood Cells					Normal Abnormal NCS Abnormal CS Not Done
<b>≫</b> Micr: Crystals	<ul><li>Positive</li><li>Negative</li></ul>				Normal Abnormal NCS Abnormal CS Not Done
<b>≫</b> Epithelial Cells	<ul><li>Positive</li><li>Negative</li></ul>				Normal Abnormal NCS Abnormal CS Not Done
<b>≫</b> Epithelial Renal Cells	Positive Negative				Normal Abnormal NCS Abnormal CS Not Done
<b>≫</b> Bacteria	Positive Negative				Normal Abnormal NCS Abnormal CS Not Done
<b>≫</b> Casts	Positive Negative				Normal Abnormal NCS Abnormal CS Not Done

Comments	
ı	



Trial: **OP109219\_JP-2266-101-FIH\_A (v.2.0)** 

Event: **P2 D2 [P2D2]** 

Page: Urine electrol(T24h) [URE]

URINE ELECTR	OLYTES TEST (T2	24h)					
Time Point			T24h				
<b>≫</b> Sample Collected?			C Yes C No				
► If No, Specify							
<b>▶</b> Date of Collection							
⇒Time of Collection							
Parameter Name	Results	Units	LLN	ULN	Assessment		
<b>≫</b> Calcium					Normal Abnormal NCS Abnormal CS Not Done		
<b>≫</b> Phosphorus					Normal Abnormal NCS Abnormal CS Not Done		
<b>≫</b> Sodium					Normal Abnormal NCS Abnormal CS Not Done		
<b>≫</b> Potassium					Normal Abnormal NCS Abnormal CS Not Done		
<b>▶</b> Chloride					Normal Abnormal NCS Abnormal CS Not Done		
Comments							



Event: **P2 D2 [P2D2]** 

Page: Vital Signs (T24h) [VS]

VITAL SIGNS (T2	4 HOUR)					
Time Point	T24h					
➤ Vitals collected?	C Yes C No					
▶If No,Specify						
Date of measurement	s					
Blood Pressure and	Heart Rate					
After	Position	Actual Time Position (hh:mm)	Actual Time Measuremen (hh:mm)	t Systolic (mmHg)	Diastolic (mmHg)	1
10 Mins			•	<b>&gt;&gt;</b>	»	<b>&gt;</b>
2 Mins		<b>3</b>	•	<b>3</b>	<b>&gt;&gt;</b>	<b>3</b> >
<b>≫</b> Result	Normal Abnormal					
Clinically Significant	C Yes C No					
Abnormal Finding/						
Relevant Comments						



Trial: **OP109219\_JP-2266-101-FIH\_A (v.2.0)** 

Event: **P2 D2 [P2D2]** 

Page: 12 Lead ECG (T24h) [EG]

12 LEAD ECG (T24	HOUR)
Time Point	T24h
<b>▶</b> ECG Performed?	C Yes C No
▶If No,Specify	
<b>▶</b> Date of ECG	
<b>≫</b> Time of ECG	
▶ Heart Rate (Beats/min)	
▶PR (ms)	
<b>&gt;</b> QRS (ms)	
<b>≫</b> QT (ms)	
<b>▶</b> QTcF (ms)	
➤ Conclusion Result	Normal Abnormal
Clinically Significant?	C Yes C No
Abnormality Finding / Relevant Comment	



Trial: **OP109219\_JP-2266-101-FIH\_A (v.2.0)** 

Event: **P2 D2 [P2D2]**Page: **PE (T36h) [PE]** 

PHYSICAL EXAMINATION (T36h)	
Time Point	T36h
<b>▶</b> Did the Physical Examination performed?	C Yes C No
If No,specify	
Date Performed	
→Time performed	
<b>≫</b> Results	C Normal C Abnormal
→ Abnormal Physical Finding	
➤ Clinically Significant?	O Yes O No



Event: **P2 D2 [P2D2]** 

Page: Blood Sample for PK [PK]

BLOOD SAMPLE FOR PK		
Time Point Sample Collected?	Schedule Date & Time	Time window (min) Meal restriction respected?
T24h Yes No	» » »	+/- 15 Mins Yes No Unknown
T36h → C Yes C No	» » »	+/- 15 Mins » C Yes C No C Unknown
Comment		



Trial: **OP109219\_JP-2266-101-FIH\_A (v.2.0)** 

Event: **P2 D2 [P2D2]** 

Page: Blood Sample for PD [PD]

BLOOD S	AMPLE FOR PD			
Time Point	Sample Collected?  Yes No	Schedule Date & Time	Actual Date & Actual Time	Time window (min) +/- 15 Mins
Comment				



Event: **P2 D2 [P2D2]** 

Page: Urine Sample PK & PD [URPKPD]

URINE SAMPLE FOR PK & PD					
Time Interval Sample Collected?  ]T12H-T24H] ➤ ↑ Yes ↑ No	Start Date	Start Time	End Date	End Time	Urine vol(g) Urine vol(ml)  ➤
]T24H-T48H] >> ( Yes ( No		₩	33-	<b>&gt;&gt;</b>	<b>3</b>
Comment					



OP109219\_JP-2266-101-FIH\_A (v.2.0) P2 D3 Event:

P2 D3 [P2\_D3]

Page: Visit Date [SV]

VISIT DATI	<b>=</b>
<b>≫</b> Date of Visit	



Event: **P2 D3 [P2\_D3]** 

Page: Vital Signs (T48h) [VS]

VITAL SIGNS (T4	18 HOUR)					
Time Point	T48h					
▶Vitals collected?	C Yes C No					
▶If No,Specify						
▶Date of measuremen	ts					
Blood Pressure and	l Heart Rate					
After	Position	Actual Time Position (hh:mm)	Actual Time Measurement (hh:mm)	Systolic (mmHg)	Diastolic (mmHg)	Heart rate (bpm)
10 Mins		<b>&gt;&gt;</b>	<b>*</b>	<b>&gt;&gt;</b>	<b>&gt;&gt;</b>	<b>&gt;&gt;</b>
2 Mins		<b>3</b>	<b>&gt;</b>	<b>3</b>	<b>»</b>	<b>&gt;&gt;</b>
<b>≫</b> Result	C Normal C Abnormal					
Clinically Significant	C Yes C No					
Abnormal Finding/ Relevant Comments						



