

## **12.2.4 Deaths, Discontinuations Due to Adverse Events, and Serious Adverse Events**

There were no deaths, discontinuations due to adverse events, or serious adverse events during this study in each study site.

## **12.3 Clinical Laboratory Evaluation**

Laboratory values (hematology, blood biochemistry and urinalysis) outside the normal reference range are flagged H (high) or L (low) as appropriate. Abnormal laboratory values by subject are listed in Appendix 8.2. Normal / abnormal rating shift in abnormal laboratory values are tabulated in Table 14.1. Summary statistics for laboratory values and shift tables for urinalysis parameters are presented in Tables 14.2 and 14.3, respectively. Follow-up/additional test by subject are listed in Appendix 8.6.

Although many subjects showed minor abnormalities in various laboratory values before and/or 48 hours after administration of the study drug, none of these except one (bilirubin in a Caucasian subject) was considered to be clinically significant. There were no apparent trends in laboratory parameters following administration of moxifloxacin.

## **12.4 Other Safety Assessments**

### **12.4.1 Renal Function**

Summary statistics for creatinine clearance are shown in Table 14.4. Individual creatinine clearance values before administration of the study drug are listed in Appendix 8.7.

Creatinine clearance values in each study site were as follows: 70 to <90 mL/min (1 in China, 4 in the US), 90 to <110 (6 in Japan, 4 in China, 3 in Korea, 9 in the US), 110 to <130 (8 in Japan, 10 in China, 10 in Korea, 6 in the US), 130 to <150 (4 in Japan, 5 in China, 3 in Korea, 1 in the US), 150 to <170 (2 in Japan, 3 in Korea).

### **12.4.2 Vital Signs**

Summary statistics for vital signs are shown in Table 14.5.

There were no clinically relevant abnormalities in vital signs, and no apparent trends following dose administration.

### **12.4.3 12-Lead ECG**

Individual 12-lead ECG abnormalities at screening, before administration, at 3, 24 and 48 hours after administration of the study drug are listed in Appendix 8.3.

Although most subjects had minor abnormalities at some time during the study, none were considered to be clinically significant.

## **12.5 Safety Conclusions**

Eighty eligible subjects were enrolled for this clinical pharmacokinetic study in order to investigate the pharmacokinetic profile of single oral dose of 400 mg of moxifloxacin in healthy adult male subjects among four ethnics. Of 80 subjects, one was withdrew his consent with personal reason and dropped out before administrating the study drug. All other subjects satisfied with all of the inclusion criteria and none of the exclusion criteria. Seventy-nine subjects completed the study and were evaluated for safety in each study site.

A total of 14 AEs (6 in 5 Japanese subjects, 1 in a Chinese subject, 4 in 3 Korean subjects and 3 in 3 Caucasian subjects) were observed during the study, of which it was considered that 4 events (urticaria in a Japanese subject, dizziness and headache in 2 Korean subjects, headache in a Caucasian subject) were considered to be probably related to the study drug. The most frequently reported AEs were malaise (3 incidents in 2 Japanese subjects) and headache (2 incidents in 2 Caucasian subjects and 1 incident in a Korean subject). All AEs except one incident of headache were mild in severity. AEs were generally short lasting and resolved without concomitant medication or other intervention. There were no deaths or serious AEs.

Laboratory measurements and clinical safety assessments (vital signs, physical examinations and 12-lead ECG) did not appear to show any clinically relevant abnormalities arising from the administration of moxifloxacin.

### **13. DISCUSSION AND OVERALL CONCLUSIONS**

All treatment-related AEs except one were mild in severity, and none required concomitant medication or intervention. Laboratory and other safety assessments did not appear to show any clinically relevant abnormalities arising from the administration of moxifloxacin. Moxifloxacin showed the similar safety results in these four ethnic groups.

The data from this study indicate that moxifloxacin given in oral dose of 400 mg is safe and relatively well-tolerated by healthy male Japanese, Chinese, Korean and Caucasian subjects.

## 14. TABLES AND FIGURES REFERRED TO BUT NOT INCLUDED IN THE TEXT

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### 14.1 Summary Table of Normal/Abnormal Rating Shift in Abnormal Laboratory Values

Parameter	Japanese				Chinese				Korean				Caucasian				
	48 Hours -1 Hour	Low	Normal	High	48 Hours -1 Hour	Low	Normal	High	48 Hours -1 Hour	Low	Normal	High	48 Hours -1 Hour	Low	Normal	High	
RBC	Low	0	0	0	Low	0	1	0	Low	0	0	0	Low	0	0	0	
	Normal	0	20	0	Normal	0	19	0	Normal	0	19	0	Normal	0	19	1	
	High	0	0	0	High	0	0	0	High	0	0	0	High	0	0	0	
Reticulocyte	Low	0	0	0	Low	0	0	0	Low	0	2	0	Low	0	0	0	
	Normal	0	20	0	Normal	0	20	0	Normal	0	17	0	Normal	0	20	0	
Hemoglobin	High	0	0	0	High	0	0	0	High	0	0	0	High	0	0	0	
	Low	0	0	0	Low	0	2	0	Low	0	0	0	Low	0	0	0	
	Normal	0	20	0	Normal	0	16	0	Normal	0	18	1	Normal	0	18	2	
Hematocrit	High	0	0	0	High	0	2	0	High	0	0	0	High	0	0	0	
	Low	3	0	0	Low	0	0	0	Low	0	0	0	Low	0	0	0	
	Normal	4	13	0	Normal	1	18	0	Normal	0	19	0	Normal	0	20	0	
Platelet	High	0	0	0	High	0	0	0	High	0	0	0	High	0	0	0	
	Low	0	0	0	Low	0	0	0	Low	0	0	0	Low	0	0	0	
	Normal	0	19	1	Normal	0	20	0	Normal	1	18	0	Normal	0	20	0	
WBC	High	0	0	0	High	0	0	0	High	0	0	0	High	0	0	0	
	Low	1	0	0	Low	0	1	0	Low	1	0	0	Low	2	0	0	
	Normal	0	19	0	Normal	0	18	0	Normal	0	18	0	Normal	3	15	0	
Neutrophil	High	0	0	0	High	0	0	1	High	0	0	0	High	0	0	0	
	Low	0	0	0	Low	5	2	0	Low	8	1	0	Low	0	0	0	
	Normal	1	19	0	Normal	1	10	0	Normal	1	9	0	Normal	1	18	0	
	High	0	0	0	High	0	0	2	High	0	0	0	High	0	1	0	
	Low	0	0	0	Low	2	0	0	Low	0	0	0	Low	0	0	0	
	Lymphocyte	Normal	0	20	0	Normal	0	11	1	Normal	0	11	3	Normal	0	19	1
		High	0	0	0	High	0	0	6	High	0	2	3	High	0	0	0
		Low	0	0	0	Low	0	0	0	Low	0	0	0	Low	0	0	0
	Monocyte	Normal	0	18	1	Normal	1	19	0	Normal	0	12	1	Normal	0	20	0
High		0	1	0	High	0	0	0	High	0	3	3	High	0	0	0	
Eosinophil	Low	0	0	0	Low	0	0	0	Low	0	0	0	Low	0	0	0	
	Normal	0	18	0	Normal	0	17	0	Normal	0	17	1	Normal	0	20	0	
Basophil	High	0	2	0	High	0	1	2	High	0	0	1	High	0	0	0	
	Low	0	0	0	Low	0	0	0	Low	0	0	0	Low	0	0	0	
	Normal	0	20	0	Normal	0	19	0	Normal	0	19	0	Normal	0	20	0	
	High	0	0	0	High	0	1	0	High	0	0	0	High	0	0	0	