Event: **P2 D3 [P2\_D3]** 

Page: Blood Sample for PK [PK]

BLOOD SAMPLE FOR PK		
Time Point Sample Collected?	Schedule Date & Time Actual Date & Actual Time	Time window (min)  Meal restriction respected?
T48h → C Yes C No	35 35	+/- 15 Mins Yes No Unknown
Comment		



Trial: **OP109219\_JP-2266-101-FIH\_A (v.2.0)** 

Event: **P2 D3 [P2\_D3]** 

Page: Blood Sample for PD [PD]

BLOOD SA	AMPLE FOR PD			
Time Point	Sample Collected?  Yes No	Schedule Date & Time	Actual Date & Actual Time	Time window (min) +/- 15 Mins
Comment				



Trial: OP109219\_JP-2266-101-FIH\_A (v.2.0)

Event: **P2 D3 [P2\_D3]** 

Page: Urine Sample PK & PD [URPKPD]

URINE SAMPLE FOR PK & PD		
Time Interval     Sample Collected?     Start Date       ]T48H-T72H]     ➤ ☐ Yes ☐ No     ➤	Start Time End Date	End Time Urine vol(g) Urine vol(ml)
Comment		



OP109219\_JP-2266-101-FIH\_A (v.2.0) P2 D4

Event: **P2 D4 [P2\_D4]** 

Page: Visit Date [SV]

VISIT DATI	E
<b>▶</b> Date of Visit	



Event: **P2 D4 [P2\_D4]** 

Page: Vital Signs (T72h) [VS]

VITAL SIGNS (T7	2 HOUR)					
Time Point	T72h					
➤ Vitals collected?	C Yes C No					
▶If No,Specify						
Date of measurement	s					
Blood Pressure and	Heart Rate					
After	Position	Actual Time Position (hh:mm)	Actual Time Measurement (hh:mm)	Systolic (mmHg)	Diastolic (mmHg)	Hear (bp:
10 Mins				(IIIIIII)	<b>→</b>	<b>≫</b>
2 Mins		<b>3</b> >	<b>≫</b>	<b>•</b>	<b>3</b>	<b>30</b>
<b>&gt;&gt;</b> Result	Normal Abnormal					
Clinically Significant	C Yes C No					
Abnormal Finding/						
Relevant Comments						



Event: **P2 D4 [P2\_D4]** 

Page: Blood Sample for PK [PK]

BLOOD SAMPLE FOR PK		
Time Point Sample Collected?	Schedule Date & Time Actual Date & Actual Time	Time window (min) Meal restriction respected?
T72h >> ( Yes ( No	35 35	+/- 15 Mins >> ( Yes ( No ( Unknown
Comment		



Trial: **OP109219\_JP-2266-101-FIH\_A (v.2.0)** 

Event: **P2 D4 [P2\_D4]** 

Page: Blood Sample for PD [PD]

BLOOD SAMPI	LE FOR PD			
Time Point Sai	mple Collected?	Schedule Date & Time	Actual Date & Actual T	ime Time window (min)
T72h <b>→</b> (	Yes 🔿 No		<b>&gt;&gt;</b>	+/- 15 Mins
Comment				



Event: **P2 D4 [P2\_D4]** 

Page: Urine Sample PD [URPKPD]

URINE SAMPLE FOR PD		
Time Interval     Sample Collected?     Start Date       ]T72H-T96H]     → ( Yes ( No ) No )	Start Time End Date	End Time Urine vol(g) Urine vol(ml)
Comment		



OP109219\_JP-2266-101-FIH\_A (v.2.0) P2 D5 Event:

P2 D5 [P2D5]

Page: Visit Date [SV]

VISIT DATE	Ξ
<b>&gt;&gt;</b> Date of Visit	



Trial: **OP109219\_JP-2266-101-FIH\_A (v.2.0)** 

Event: **P2 D5 [P2D5]**Page: **PE (T96h) [PE]** 

PHYSICAL EXAMINATION (T96h)	
Time Point	T96h
<b>▶</b> Did the Physical Examination performed?	C Yes C No
If No,specify	
<b>&gt;</b> Date Performed	
→Time performed	
<b>≫</b> Results	Normal Abnormal
<b>▶</b> Abnormal Physical Finding	
➤Clinically Significant?	○ Yes ○ No



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Trial: **OP109219\_JP-2266-101-FIH\_A (v.2.0)** 

Event: **P2 D5 [P2D5]** 

Page: Hematology (T96h) [LH]

HEMATOLOGY (T96 HOUR)				
ne Point T96h				
Sample Collected?	ſ			
If No,Specify				
Date of Collection				
Time of Collection				
Parameter Name	Result	Uni	it	it LLN
Red Blood Cells (RBC)				
·Hemoglobin			]	
·Hematocrit				
Mean Corpuscular Volume (MCV)				
Mean Corpuscular Hemoglobin (MCH)				
Mean Corpuscular Hemoglobin Concentration	n (MCHC)			
White Blood Cells (WBC)				
Neutrophils				
Eosinophils				

<b>≫</b> Basophils			Normal Abnormal NCS Abnormal CS Not Done
<b>≫</b> Lymphocytes		<b>3</b>	Normal Abnormal NCS Abnormal CS Not Done
<b>≫</b> Monocytes		<b>3</b>	Normal Abnormal NCS Abnormal CS Not Done
▶Platelet count		3>	Normal Abnormal NCS Abnormal CS Not Done
Comment			



Trial: **OP109219\_JP-2266-101-FIH\_A (v.2.0)** 

Event: **P2 D5 [P2D5]** 

Page: Coagulation (T96h) [LT]

T96h				
C Yes C No				
Result	Unit	LLN	ULN	Assessment
				Normal Abnormal NCS Abnormal CS Not Done
				Normal Abnormal NCS Abnormal CS Not Done
				Normal Abnormal NCS Abnormal CS Not Done
,		C Yes C No	C Yes C No	C Yes C No



Trial: **OP109219\_JP-2266-101-FIH\_A (v.2.0)** 

Event: **P2 D5 [P2D5]** 

Page: Biochemistry (T96h) [LC]