14.1 Summary Table of Normal/Abnormal Rating Shift in Abnormal Laboratory Values (continued)

Parameter	Japanese				Chinese				Korean				Caucasian			
	48 Hours -1 Hour	Low	Normal	High	48 Hours -1 Hour	Low	Normal	High	48 Hours -1 Hour	Low	Normal	High	48 Hours -1 Hour	Low	Normal	High
Total Protein	Low	1	0	0	Low	0	0	0	Low	0	0	0	Low	0	0	0
	Normal	0	19	0	Normal	0	18	0	Normal	0	19	0	Normal	0	20	0
	High	0	0	0	High	0	2	0	High	0	0	0	High	0	0	0
Albumin	Low	0	0	0	Low	0	0	0	Low	0	0	0	Low	0	0	0
	Normal	0	20	0	Normal	0	20	0	Normal	0	19	0	Normal	0	20	0
	High	0	0	0	High	0	0	0	High	0	0	0	High	0	0	0
Total Cholesterol	Low	0	0	0	Low	0	0	0	Low	0	0	0	Low	0	1	0
	Normal	1	19	0	Normal	0	18	0	Normal	0	18	1	Normal	0	16	0
	High	0	0	0	High	0	1	1	High	0	0	0	High	0	1	2
HDL Cholesterol	Low	0	0	0	Low	1	0	0	Low	1	0	0	Low	4	0	0
	Normal	1	18	0	Normal	2	12	0	Normal	0	10	1	Normal	0	16	0
	High	0	1	0	High	0	3	2	High	0	2	5	High	0	0	0
LDL Cholesterol	Low	2	0	0	Low	2	0	0	Low	0	0	0	Low	0	1	0
	Normal	0	15	0	Normal	2	10	1	Normal	0	13	2	Normal	0	7	2
	High	0	1	2	High	0	0	5	High	0	0	4	High	0	0	10
Triglyceride	Low	0	0	0	Low	0	0	0	Low	0	0	0	Low	0	0	0
	Normal	0	20	0	Normal	0	14	2	Normal	0	17	1	Normal	0	19	0
	High	0	0	0	High	0	3	1	High	0	0	1	High	0	1	0
BUN	Low	0	0	0	Low	0	0	0	Low	3	1	0	Low	0	0	0
	Normal	0	20	0	Normal	0	20	0	Normal	4	11	0	Normal	0	20	0
	High	0	0	0	High	0	0	0	High	0	0	0	High	0	0	0
Creatinine	Low	0	0	0	Low	0	0	0	Low	0	0	0	Low	0	1	0
	Normal	0	20	0	Normal	0	20	0	Normal	0	19	0	Normal	0	19	0
	High	0	0	0	High	0	0	0	High	0	0	0	High	0	0	0
Uric Acid	Low	1	0	0	Low	0	0	0	Low	0	0	0	Low	0	0	0
	Normal	0	19	0	Normal	0	17	3	Normal	0	15	0	Normal	0	19	0
	High	0	0	0	High	0	0	0	High	0	2	2	High	0	1	0