BIOCHEMISTRY (T96h)						
Time Point T96h						
➤ Sample Collected?						
▶If No,Specify						
▶ Fasting State	Unknown					
<b>▶</b> Date of Collection						
<b>▶</b> Time of Collection						
Parameter Name	Symbol	Results	Units	LLN	ULN	Assessment
Fasting Glucose		<b>3</b>				Normal Abnormal NCS Abnormal CS Not Done
Creatinine		<b>»</b>			1	Normal Abnormal NCS Abnormal CS Not Done
Urea		<b>»</b>				Normal Abnormal NCS Abnormal CS Not Done
Blood Urea Nitrogen (BUN)		»			1	Normal Abnormal NCS Abnormal CS Not Done
Creatinine clearance		<b>3</b> >			1	Normal Abnormal NCS Abnormal CS Not Done
Alanine Serine Transferase (AST)		<b>3</b>				Normal Abnormal NCS Abnormal CS Not Done
Alanine Leucine Transferase (ALT)		<b>3</b>				Normal Abnormal NCS Abnormal CS Not Done
Gamma Glutamyl Transferase (GGT)	< <= > >=	<b>30</b>				Normal Abnormal NCS Abnormal CS Not Done

Alkaline Phosphatases (ALP)		<b>»</b>			Normal Abnormal NCS Abnormal CS Not Done
Lactate Dehydrogenase (LDH)		<b>&gt;&gt;</b>			Normal Abnormal NCS Abnormal CS Not Done
Creatine Phosphokinase (CPK)		<b>&gt;&gt;</b>		,	Normal Abnormal NCS Abnormal CS Not Done
Lipase		<b>3</b> >			Normal Abnormal NCS Abnormal CS Not Done
Total Bilirubin	< <= >> >=	<b>&gt;&gt;</b>			Normal Abnormal NCS Abnormal CS Not Done
Conjugated Bilirubin	< <= > >=	<b>&gt;&gt;</b>			Normal Abnormal NCS Abnormal CS Not Done
Unconjugated Bilirubin	< <= > >=	<b>&gt;&gt;</b>			Normal Abnormal NCS Abnormal CS Not Done
Total Cholesterol		<b>&gt;&gt;</b>			Normal Abnormal NCS Abnormal CS Not Done
Triglycerides	< <= >> >=	<b>»</b>			Normal Abnormal NCS Abnormal CS Not Done
Sodium		<b>»</b>		,	Normal Abnormal NCS Abnormal CS Not Done
Potassium		<b>»</b>			Normal Abnormal NCS Abnormal CS Not Done
Chloride		<b>&gt;&gt;</b>			Normal Abnormal NCS Abnormal CS Not Done

Calcium	<b>3</b>		•	Normal Abnormal NCS Abnormal CS Not Done
Phosphorus	3>		<b>&gt;&gt;</b>	Normal Abnormal NCS Abnormal CS Not Done
Total Protein	<b>3</b>		<b>&gt;&gt;</b>	Normal Abnormal NCS Abnormal CS Not Done
Comment				



Trial: **OP109219\_JP-2266-101-FIH\_A (v.2.0)** 

Event: **P2 D5 [P2D5]** 

Page: Urinalysis (T96h) [UR]

URINALYSIS (T	96h)				
Time Point	T96h				
➤ Sample Collected?	C Yes C	) No			
► If No, Specify					
▶ Date of Collection					
⇒Time of Collection					
Parameter Name	Symbol	Results	LLN	ULN	Assessmer
Glucose		<ul><li>Positive</li><li>Negative</li></ul>		1	Normal Abnormal Abnormal Not Done
Proteins		<ul><li>Positive</li><li>Negative</li></ul>		1	Normal Abnormal Abnormal Not Done
Ketones		Positive Negative		1	Normal Abnormal Abnormal Not Done
Occult Blood		<ul><li>Positive</li><li>Negative</li></ul>		1	Normal Abnormal Abnormal Not Done
Bilirubin		Positive Negative		1	Normal Abnormal Abnormal Not Done
Urobilinogen		<ul><li>Positive</li><li>Negative</li></ul>		1	Normal Abnormal Abnormal Not Done
рН		<b>»</b>			Normal Abnormal Abnormal Not Done
Nitrites		Positive Negative		1	Normal Abnormal Abnormal Not Done
Specific Gravity	< <= >> >=	<b>3</b> >		1	Normal Abnormal Abnormal Not Done

White Blood (	Positive Cells  Negative	Normal Abnormal NCS Abnormal CS Not Done	
Comments			

MICROSCOPIC RES	elli Te				
Parameter Name	Results	Units	LLN	ULN	Assessment
<b>≫</b> Micr: Glucose					Normal Abnormal NCS Abnormal CS Not Done
<b>&gt;&gt;</b> Micr: Protein					Normal Abnormal NCS Abnormal CS Not Done
➤Micr: Red Blood Cells					Normal Abnormal NCS Abnormal CS Not Done
➤Micr: White Blood Cells					Normal Abnormal NCS Abnormal CS Not Done
<b>≫</b> Micr: Crystals	<ul><li>Positive</li><li>Negative</li></ul>				Normal Abnormal NCS Abnormal CS Not Done
<b>≫</b> Epithelial Cells	<ul><li>Positive</li><li>Negative</li></ul>				Normal Abnormal NCS Abnormal CS Not Done
<b>≫</b> Epithelial Renal Cells	Positive Negative				Normal Abnormal NCS Abnormal CS Not Done
<b>≫</b> Bacteria	Positive Negative				Normal Abnormal NCS Abnormal CS Not Done
<b>≫</b> Casts	Positive Negative				Normal Abnormal NCS Abnormal CS Not Done

Comments	
ı	



Trial: **OP109219\_JP-2266-101-FIH\_A (v.2.0)** 

Event: **P2 D5 [P2D5]** 

Page: Urine electrol(T96h) [URE]