### 14.1 Summary Table of Normal/Abnormal Rating Shift in Abnormal Laboratory Values (continued)

Parameter	Japanese			Chinese			Korean			Caucasian						
	48 Hours -1 Hour	Low	Normal	High	48 Hours -1 Hour	Low	Normal	High	48 Hours -1 Hour	Low	Normal	High	48 Hours -1 Hour	Low	Normal	High
AST	Low	0	0	0	Low	0	0	0	Low	0	0	0	Low	0	0	0
	Normal	0	20	0	Normal	0	20	0	Normal	0	18	0	Normal	0	18	0
	High	0	0	0	High	0	0	0	High	0	1	0	High	0	2	0
ALT	Low	0	0	0	Low	0	0	0	Low	0	0	0	Low	0	0	0
	Normal	0	20	0	Normal	0	19	1	Normal	0	19	0	Normal	0	20	0
	High	0	0	0	High	0	0	0	High	0	0	0	High	0	0	0
γ-GTP	Low	0	0	0	Low	0	0	0	Low	0	2	0	Low	0	0	0
	Normal	0	19	0	Normal	0	20	0	Normal	0	17	0	Normal	0	19	0
	High	0	1	0	High	0	0	0	High	0	0	0	High	0	1	0
Total Bilirubin	Low	0	0	0	Low	0	0	0	Low	0	0	0	Low	0	0	0
	Normal	0	19	1	Normal	0	16	0	Normal	0	8	0	Normal	0	18	0
	High	0	0	0	High	0	3	1	High	0	6	5	High	0	1	1
Direct Bilirubin	Low	0	0	0	Low	0	0	0	Low	0	0	0	Low	0	0	0
	Normal	0	20	0	Normal	0	19	0	Normal	0	19	0	Normal	0	20	0
	High	0	0	0	High	0	0	1	High	0	0	0	High	0	0	0
ALP	Low	0	0	0	Low	0	0	0	Low	0	0	0	Low	0	0	0
	Normal	1	18	0	Normal	0	20	0	Normal	0	19	0	Normal	0	20	0
	High	0	0	1	High	0	0	0	High	0	0	0	High	0	0	0
LDH	Low	1	0	0	Low	0	1	0	Low	0	0	0	Low	0	0	0
	Normal	1	17	0	Normal	3	16	0	Normal	0	11	1	Normal	0	20	0
	High	0	1	0	High	0	0	0	High	0	7	0	High	0	0	0
CK	Low	1	0	0	Low	0	0	0	Low	0	0	0	Low	0	0	0
	Normal	1	17	0	Normal	0	20	0	Normal	0	19	0	Normal	0	19	0
	High	0	1	0	High	0	0	0	High	0	0	0	High	0	1	0
Na	Low	0	0	0	Low	0	0	0	Low	0	1	0	Low	0	0	0
	Normal	0	20	0	Normal	0	20	0	Normal	0	18	0	Normal	0	20	0
	High	0	0	0	High	0	0	0	High	0	0	0	High	0	0	0
K	Low	0	0	0	Low	0	0	0	Low	0	0	0	Low	0	0	0
	Normal	0	20	0	Normal	0	20	0	Normal	0	19	0	Normal	0	20	0
	High	0	0	0	High	0	0	0	High	0	0	0	High	0	0	0
Cl	Low	0	0	0	Low	0	0	0	Low	0	0	0	Low	0	0	0
	Normal	0	20	0	Normal	0	20	0	Normal	0	19	0	Normal	0	20	0
	High	0	0	0	High	0	0	0	High	0	0	0	High	0	0	0

14.1 Summary Table of Normal/Abnormal Rating Shift in Abnormal Laboratory Values (continued)

Parameter	Japanese				Chinese				Korean				Caucasian			
	48 Hours -1 Hour	Low	Normal	High	48 Hours -1 Hour	Low	Normal	High	48 Hours -1 Hour	Low	Normal	High	48 Hours -1 Hour	Low	Normal	High
Blood Sugar	Low	0	0	0	Low	0	0	0	Low	0	2	0	Low	0	0	0
	Normal	0	19	0	Normal	0	20	0	Normal	0	17	0	Normal	0	20	0
	High	0	1	0	High	0	0	0	High	0	0	0	High	0	0	0
CRP	Low	0	0	0	Low	0	0	0	Low	0	0	0	Low	0	0	0
	Normal	0	19	0	Normal	0	19	1	Normal	0	19	0	Normal	0	18	0
	High	0	1	0	High	0	0	0	High	0	0	0	High	0	2	0
Urine Protein	Low	0	0	0	Low	0	0	0	Low	0	0	0	Low	0	0	0
	Normal	0	20	0	Normal	0	19	0	Normal	0	18	1	Normal	0	20	0
	High	0	0	0	High	0	1	0	High	0	0	0	High	0	0	0
Urine Glucose	Low	0	0	0	Low	0	0	0	Low	0	0	0	Low	0	0	0
	Normal	0	20	0	Normal	0	20	0	Normal	0	19	0	Normal	0	20	0
	High	0	0	0	High	0	0	0	High	0	0	0	High	0	0	0
Bilirubin	Low	0	0	0	Low	0	0	0	Low	0	0	0	Low	0	0	0
	Normal	0	20	0	Normal	0	20	0	Normal	0	19	0	Normal	0	18	0
	High	0	0	0	High	0	0	0	High	0	0	0	High	0	2	0
Ketone bodies	Low	0	0	0	Low	0	0	0	Low	0	0	0	Low	0	0	0
	Normal	0	20	0	Normal	0	20	0	Normal	0	18	0	Normal	0	15	1
	High	0	0	0	High	0	0	0	High	0	1	0	High	0	3	1
Occult Blood	Low	0	0	0	Low	0	0	0	Low	0	0	0	Low	0	0	0
	Normal	0	19	0	Normal	0	19	0	Normal	0	18	1	Normal	0	19	0
	High	0	1	0	High	0	1	0	High	0	0	0	High	0	0	1
pH	Low	0	0	0	Low	0	0	0	Low	0	0	0	Low	1	0	0
	Normal	0	20	0	Normal	0	20	0	Normal	0	19	0	Normal	0	19	0
	High	0	0	0	High	0	0	0	High	0	0	0	High	0	0	0
Urobilinogen	Low	0	0	0	Low	0	0	0	Low	0	0	0	Low	0	0	0
	Normal	0	20	0	Normal	0	20	0	Normal	0	19	0	Normal	0	20	0
	High	0	0	0	High	0	0	0	High	0	0	0	High	0	0	0
Urinary Sediment	Low	0	0	0	Low	0	0	0	Low	0	0	0	Low	0	0	0
	Normal	0	7	5	Normal	0	20	0	Normal	0	19	0	Normal	0	20	0
	High	0	6	2	High	0	0	0	High	0	0	0	High	0	0	0



## 14.2 Summary Statistics for Laboratory Values

### Hematology

Parameter		Japanese			Chinese			Korean			Caucasian		
		Unit	-1 Hour	48 Hours	Unit	-1 Hour	48 Hours	Unit	-1 Hour	48 Hours	Unit	-1 Hour	48 Hours
RBC	Number of subjects	10 <sup>4</sup> /μL	20	20	10 <sup>13</sup> /L	20	20	×10 <sup>3</sup> /mm <sup>3</sup>	19	19	10E6/uL	20	20
	Mean		494.1	480.3		4.9	5.0		518.1	523.5		5.0	5.1
	SD		33.36	22.42		0.37	0.34		26.09	31.36		0.27	0.31
	Minimum		453.0	444.0		4.3	4.4		468.0	453.0		4.5	4.6
	Median		499.00	474.00		4.86	5.07		522.00	520.00		4.97	5.02
	Maximum		550.0	521.0		5.5	5.7		560.0	586.0		5.5	5.7
Reticulocyte	Number of subjects	‰	20	20	10 <sup>9</sup> /L	20	20	‰	19	19	‰	20	20
	Mean		12.5	11.2		48.0	51.9		10.7	11.3		1.2	1.1
	SD		2.76	3.07		11.84	12.00		3.24	3.14		0.45	0.38
	Minimum		8.0	5.1		32.4	34.9		5.1	7.0		0.5	0.6
	Median		13.00	10.40		46.73	52.60		10.10	10.90		1.15	1.05
	Maximum		18.2	17.4		77.6	83.4		17.5	17.2		2.3	2.0
Hemoglobin	Number of subjects	g/dL	20	20	g/L	20	20	g/dL	19	19	g/dL	20	20
	Mean		15.1	14.7		160.1	161.1		15.5	15.7		15.3	15.5
	SD		0.97	0.69		14.30	10.32		0.84	0.85		0.91	0.84
	Minimum		13.6	13.4		131.0	140.0		13.8	14.0		13.9	14.6
	Median		15.00	14.75		160.00	162.50		15.50	15.80		15.25	15.40
	Maximum		16.6	15.7		181.0	176.0		16.6	17.2		16.8	17.4
Hematocrit	Number of subjects	%	20	20	%	19	20	%	19	19	%	20	20
	Mean		43.8	42.5		43.8	45.0		46.0	46.4		44.3	44.5
	SD		2.48	1.91		2.51	2.82		2.05	2.08		2.34	2.22
	Minimum		39.7	38.9		40.5	39.6		42.0	41.8		40.0	41.6
	Median		43.15	42.45		43.70	45.90		46.20	46.80		44.45	44.45
	Maximum		47.7	45.6		48.2	49.9		48.9	50.7		48.5	49.1
Platelet	Number of subjects	10 <sup>4</sup> /μL	20	20	10 <sup>9</sup> /L	20	20	×10 <sup>4</sup> /mm <sup>3</sup>	19	19	10E3/uL	20	20
	Mean		24.6	23.9		200.5	217.2		23.8	24.1		203.9	206.0
	SD		4.01	4.11		34.23	41.76		6.14	5.98		27.09	29.75
	Minimum		16.6	16.4		130.0	133.0		13.1	11.5		153.0	156.0
	Median		24.60	23.55		208.00	224.00		23.70	25.10		201.50	204.50
	Maximum		31.8	32.6		244.0	299.0		36.1	34.9		267.0	264.0
WBC	Number of subjects	10 <sup>2</sup> /μL	20	20	10 <sup>9</sup> /L	20	20	/mm <sup>3</sup>	19	19	10E3/uL	20	20
	Mean		56.9	51.8		5.4	5.3		5,832.1	5,350.5		5.4	4.6
	SD		11.96	11.11		1.55	1.34		1,114.20	927.95		1.29	0.85
	Minimum		34.4	33.8		3.3	4.0		3,780.0	3,490.0		3.0	3.3
	Median		55.15	49.70		5.29	4.89		5,740.00	5,500.00		5.10	4.50
	Maximum		77.9	81.7		10.1	9.8		7,880.0	7,750.0		8.9	5.9

### 14.2 Summary Statistics for Laboratory Values (continued)

#### Hematology

Parameter		Japanese			Chinese			Korean			Caucasian		
		Unit	-1 Hour	48 Hours	Unit	-1 Hour	48 Hours	Unit	-1 Hour	48 Hours	Unit	-1 Hour	48 Hours
Neutrophil	Number of subjects	%	20	20	%	20	20	%	19	19	%	20	20
	Mean		53.8	53.8		57.1	56.9		50.2	49.2		57.3	54.9
	SD		7.16	5.87		10.06	10.52		7.86	7.22		8.65	7.10
	Minimum		43.6	39.5		43.4	43.2		37.8	35.8		43.0	41.0
	Median		52.05	54.25		58.25	56.35		50.20	51.60		56.00	56.00
	Maximum		68.3	62.1		81.8	82.9		64.3	61.3		76.0	67.0
Lymphocyte	Number of subjects	%	20	20	%	20	20	%	19	19	%	20	20
	Mean		36.1	36.1		32.2	33.5		37.9	39.3		31.0	34.2
	SD		6.94	5.42		8.86	9.05		7.62	6.89		7.32	7.11
	Minimum		20.4	27.9		13.1	13.2		23.9	27.5		16.0	23.0
	Median		36.30	37.45		30.40	34.40		37.40	38.30		32.00	34.00
	Maximum		46.8	47.3		44.7	47.5		47.8	49.3		44.0	47.0
Monocyte	Number of subjects	%	20	20	%	20	20	%	19	19	%	20	20
	Mean		5.9	5.9		5.6	4.6		8.6	8.0		8.3	8.0
	SD		1.43	1.34		1.02	1.08		2.03	1.78		1.89	1.00
	Minimum		3.8	4.3		3.3	2.2		6.0	5.2		5.0	5.0
	Median		5.60	5.85		5.55	4.70		8.10	8.10		8.00	8.00
	Maximum		9.6	10.1		7.7	6.8		13.2	12.6		13.0	9.0
Eosinophil	Number of subjects	%	20	20	%	20	20	%	19	19	%	20	20
	Mean		3.6	3.7		3.1	2.6		2.8	3.0		2.9	2.3
	SD		2.02	1.98		1.86	1.93		1.02	1.42		1.66	1.45
	Minimum		1.3	1.3		0.9	0.5		1.3	1.4		1.0	1.0
	Median		3.35	3.45		2.60	2.20		2.50	2.50		3.00	2.00
	Maximum		8.8	7.3		8.6	8.5		5.1	6.1		6.0	6.0
Basophil	Number of subjects	%	20	20	%	20	20	%	19	19	%	20	20
	Mean		0.6	0.6		0.7	0.5		0.5	0.5		0.6	0.7
	SD		0.32	0.32		0.24	0.21		0.33	0.24		0.51	0.47
	Minimum		0.2	0.2		0.2	0.1		0.2	0.2		0.0	0.0
	Median		0.55	0.50		0.70	0.50		0.30	0.50		1.00	1.00
	Maximum		1.3	1.6		1.2	1.0		1.5	1.1		1.0	1.0