URINE ELECT	ROLYTES TEST (T9	6h)			
Time Point			T96h		
<b>≫</b> Sample Collected?			C Yes C No		
► If No,Specify				-	
<b>&gt;&gt;</b> Date of Collection					
<b>≫</b> Time of Collection					
Parameter Name	Results	Units	LLN	ULN	Assessment
<b>≫</b> Calcium					Normal Abnormal NCS Abnormal CS Not Done
<b>≫</b> Phosphorus					Normal Abnormal NCS Abnormal CS Not Done
<b>≫</b> Sodium					Normal Abnormal NCS Abnormal CS Not Done
<b>≫</b> Potassium					Normal Abnormal NCS Abnormal CS Not Done
<b>&gt;&gt;</b> Chloride					Normal Abnormal NCS Abnormal CS Not Done
Comments					



Event: **P2 D5 [P2D5]** 

Page: Vital Signs (T96h) [VS]

VITAL SIGNS (TS) Time Point  ➤ Vitals collected?  ➤ If No,Specify  ➤ Date of measurement	T96h Yes No					
Blood Pressure and	i Heart Rate Position	Actual Time Position		•	Diastolic	Heart rate
10 Mins		(hh:mm) <b>&gt;&gt;</b>	(hh:mm) <b>▶</b>	(mmHg) <b>&gt;&gt;</b>	(mmHg) <b>▶</b>	(bpm) <b>→</b>
2 Mins		20	<b>&gt;&gt;</b>	20-	<b>»</b>	<b>3</b>
<b>≫</b> Result	O Normal O Abnormal					
Clinically Significant	C Yes C No					
Abnormal Finding/ Relevant Comments						



Trial: **OP109219\_JP-2266-101-FIH\_A (v.2.0)** 

Event: **P2 D5 [P2D5]** 

Page: 12 Lead ECG (T96h) [EG]

12 LEAD ECG (T96	HOUR)
Time Point	T96h
<b>▶</b> ECG Performed?	C Yes C No
▶If No,Specify	
<b>▶</b> Date of ECG	
<b>≫</b> Time of ECG	
→ Heart Rate (Beats/min)	
▶PR (ms)	
<b>&gt;</b> QRS (ms)	
<b>&gt;</b> QT (ms)	
<b>&gt;</b> QTcF (ms)	
Conclusion Result	Normal Abnormal
Clinically Significant?	C Yes C No
Abnormality Finding / Relevant Comment	



Trial: **OP109219\_JP-2266-101-FIH\_A (v.2.0)** 

D10 Event: P2 D10 [P2D10]
Page: Visit Date [SV]

P2

VISIT DATE	<b></b>
<b>▶</b> Date of Visit	



Trial: **OP109219\_JP-2266-101-FIH\_A (v.2.0)** 

Event: **P2 D10 [P2D10]** 

Page: Physical Examination [PE]

PHYSICAL EXAMINATION	
<b>▶</b> Did the Physical Examination performed?	C Yes C No
<b>▶</b> If No,specify	
<b>≫</b> Date Performed	
<b>≫</b> Results	C Normal C Abnormal
→ Abnormal Physical Finding	
➤ Clinically Significant?	C Yes C No
<b>&gt;&gt;</b> Weight	kg



Trial: **OP109219\_JP-2266-101-FIH\_A (v.2.0)** 

Event: P2 D10 [P2D10]
Page: Hematology [LH]

HEMATOLOGY					
➤Sample Collected?					
▶If No,Specify					
<b>▶</b> Date of Collection					
<b>▶</b> Time of Collection					
Parameter Name	Result	Unit	LLN	ULN	Assessment
▶Red Blood Cells (RBC)				<b>&gt;</b>	Normal Abnormal NCS Abnormal CS Not Done
<b>&gt;&gt;</b> Hemoglobin				3>	Normal Abnormal NCS Abnormal CS Not Done
<b>&gt;&gt;</b> Hematocrit				<b>3</b> >	Normal Abnormal NCS Abnormal CS Not Done
➤ Mean Corpuscular Volume (MCV)				<b>&gt;&gt;</b>	Normal Abnormal NCS Abnormal CS Not Done
➤Mean Corpuscular Hemoglobin (MCH)				<b>&gt;&gt;</b>	Normal Abnormal NCS Abnormal CS Not Done
▶Mean Corpuscular Hemoglobin Concentration (MCHC)				<b>&gt;&gt;</b>	Normal Abnormal NCS Abnormal CS Not Done
<b>&gt;&gt;</b> White Blood Cells (WBC)				**	Normal Abnormal NCS Abnormal CS Not Done
<b>▶</b> Neutrophils				<b>&gt;&gt;</b>	Normal Abnormal NCS Abnormal CS Not Done
<b>≫</b> Eosinophils				<b>&gt;&gt;</b>	Normal Abnormal NCS Abnormal CS Not Done

<b>≫</b> Basophils			Normal Abnormal NCS Abnormal CS Not Done
<b>≫</b> Lymphocytes		35	Normal Abnormal NCS Abnormal CS Not Done
<b>≫</b> Monocytes		<b>3</b> >	Normal Abnormal NCS Abnormal CS Not Done
▶Platelet count		3>	Normal Abnormal NCS Abnormal CS Not Done
Comment			



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Trial: **OP109219\_JP-2266-101-FIH\_A (v.2.0)** 

Event: **P2 D10 [P2D10]**Page: **Coagulation [LT]** 

COAGULATION					
▶Sample Collected?	C Yes C No				
▶If No,Specify					
<b>▶</b> Date of Collection (dd-mmm-yyyy)					
▶Time of Collection (hh:mm)					
Parameter Name	Result	Unit	LLN	ULN	Assessment
▶Prothrombin time (PT)					Normal Abnormal NCS Abnormal CS Not Done
➤International normalized ratio (INR)					Normal Abnormal NCS Abnormal CS Not Done
<b>≫</b> aPTT(ratio)					Normal Abnormal NCS Abnormal CS Not Done



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Trial: **OP109219\_JP-2266-101-FIH\_A (v.2.0)** 

Event: P2 D10 [P2D10]
Page: Biochemistry [LC]

BIOCHEMISTRY						
▶Sample Collected?						
<b>▶</b> If No,Specify						
▶ Fasting State    \( \text{Yes} \)   \( \text{No} \)   \( \text{O} \)	nknown					
<b>▶</b> Date of Collection						
<b>≫</b> Time of Collection						
Parameter Name S	Symbol	Results	Units	LLN	ULN	Assessment
Fasting Glucose		<b>»</b>			<b>&gt;&gt;</b>	Normal Abnormal NCS Abnormal CS Not Done
Creatinine		<b>&gt;&gt;</b>			<b>&gt;&gt;</b>	Normal Abnormal NCS Abnormal CS Not Done
Urea		<b>3</b>			<b>&gt;&gt;</b>	Normal Abnormal NCS Abnormal CS Not Done
Blood Urea Nitrogen (BUN)		<b>3</b>			<b>&gt;</b>	Normal Abnormal NCS Abnormal CS Not Done
Creatinine clearance		<b>3</b> >			<b>&gt;</b>	Normal Abnormal NCS Abnormal CS Not Done
Alanine Serine Transferase (AST)		<b>&gt;&gt;</b>			<b>&gt;&gt;</b>	Normal Abnormal NCS Abnormal CS Not Done
Alanine Leucine Transferase (ALT)		<b>&gt;&gt;</b>			<b>&gt;&gt;</b>	Normal Abnormal NCS Abnormal CS Not Done
Gamma Glutamyl Transferase (GGT)	< <= >> >=	<b>&gt;&gt;</b>			<b>&gt;&gt;</b>	Normal Abnormal NCS Abnormal CS Not Done
Alkaline Phosphatases (ALP)		<b>»</b>			<b>&gt;</b>	Normal Abnormal NCS Abnormal CS Not Done

Lactate Dehydrogenase (LDH)		<b>»</b>		3)	Normal Abnormal NCS Abnormal CS Not Done
Creatine Phosphokinase (CPK)		<b>»</b>		<b>3</b>	Normal Abnormal NCS Abnormal CS Not Done
Lipase		<b>3</b> >		2)	Normal Abnormal NCS Abnormal CS Not Done
Total Bilirubin	< <= >> =	<b>&gt;&gt;</b>		<b>3</b>	Normal Abnormal NCS Abnormal CS Not Done
Conjugated Bilirubin	< <= >> =	<b>&gt;&gt;</b>		<b>3</b>	Normal Abnormal NCS Abnormal CS Not Done
Unconjugated Bilirubin	< <= >> =	<b>»</b>		<b>3</b> 1	Normal Abnormal NCS Abnormal CS Not Done
Total Cholesterol		<b>&gt;&gt;</b>		<b>3</b> )	Normal Abnormal NCS Abnormal CS Not Done
Triglycerides	< <= >> =	<b>»</b>		<b>3</b> )	Normal Abnormal NCS Abnormal CS Not Done
Sodium		<b>33</b>		<b>3</b> )	Normal Abnormal NCS Abnormal CS Not Done
Potassium		<b>»</b>		<b>3</b>	Normal Abnormal NCS Abnormal CS Not Done
Chloride		<b>&gt;&gt;</b>		3)	Normal Abnormal NCS Abnormal CS Not Done
Calcium		<b>»</b>		3)	Normal Abnormal NCS Abnormal CS Not Done

Phosphorus	3)			Normal Abnormal NCS Abnormal CS Not Done
Total Protein	36		<b>&gt;&gt;</b>	Normal Abnormal NCS Abnormal CS Not Done
Comment				



Trial: **OP109219\_JP-2266-101-FIH\_A (v.2.0)** 

Event: P2 D10 [P2D10]
Page: Urinalysis [UR]

URINALYSIS					
Sample Collected?	C Yes (	<sup>↑</sup> No			
▶If No,Specify					
<b>&gt;&gt;</b> Date of Collection					
▶Time of Collection					
Parameter Name	Symbol	Results	LLN	ULN	Assessment
		© Desitive		3	Normal
Glucose		Positive			Abnormal NCS
		Negative			Abnormal CS Not Done
		Positive		_	Normal Abnormal NCS
Proteins		Negative	1		Abnormal CS
					Not Done
		C Desirius		3	Normal
Ketones		<ul><li>Positive</li><li>Negative</li></ul>			Abnormal NCS Abnormal CS
		Negative			Not Done
				3	
		Positive		_	Normal Abnormal NCS
Occult Blood		Negative			Abnormal CS
					Not Done
		➤ ○ Positive		3	Normal
Bilirubin		Negative	ı		Abnormal NCS Abnormal CS
		Nogalive			Not Done
				3	
		Positive			Normal Abnormal NCS
Urobilinogen		Negative			Abnormal CS
					Not Done
					Normal
рН		<b>&gt;&gt;</b>			Abnormal NCS Abnormal CS
					Not Done
				3	Normal
Nitrites		Positive			Normal Abnormal NCS
Millies		Negative			Abnormal CS Not Done
	<				Normal
Specific Gravity	>	<b>&gt;&gt;</b>			Abnormal NCS Abnormal CS
	>=				Not Done

White Blood Cells	Positive Negative	Normal Abnormal NCS Abnormal CS Not Done	
Comments			

MICROSCOPIC RES	Results	Units	LLN	ULN	Assessment
<b>≫</b> Micr: Glucose					Normal Abnormal NCS Abnormal CS Not Done
<b>≫</b> Micr: Protein					Normal Abnormal NCS Abnormal CS Not Done
<b>≫</b> Micr: Red Blood Cells					Normal Abnormal NCS Abnormal CS Not Done
Micr: White Blood Cells					Normal Abnormal NCS Abnormal CS Not Done
<b>≫</b> Micr: Crystals	Positive Negative				Normal Abnormal NCS Abnormal CS Not Done
<b>≫</b> Epithelial Cells	<ul><li>Positive</li><li>Negative</li></ul>				Normal Abnormal NCS Abnormal CS Not Done
<b>≫</b> Epithelial Renal Cells	Positive Negative				Normal Abnormal NCS Abnormal CS Not Done
<b>≫</b> Bacteria	Positive Negative				Normal Abnormal NCS Abnormal CS Not Done
<b>▶</b> Casts	Positive Negative				Normal Abnormal NCS Abnormal CS Not Done

Comments		



Trial: **OP109219\_JP-2266-101-FIH\_A (v.2.0)** 

Event: **P2 D10 [P2D10]** 

Page: Urine electro test [URE]