### 14.2 Summary Statistics for Laboratory Values (continued)

#### Blood Biochemistry

Parameter		Japanese			Chinese			Korean			Caucasian		
		Unit	-1 Hour	48 Hours	Unit	-1 Hour	48 Hours	Unit	-1 Hour	48 Hours	Unit	-1 Hour	48 Hours
Total Protein	Number of subjects	g/dL	20	20	g/L	20	20	g/dL	19	19	g/dL	20	20
	Mean		7.1	6.9		77.4	76.5		7.1	7.2		6.9	7.1
	SD		0.45	0.32		3.52	3.43		0.39	0.50		0.40	0.42
	Minimum		6.0	6.2		67.2	67.4		6.2	6.2		6.3	6.4
	Median		7.10	6.90		78.00	77.55		7.10	7.30		6.90	7.10
	Maximum		7.8	7.5		83.0	81.0		7.8	8.0		7.6	8.0
Albumin	Number of subjects	g/dL	20	20	g/L	20	20	g/dL	19	19	g/dL	20	20
	Mean		4.6	4.5		45.8	45.1		4.4	4.5		4.5	4.6
	SD		0.24	0.17		2.63	3.09		0.23	0.31		0.26	0.25
	Minimum		4.2	4.2		40.7	38.4		4.1	4.0		4.1	4.2
	Median		4.50	4.50		46.10	45.55		4.40	4.50		4.50	4.60
	Maximum		4.9	4.8		49.4	50.0		4.8	5.0		5.0	5.2
Total Cholesterol	Number of subjects	mg/dL	20	20	mmol/L	20	20	mg/dL	19	19	mg/dL	20	20
	Mean		178.1	169.1		4.4	4.4		174.8	183.9		170.0	175.2
	SD		31.28	30.30		0.53	0.59		35.39	35.21		26.88	26.26
	Minimum		119.0	108.0		3.6	3.5		115.0	123.0		97.0	101.0
	Median		181.00	162.00		4.31	4.37		170.00	181.00		170.50	178.00
	Maximum		230.0	223.0		5.4	5.6		237.0	248.0		212.0	215.0
HDL Cholesterol	Number of subjects	mg/dL	20	20	mmol/L	20	20	mg/dL	19	19	mg/dL	20	20
	Mean		60.5	55.0		1.2	1.2		51.2	52.1		51.9	47.7
	SD		11.84	9.82		0.25	0.26		10.79	9.16		12.44	8.96
	Minimum		36.0	33.0		0.7	0.7		28.0	30.0		35.0	32.0
	Median		61.50	55.50		1.19	1.16		50.00	53.00		53.50	47.00
	Maximum		91.0	73.0		2.0	1.9		78.0	71.0		90.0	70.0
LDL Cholesterol	Number of subjects	mg/dL	20	20	mmol/L	20	20	mg/dL	19	19	mg/dL	20	20
	Mean		105.1	102.6		2.7	2.6		105.4	115.6		99.3	108.9
	SD		25.88	25.64		0.55	0.55		32.02	31.32		23.80	23.42
	Minimum		62.0	58.0		1.8	1.9		61.0	75.0		49.0	50.0
	Median		100.50	97.50		2.74	2.57		102.00	112.00		99.50	112.50
	Maximum		153.0	151.0		3.8	3.5		165.0	173.0		143.0	155.0
Triglyceride	Number of subjects	mg/dL	20	20	mmol/L	20	20	mg/dL	19	19	mg/dL	20	20
	Mean		87.4	86.4		1.3	1.3		100.9	110.8		94.5	93.0
	SD		35.36	29.67		0.38	0.36		48.40	54.93		26.42	23.04
	Minimum		40.0	53.0		0.7	0.6		45.0	54.0		35.0	35.0
	Median		85.50	79.50		1.24	1.27		89.00	81.00		96.50	94.50
	Maximum		161.0	148.0		2.0	1.9		226.0	243.0		160.0	125.0