JIMIL LLLOTHOL	LYTES TEST				
Sample Collected?		_	C Yes C No		
▶If No,Specify		Γ			
<b>▶</b> Date of Collection					
▶Time of Collection		Γ			
Parameter Name	Results	Units	LLN	ULN	Assessment
<b>≫</b> Calcium					Normal Abnormal NCS Abnormal CS Not Done
<b>≫</b> Phosphorus					Normal Abnormal NCS Abnormal CS Not Done
<b>≫</b> Sodium					Normal Abnormal NCS Abnormal CS Not Done
<b>≫</b> Potassium					Normal Abnormal NCS Abnormal CS Not Done
<b>&gt;&gt;</b> Chloride					Normal Abnormal NCS Abnormal CS Not Done



Trial: **OP109219\_JP-2266-101-FIH\_A (v.2.0)** 

Event: P2 D10 [P2D10]
Page: Vital Signs [VS]

VITAL SIGNS					
▶Vitals collected?	C Yes C No				
■If No,Specify					
Date of measurements					
■Body Temperature (°C)					
<b>▶</b> Result	Normal Abnorm	nal			
Clinically Significant	C Yes C No				
Blood Pressure and	Heart Rate				
		Actual Time Position		nent Systolic	Diastolic
After	Heart Rate Position	(hh:mm)	(hh:mm)	(mmHg)	(mmHg)
		(hh:mm)		•	
After 10 Mins 2 Mins		(hh:mm)	(hh:mm) <b>&gt;&gt;</b>	(mmHg) <b>▶</b>	(mmHg)
After 10 Mins 2 Mins	Position  Normal Abnormal	(hh:mm)	(hh:mm) <b>&gt;&gt;</b>	(mmHg) <b>▶</b>	(mmHg)



Trial: **OP109219\_JP-2266-101-FIH\_A (v.2.0)** 

Event: **P2 D10 [P2D10]**Page: **12 Lead ECG [EG]** 

12 LEAD ECG	
▶ECG Performed?	C Yes C No
▶If No,Specify	
<b>▶</b> Date of ECG	
<b>▶</b> Time of ECG	
→ Heart Rate (Beats/min)	
▶PR (ms)	
<b>&gt;</b> QRS (ms)	
<b>&gt;</b> QT (ms)	
<b>▶</b> QTcF (ms)	
Conclusion Result	Normal Abnormal
Clinically Significant?	C Yes C No
Abnormality Finding / Relevant Comment	



Trial: **OP109219\_JP-2266-101-FIH\_A (v.2.0)** 

Event: **P2 D10 [P2D10]** 

Page: Study Restriction [SR]

STUDY RESTRICTIONS
▶ Did the subject respect the study restrictions throughout the course of the study?
▶If no, Please Clarify



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Trial: **OP109219\_JP-2266-101-FIH\_A (v.2.0)** 

Event: **P2 D10 [P2D10]** 

Page: Study Comments [CO]

STUDY C	COMMENTS
Comments	



Trial: **OP109219\_JP-2266-101-FIH\_A (v.2.0)** 

Event: **P2 D10 [P2D10]** 

Page: Study Completion [DS]

STUDY COMPLETION	
<b>&gt;&gt;</b> Completion/Discontinuation Date	
<b>&gt;</b> Status	Completed
	Adverse Event
	C Lost to Follow-Up
	Withdrawal by Subject
	Physician Decision
	C Death
	Protocol Violation
	Study Terminated by Sponsor
	Other
⇒If Other Specify	



### UNS Physical

Sponsor: JEIL Pharmaceutical Co., Ltd.

Trial: OP109219\_JP-2266-101-FIH\_A (v.2.0)

Event: UNS Physical Examination [UNSPE]

Examination Page: Physical Examination [PE]

PHYSICAL EXAMINATION	
<b>≫</b> Did the Physical Examination performed?	C Yes C No
Date Performed	
<b>≫</b> Results	C Normal C Abnormal
▶Abnormal Physical Finding	
➤ Clinically Significant?	C Yes C No



### UNS Hematology

Sponsor: JEIL Pharmaceutical Co., Ltd.

Trial: **OP109219\_JP-2266-101-FIH\_A (v.2.0)** 

Event: UNS Hematology [UNSLH]

Page: Hematology [LH]

HEMATOLOGY					
▶Sample Collected?   Ĉ Yes   Ĉ No					
Date of Collection □					
Time of Collection					
Parameter Name	Result	Unit	LLN	ULN	Assessment
Red Blood Cells (RBC)					Normal Abnormal NCS Abnormal CS Not Done
Hemoglobin					Normal Abnormal NCS Abnormal CS Not Done
Hematocrit					Normal Abnormal NCS Abnormal CS Not Done
Mean Corpuscular Volume (MCV)					Normal Abnormal NCS Abnormal CS Not Done
Mean Corpuscular Hemoglobin (MCH)					Normal Abnormal NCS Abnormal CS Not Done
Mean Corpuscular Hemoglobin Concentration (MCHC	C)				Normal Abnormal NCS Abnormal CS Not Done
White Blood Cells (WBC)					Normal Abnormal NCS Abnormal CS Not Done
Neutrophils					Normal Abnormal NCS Abnormal CS Not Done
Eosinophils					Normal Abnormal NCS Abnormal CS Not Done

Basophils		<b>&gt;&gt;</b>	Normal Abnormal NCS Abnormal CS Not Done
Lymphocytes		<b>3</b> >	Normal Abnormal NCS Abnormal CS Not Done
Monocytes		<b>&gt;&gt;</b>	Normal Abnormal NCS Abnormal CS Not Done
Platelet count		3>	Normal Abnormal NCS Abnormal CS Not Done
Comment			



### UNS Biochemistry

Sponsor: JEIL Pharmaceutical Co., Ltd.