### 14.2 Summary Statistics for Laboratory Values (continued)

Blood Biochemistry													
Parameter		Japanese			Chinese			Korean			Caucasian		
		Unit	-1 Hour	48 Hours	Unit	-1 Hour	48 Hours	Unit	-1 Hour	48 Hours	Unit	-1 Hour	48 Hours
BUN	Number of subjects	mg/dL	20	20	mmol/L	20	20	mg/dL	19	19	mg/dL	20	20
	Mean		12.9	11.3	(as Uretra)	4.8	4.1		11.3	10.0		12.5	13.9
	SD		2.76	2.62		0.73	0.61		1.86	1.53		2.44	1.77
	Minimum		9.0	8.0		3.4	3.1		9.0	7.0		8.0	11.0
	Median		13.00	11.00		4.72	4.19		11.00	10.00		12.00	14.00
	Maximum		18.0	17.0		6.0	5.2		15.0	13.0		19.0	18.0
Creatinine	Number of subjects	mg/dL	20	20	μ mol/L	20	20	mg/dL	19	19	mg/dL	20	20
	Mean		0.8	0.8		79.8	84.8		0.9	1.0		1.0	1.0
	SD		0.10	0.10		7.82	6.65		0.08	0.09		0.10	0.11
	Minimum		0.7	0.7		70.0	72.0		0.8	0.8		0.8	0.8
	Median		0.85	0.82		78.00	83.50		0.90	1.00		0.98	1.02
	Maximum		1.0	1.1		95.0	97.0		1.1	1.2		1.1	1.2
Uric Acid	Number of subjects	mg/dL	20	20	μ mol/L	20	20	mg/dL	19	19	mg/dL	20	20
	Mean		5.9	5.8		340.9	356.5		6.4	6.1		6.2	6.0
	SD		0.80	0.77		42.57	47.39		0.94	0.88		0.98	0.87
	Minimum		3.5	3.5		271.0	277.0		4.7	5.0		4.6	4.5
	Median		5.85	5.95		336.00	355.00		6.30	6.00		6.05	6.05
	Maximum		7.5	7.0		415.0	436.0		8.2	8.3		8.6	7.6
AST	Number of subjects	U/L	20	20	IU/L	20	20	IU/L	19	19	U/L	20	20
	Mean		18.9	17.2		19.4	20.3		21.2	18.4		22.1	21.2
	SD		4.72	4.09		3.55	4.58		6.29	3.10		6.82	4.07
	Minimum		13.0	12.0		13.0	15.0		15.0	13.0		15.0	16.0
	Median		19.00	16.00		19.00	19.50		20.00	17.00		20.00	20.50
	Maximum		29.0	26.0		25.0	35.0		42.0	25.0		41.0	30.0
ALT	Number of subjects	U/L	20	20	IU/L	20	20	IU/L	19	19	U/L	20	20
	Mean		18.7	16.0		16.4	18.9		17.5	17.6		20.0	19.1
	SD		7.86	6.64		6.89	8.17		6.70	7.09		9.00	7.19
	Minimum		7.0	8.0		7.0	8.0		10.0	10.0		11.0	11.0
	Median		19.00	15.00		15.00	17.00		15.00	15.00		17.50	17.00
	Maximum		34.0	30.0		32.0	42.0		35.0	31.0		46.0	33.0
γ-GTP	Number of subjects	U/L	20	20	IU/L	20	20	IU/L	19	19	U/L	20	20
	Mean		23.0	20.9		17.7	17.5		24.0	23.3		20.2	19.9
	SD		10.11	8.49		4.46	4.58		13.99	12.04		14.36	12.81
	Minimum		13.0	12.0		12.0	11.0		9.0	11.0		4.0	4.0
	Median		21.00	18.50		16.50	16.50		18.00	19.00		17.50	16.00
	Maximum		55.0	45.0		25.0	24.0		57.0	49.0		72.0	65.0

### 14.2 Summary Statistics for Laboratory Values (continued)

#### Blood Biochemistry

Parameter		Japanese			Chinese			Korean			Caucasian		
		Unit	-1 Hour	48 Hours	Unit	-1 Hour	48 Hours	Unit	-1 Hour	48 Hours	Unit	-1 Hour	48 Hours
Total Bilirubin	Number of subjects	mg/dL	20	20	$\mu$ mol/L	20	20	mg/dL	19	19	mg/dL	20	20
	Mean		1.0	1.0		15.6	13.2		1.2	1.2		0.9	0.8
	SD		0.24	0.26		6.49	6.51		0.26	0.24		0.58	0.44
	Minimum		0.6	0.7		7.9	7.5		0.7	0.8		0.4	0.3
	Median		1.05	1.00		15.35	12.30		1.30	1.20		0.70	0.80
	Maximum		1.5	1.6		36.2	35.8		1.6	1.8		3.0	2.5
Direct Bilirubin	Number of subjects	mg/dL	20	20	$\mu$ mol/L	20	20	mg/dL	19	19	mg/dL	20	20
	Mean		0.2	0.2		2.7	2.5		0.3	0.3		0.1	0.1
	SD		0.06	0.07		1.88	2.03		0.08	0.06		0.06	0.05
	Minimum		0.1	0.1		0.3	0.3		0.2	0.2		0.1	0.1
	Median		0.20	0.20		2.73	2.14		0.30	0.30		0.12	0.11
	Maximum		0.3	0.4		8.4	9.1		0.5	0.4		0.3	0.3
ALP	Number of subjects	U/L	20	20	IU/L	20	20	IU/L	19	19	IU/L	20	20
	Mean		216.2	204.3		72.1	71.6		58.7	56.7	KAU	60.2	57.9
	SD		58.43	55.98		21.87	19.51		15.07	12.87		10.74	9.80
	Minimum		139.0	128.0		56.0	53.0		40.0	37.0		36.0	38.0
	Median		223.50	209.50		69.00	65.00		55.00	54.00		60.50	56.00
	Maximum		365.0	360.0		151.0	135.0		105.0	88.0		82.0	76.0
LDH	Number of subjects	U/L	20	20	IU/L	20	20	IU/L	19	19	IU/L	20	20
	Mean		142.8	130.1		123.2	112.3		220.6	169.6		155.2	146.5
	SD		26.88	22.03		17.59	13.02		46.79	33.14		26.84	23.07
	Minimum		90.0	91.0		95.0	86.0		150.0	135.0		127.0	115.0
	Median		140.50	132.00		121.00	112.00		217.00	165.00		146.50	139.50
	Maximum		215.0	176.0		164.0	138.0		324.0	289.0		224.0	198.0
CK	Number of subjects	U/L	20	20	IU/L	20	20	U/L	19	19	U/L	20	20
	Mean		106.1	80.3		69.9	70.3		95.0	80.1		89.2	66.6
	SD		49.76	22.87		27.29	41.15		22.53	19.92		40.59	18.65
	Minimum		54.0	46.0		38.0	26.0		62.0	53.0		45.0	36.0
	Median		90.50	72.50		64.00	60.00		92.00	73.00		74.50	65.50
	Maximum		277.0	129.0		171.0	195.0		142.0	126.0		214.0	114.0