Trial: **OP109219\_JP-2266-101-FIH\_A (v.2.0)** 

Event: UNS Biochemistry [UNSLC]

Page: Biochemistry [LC]

BIOCHEMISTRY						
<b>≫</b> Sample Collected?						
▶ Fasting State	Unknown					
▶Date of Collection						
▶Time of Collection						
Parameter Name	Symbol	Results	Units	LLN	ULN	Assessment
						Normal
Fasting Glucose						Abnormal NCS Abnormal CS
						Not Done
						Normal
Creatinine						Abnormal NCS
						Abnormal CS Not Done
					<b>3</b>	
						Normal Abnormal NCS
Urea		1				Abnormal CS
						Not Done
						Normal
Blood Urea Nitrogen (BUN)						Abnormal NCS Abnormal CS
						Not Done
						Normal
Creatinine clearance						Abnormal NCS
						Abnormal CS Not Done
Alasia - Ossia - Transfers - (AOT)						Normal Abnormal NCS
Alanine Serine Transferase (AST)		1				Abnormal CS Not Done
						Not Done
						Normal
Alanine Leucine Transferase (ALT)						Abnormal NCS Abnormal CS
						Not Done
	<					Normal
Gamma Glutamyl Transferase (GGT)	<=					Abnormal NCS Abnormal CS
	>=					Not Done
						Normal
Alkaline Phosphatases (ALP)						Normal Abnormal NCS
Amamo i noophalasos (ALI )						Abnormal CS Not Done
						1

Lactate Dehydrogenase (LDH)			•	Normal Abnormal NCS Abnormal CS Not Done
Creatine Phosphokinase (CPK)				Normal Abnormal NCS Abnormal CS Not Done
Lipase				Normal Abnormal NCS Abnormal CS Not Done
Total Bilirubin	< <= > >=			Normal Abnormal NCS Abnormal CS Not Done
Conjugated Bilirubin	< <= >> >=			Normal Abnormal NCS Abnormal CS Not Done
Unconjugated Bilirubin	<=			Normal Abnormal NCS Abnormal CS Not Done
Total Cholesterol				Normal Abnormal NCS Abnormal CS Not Done
riglycerides	<=			Normal Abnormal NCS Abnormal CS Not Done
Sodium				Normal Abnormal NCS Abnormal CS Not Done
Potassium				Normal Abnormal NCS Abnormal CS Not Done
Chloride				Normal Abnormal NCS Abnormal CS Not Done
Calcium				Normal Abnormal NCS Abnormal CS Not Done

Phosphorus			Normal Abnormal NCS Abnormal CS Not Done
Total Protein		<b>&gt;&gt;</b>	Normal Abnormal NCS Abnormal CS Not Done
Comment			



### UNS Urinalysis

Sponsor: JEIL Pharmaceutical Co., Ltd.

Trial: **OP109219\_JP-2266-101-FIH\_A (v.2.0)** 

Event: UNS Urinalysis [UNSUR]

Page: Urinalysis [UR]

URINALYSIS					
Sample Collected?	C Yes C No	)			
<b>≫</b> Date of Collection					
➡Time of Collection					
Parameter Name	Symbol I	Results	LLN	ULN	Assessment
Glucose		Positive Negative		•	Normal Abnormal NCS Abnormal CS Not Done
Proteins		<ul><li>Positive</li><li>Negative</li></ul>		•	Normal Abnormal NCS Abnormal CS Not Done
Ketones		<ul><li>Positive</li><li>Negative</li></ul>		,	Normal Abnormal NCS Abnormal CS Not Done
Occult Blood		<ul><li>Positive</li><li>Negative</li></ul>		•	Normal Abnormal NCS Abnormal CS Not Done
Bilirubin		<ul><li>Positive</li><li>Negative</li></ul>		,	Normal Abnormal NCS Abnormal CS Not Done
Urobilinogen		<ul><li>Positive</li><li>Negative</li></ul>		•	Normal Abnormal NCS Abnormal CS Not Done
рН					Normal Abnormal NCS Abnormal CS Not Done
Nitrites	_	<ul><li>Positive</li><li>Negative</li></ul>		•	Normal Abnormal NCS Abnormal CS Not Done
Specific Gravity	< <= >> >=				Normal Abnormal NCS Abnormal CS Not Done

White Blood Cells	<ul><li>Positive</li><li>Negative</li></ul>	Normal Abnormal NCS Abnormal CS Not Done
Comments		

MICROSCOPIC RESULTS									
Parameter Name	Results	Units	LLN	ULN	Assessment				
Micr: Glucose					Normal Abnormal NCS Abnormal CS Not Done				
Micr: Protein					Normal Abnormal NCS Abnormal CS Not Done				
Micr: Red Blood Cells					Normal Abnormal NCS Abnormal CS Not Done				
Micr: White Blood Cells					Normal Abnormal NCS Abnormal CS Not Done				
Micr: Crystals	<ul><li>Positive</li><li>Negative</li></ul>				Normal Abnormal NCS Abnormal CS Not Done				
Epithelial Cells	Positive Negative				Normal Abnormal NCS Abnormal CS Not Done				
Epithelial Renal Cells	<ul><li>Positive</li><li>Negative</li></ul>				Normal Abnormal NCS Abnormal CS Not Done				
Bacteria	Positive Negative				Normal Abnormal NCS Abnormal CS Not Done				
Casts	Positive Negative				Normal Abnormal NCS Abnormal CS Not Done				

Comments	
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UNS

Sponsor: JEIL Pharmaceutical Co., Ltd.

Urine

OP109219\_JP-2266-101-FIH\_A (v.2.0)

electro

Event: UNS Urine electro test [UNS\_ELECTRO]

test

Page:

Urine electro test [URE]

LYTES TEST				
		C Yes	○ No	
			_	
		I		
Results	Units	LLN	ULN	Assessment
				Normal Abnormal NCS Abnormal CS Not Done
				Normal Abnormal NCS Abnormal CS Not Done
				Normal Abnormal NCS Abnormal CS Not Done
				Normal Abnormal NCS Abnormal CS Not Done
				Normal Abnormal NCS Abnormal CS Not Done
			© Yes	C Yes C No



# UNS Coagulation

Sponsor: JEIL Pharmaceutical Co., Ltd.