## 14.2 Summary Statistics for Laboratory Values (continued)

### Blood Biochemistry

Parameter		Japanese			Chinese			Korean			Caucasian		
		Unit	-1 Hour	48 Hours	Unit	-1 Hour	48 Hours	Unit	-1 Hour	48 Hours	Unit	-1 Hour	48 Hours
Na	Number of subjects	mEq/L	20	20	mmol/L	20	20	mEq/L	19	19	mmol/L	20	20
	Mean		141.4	141.4		140.5	140.3		139.6	140.7		138.9	138.7
	SD		0.88	1.04		1.40	1.17		2.06	0.99		1.73	1.04
	Minimum		140.0	139.0		138.2	138.3		133.0	139.0		135.0	137.0
	Median		141.50	141.00		140.90	140.50		140.00	141.00		139.00	138.50
	Maximum		143.0	143.0		143.2	142.4		142.0	142.0		141.0	141.0
K	Number of subjects	mEq/L	20	20	mmol/L	20	20	mEq/L	19	19	mmol/L	20	20
	Mean		4.2	4.1		4.0	4.1		4.1	4.0		4.5	4.3
	SD		0.28	0.26		0.31	0.30		0.20	0.21		0.31	0.21
	Minimum		3.6	3.6		3.5	3.7		3.7	3.5		3.9	4.0
	Median		4.30	4.10		3.92	3.97		4.10	4.10		4.50	4.30
	Maximum		4.9	4.7		4.5	4.6		4.5	4.4		5.0	4.7
Cl	Number of subjects	mEq/L	20	20	mmol/L	20	20	mEq/L	19	19	mEq/L	20	20
	Mean		103.3	104.4		105.1	103.9		105.3	104.7		100.5	100.9
	SD		1.62	1.50		1.76	1.32		2.11	1.97		1.99	1.68
	Minimum		101.0	102.0		102.2	101.7		100.0	101.0		96.0	98.0
	Median		103.50	104.00		105.05	104.00		105.00	105.00		101.00	101.00
	Maximum		106.0	107.0		108.5	105.9		110.0	109.0		104.0	105.0
Blood Sugar	Number of subjects	mg/dL	20	20	mmol/L	20	20	mg/dL	19	19	mg/dL	20	20
	Mean		96.1	92.0		5.3	5.1		77.5	83.0		86.0	84.7
	SD		6.55	3.76		0.34	0.26		5.18	4.74		6.55	5.69
	Minimum		85.0	84.0		4.7	4.6		69.0	72.0		75.0	76.0
	Median		95.00	91.50		5.26	5.13		77.00	85.00		85.00	84.50
	Maximum		117.0	101.0		5.9	5.7		88.0	89.0		99.0	96.0
CRP	Number of subjects	mg/dL	20	20	mg/L	20	20	mg/dL	19	19	mg/L	20	20
	Mean		0.3	0.2		0.5	0.9		0.0	0.1		1.5	0.8
	SD		0.29	0.14		0.63	2.39		0.08	0.07		1.66	0.76
	Minimum		0.1	0.1		0.1	0.1		0.0	0.0		0.1	0.0
	Median		0.10	0.20		0.30	0.23		0.00	0.00		0.70	0.55
	Maximum		0.6	0.3		2.4	11.0		0.3	0.2		6.0	2.9

## 14.2 Summary Statistics for Laboratory Values (continued)

### Urinalysis

Parameter		Japanese		Chinese		Korean		Caucasian	
		-1 Hour	48 Hours	-1 Hour	48 Hours	-1 Hour	48 Hours	-1 Hour	48 Hours
pH	Number of subjects	20	20	20	20	19	19	20	20
	Mean	6.4	6.1	5.8	5.7	5.7	5.8	6.1	6.3
	SD	0.32	0.28	0.44	0.47	0.31	0.34	0.21	0.38
	Minimum	6.0	6.0	5.0	5.0	5.5	5.5	6.0	6.0
	Median	6.50	6.00	5.50	5.50	5.50	6.00	6.00	6.00
	Maximum	7.0	7.0	7.0	6.5	6.5	6.5	6.5	7.0