Trial: OP109219\_JP-2266-101-FIH\_A (v.2.0)
Event: UNS Coagulation [UNS\_COAG]

Page: Coagulation [LT]

COAGULATION					
Sample Collected?	C Yes C No				
Date of Collection (dd-mmm-yyyy)					
Time of Collection (hh:mm)					
Parameter Name	Result	Unit	LLN	ULN	Assessment
Prothrombin time (PT)					Normal Abnormal NCS Abnormal CS Not Done
International normalized ratio (INR)					Normal Abnormal NCS Abnormal CS Not Done
aPTT(ratio)					Normal Abnormal NCS Abnormal CS Not Done



12 Trial: OP109219\_JP-2266-101-FIH\_A (v.2.0)

Lead Event: UNS 12 Lead ECG [UNSEG]

ECG Page: 12 Lead ECG [EG]

12 LEAD ECG	
<b>▶</b> ECG Performed?	C Yes C No
<b>▶</b> Date of ECG	
<b>▶</b> Time of ECG	
▶ Heart Rate (Beats/min)	
▶PR (ms)	
<b>⇒</b> QRS (ms)	
<b>&gt;</b> QT (ms)	
<b>▶</b> QTcF (ms)	
➤ Conclusion Result	Normal Abnormal
Clinically Significant?	C Yes C No
Abnormality Finding / Relevant Comment	



### **UNS Vital Signs**

Sponsor: **JEIL Pharmaceutical Co., Ltd.**Trial: **OP109219\_JP-2266-101-FIH\_A (v.2.0)** 

Event: UNS Vital Signs [UNSVS]

Page: Vital Signs [VS]

VITAL SIGNS				
<b>&gt;</b> Vitals collected?	○ Yes ○ No			
▶Date of measurement	s			
▶Body Temperature (°C				
⇒Result	Normal Abnorm	nal		
Clinically Significant	C Yes C No			
- Omnouny Organicant				
Blood Pressure and	Heart Rate			
After	Position	Actual Time Position		al Time Measureme
10 Mins		(hh:mm)	(hh:mm) ▶	
2 Mins		<b>3</b>	<b>&gt;&gt;</b>	
<b>&gt;&gt;</b> Result	○ Normal ○ Abnormal			
Clinically Significant	C Yes C No			
Abnormal Finding/				



### Medical/Surgical History

Sponsor: JEIL Pharmaceutical Co., Ltd.

Trial: OP109219\_JP-2266-101-FIH\_A (v.2.0)

Event: Medical/Surgical History [MH]

Page: Medical/Surgical His [MH]

MEDICAL / SURGIO	CAL HISTORY
<b>&gt;&gt;</b> Seq. No	
▶Medical/Surgical History	
	SOC
	HLGT
	HLT
	PT
	ш
<b>≫</b> Start Date	
→Ongoing	C Yes C No
<b>≫</b> End Date	



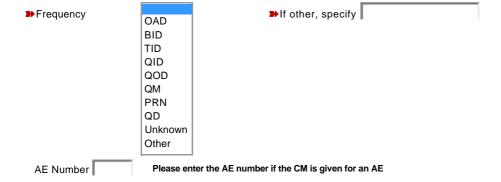
## Prior/Concomitant Trial: Medication Event

Sponsor: JEIL Pharmaceutical Co., Ltd.

Trial: OP109219\_JP-2266-101-FIH\_A (v.2.0)
Event: Prior/Concomitant Medication [CM]

Page: Prior/Concomitant [CM]

PRIO	R/CONCOM	IITANT	MEDICATION		
<b>≫</b> Medicati	on No.				
<b>≫</b> Taken P	rior to Study?	C Yes	○ No		
<b>≫</b> Medicati	on Name			_	
WhoDD	Product name	е			
	Medicinal pro	duct Id			
	Drug code				
	Preferred bas	se name			
	Preferred sal	t name			
	Product type				
	Generic/Prefe	erred		_	
	Pharmaceution	cal form	Ingredient(s)		
	Strength				
	Country				
	MAH				
	Company				
	Name source	)			
	ATC code(s)				
<b>≫</b> Indicatio	n				
<b>≫</b> Start Da	te				
<b>≫</b> Ongoing		C Yes	Yes No		
<b>≫</b> End Dat	е				
<b>&gt;</b> Dose					
<b>&gt;&gt;</b> Unit		mg		▶If other, specify	
		ug			
		mL			
		g IU			
		Other			
<b>≫</b> Route		Oral		► If other, specify	
		Cutaneo			
		Subcuta Transde			
		Intraocu			
		Intramus			
		Respirat	tory (Inhalation)		
		Intraperi			
		Nasal			
		Vaginal			
Recta		Injectab	le		
		Intraven			
		Intraderi			
		Intra-arte Epidural			
		Pulmona			
		Auricula	r		
		Sublingu Ocular	ıal		
		Intrauter	ine		
		Other			





#### Adverse Event

Sponsor: JEIL Pharmaceutical Co., Ltd.

Trial: OP109219\_JP-2266-101-FIH\_A (v.2.0)

Event: Adverse Event [AE1]
Page: Adverse Event [AE]

ADVERSE EVENT						
→ Adverse Event Number				_		
→Adverse Event	I					
MedDRA SOC						
HLGT						
HLT						
PT						
LLT						
<b>≫</b> Start Date	<b>≫</b> Start Time	_				
<b>≫</b> End Date	<b>≫</b> End Time	_				
<b>≫</b> Severity	Mild Moderate	Severe				
<b>≫</b> Serious	C Yes C No					
➤ Congenital Anomaly or Birth Defect	C Yes C No					
<b>&gt;&gt;</b> Significant Disability	C Yes C No					
<b>&gt;</b> Death	C Yes C No					
▶Life Threatening	C Yes C No					
→Other Medically Important Event	C Yes C No					
➤ Hospitalization/Prolonged	C Yes C No					
Date of Hospitalization						
▶ Relationship to Study Treatment	Probable Possible	Unlikely Unrelated	Not Assessable			
<b>≫</b> Outcome	Recovered/Resolved	Recovering/Resolving	Recovered/Resolved with Sequelae	Not Recovered/Not Resolved	Fatal	Unknown
■ Action Taken with Study Treatment	Dose Not Changed	Drug Interrupted Drug	Withdrawn Not Applicable	Unknown		
→Other Action	C Yes C No					
▶If Yes, Specify						
➤Any relevent concomitant medication recorded?	C Yes C No					