### 14.3 Shift Tables for Urinalysis Parameters

Parameter	Japanese					Chinese					Korean					Caucasian								
	48 Hours	Negative	(+)	+	++	+++	48 Hours	Negative	(+)	+	++	+++	48 Hours	Negative	(+)	+	++	+++	48 Hours	Negative	(+)	+	++	+++
	-1 Hour						-1 Hour						-1 Hour						-1 Hour					
Urine Protein	Negative	14	6	0	0	0	Negative	19	0	0	0	0	Negative	18	1	0	0	0	Negative	17	3	0	0	0
	(+)	0	0	0	0	0	(+)	1	0	0	0	0	(+)	0	0	0	0	0	(+)	0	0	0	0	0
	+	0	0	0	0	0	+	0	0	0	0	0	+	0	0	0	0	0	+	0	0	0	0	0
	++	0	0	0	0	0	++	0	0	0	0	0	++	0	0	0	0	0	++					
	+++	0	0	0	0	0	+++	0	0	0	0	0	+++	0	0	0	0	0	+++	0	0	0	0	0
Urine Glucose	Negative	20	0	0	0	0	Negative	20	0	0	0	0	Negative	19	0	0	0	0	Negative	20	0	0	0	0
	(+)	0	0	0	0	0	(+)	0	0	0	0	0	(+)	0	0	0	0	0	(+)	0	0	0	0	0
	+	0	0	0	0	0	+	0	0	0	0	0	+	0	0	0	0	0	+	0	0	0	0	0
	++	0	0	0	0	0	++	0	0	0	0	0	++	0	0	0	0	0	++					
	+++	0	0	0	0	0	+++	0	0	0	0	0	+++	0	0	0	0	0	+++	0	0	0	0	0
Bilirubin	Negative	20	0	0	0	0	Negative	20	0	0	0	0	Negative	19	0	0	0	0	Negative	18	0	0	0	0
	(+)	0	0	0	0	0	(+)	0	0	0	0	0	(+)	0	0	0	0	0	(+)	0	0	0	0	0
	+	0	0	0	0	0	+	0	0	0	0	0	+	0	0	0	0	0	+	2	0	0	0	0
	++	0	0	0	0	0	++	0	0	0	0	0	++	0	0	0	0	0	++					
	+++	0	0	0	0	0	+++	0	0	0	0	0	+++	0	0	0	0	0	+++	0	0	0	0	0
Ketone bodies	Negative	20	0	0	0	0	Negative	20	0	0	0	0	Negative	18	0	0	0	0	Negative	15	1	0	0	0
	(+)	0	0	0	0	0	(+)	0	0	0	0	0	(+)	0	0	0	0	0	(+)	0	0	0	0	0
	+	0	0	0	0	0	+	0	0	0	0	0	+	1	0	0	0	0	+	2	1	0	0	0
	++	0	0	0	0	0	++	0	0	0	0	0	++	0	0	0	0	0	++					
	+++	0	0	0	0	0	+++	0	0	0	0	0	+++	0	0	0	0	0	+++	1	0	0	0	0
Occult Blood	Negative	19	0	0	0	0	Negative	19	0	0	0	0	Negative	18	1	0	0	0	Negative	19	0	0	0	0
	(+)	1	0	0	0	0	(+)	1	0	0	0	0	(+)	0	0	0	0	0	(+)	0	0	1	0	0
	+	0	0	0	0	0	+	0	0	0	0	0	+	0	0	0	0	0	+	0	0	0	0	0
	++	0	0	0	0	0	++	0	0	0	0	0	++	0	0	0	0	0	++					
	+++	0	0	0	0	0	+++	0	0	0	0	0	+++	0	0	0	0	0	+++	0	0	0	0	0
Urobilinogen	Negative	0	0	0	0	0	Negative	20	0	0	0	0	Negative	0	0	0	0	0	Negative	20	0	0	0	0
	(+)	0	20	0	0	0	(+)	0	0	0	0	0	(+)	1	18	0	0	0	(+)	0	0	0	0	0
	+	0	0	0	0	0	+	0	0	0	0	0	+	0	0	0	0	0	+	0	0	0	0	0
	++	0	0	0	0	0	++	0	0	0	0	0	++	0	0	0	0	0	++					
	+++	0	0	0	0	0	+++	0	0	0	0	0	+++	0	0	0	0	0	+++	0	0	0	0	0
Urinary Sediment	Negative	9	0	5	0	0	Negative	20	0	0	0	0	Negative	19	0	0	0	0	Negative	20	0	0	0	0
	(+)	0	0	0	0	0	(+)	0	0	0	0	0	(+)	0	0	0	0	0	(+)	0	0	0	0	0
	+	4	0	2	0	0	+	0	0	0	0	0	+	0	0	0	0	0	+	0	0	0	0	0
	++	0	0	0	0	0	++	0	0	0	0	0	++	0	0	0	0	0	++					
	+++	0	0	0	0	0	+++	0	0	0	0	0	+++	0	0	0	0	0	+++	0	0	0	0	0



## 14.4 Summary Statistics for Creatinine clearance

Race	Parameter	Number of Subjects	Creatinine clearance [mL/min] at -1 Hour				
			Mean	SD	Minimum	Median	Maximum
Japanese	Creatinine clearance	20	122.1	19.26	96.0	120.00	169.0
Chinese	Creatinine clearance	20	118.7	17.49	84.0	123.00	144.0
Korean	Creatinine clearance	19	125.8	20.62	93.0	122.00	169.0
Caucasian	Creatinine clearance	20	101.5	14.36	77.0	103.00	130.0

## 14.5 Summary Statistics for Vital Signs

Race	Parameter	Scheduled Time	Number of Subjects	Mean	SD	Minimum	Median	Maximum
Japanese	SBP [mmHg]	-1 Hour	20	103.7	8.27	88.0	102.50	119.0
		3 Hours	20	97.3	9.49	77.0	97.50	113.0
		24 Hours	20	101.8	9.30	82.0	100.50	120.0
		48 Hours	20	101.2	10.40	85.0	100.50	119.0
	DBP [mmHg]	-1 Hour	20	61.4	8.56	49.0	60.00	76.0
		3 Hours	20	54.4	7.30	41.0	53.00	67.0
		24 Hours	20	58.5	6.86	47.0	57.50	74.0
		48 Hours	20	58.6	8.22	46.0	58.50	77.0
	Pulse rate [bpm]	-1 Hour	20	65.1	4.96	57.0	64.00	74.0
		3 Hours	20	67.7	7.13	57.0	66.50	81.0
		24 Hours	20	68.0	7.15	51.0	69.50	81.0
		48 Hours	20	66.2	7.66	53.0	66.00	82.0
	Body temperature [°C]	-1 Hour	20	36.2	0.35	35.3	36.20	36.6
		3 Hours	20	36.5	0.29	35.7	36.55	36.9
		24 Hours	20	36.3	0.38	35.4	36.30	36.8
		48 Hours	20	36.4	0.20	36.0	36.40	36.8
Chinese	SBP [mmHg]	-1 Hour	20	116.5	9.71	100.0	119.00	134.0
		3 Hours	20	113.3	8.97	100.0	110.00	130.0
		24 Hours	20	110.9	11.19	94.0	110.00	138.0
		48 Hours	20	114.7	11.23	96.0	115.00	136.0
	DBP [mmHg]	-1 Hour	20	74.7	10.31	60.0	79.00	88.0
		3 Hours	20	75.1	8.98	60.0	78.00	86.0
		24 Hours	20	73.0	8.84	60.0	72.00	86.0
		48 Hours	20	77.1	7.38	60.0	78.00	88.0
	Pulse rate [bpm]	-1 Hour	20	62.5	6.42	52.0	62.00	78.0
		3 Hours	20	58.6	5.35	52.0	57.00	68.0
		24 Hours	20	59.3	4.17	52.0	60.00	68.0
		48 Hours	20	64.3	7.71	50.0	62.00	80.0
	Body temperature [°C]	-1 Hour	20	36.0	0.20	35.8	36.00	36.4
		3 Hours	20	36.1	0.32	35.8	36.00	37.0
		24 Hours	20	36.0	0.22	35.8	36.00	36.5
		48 Hours	20	36.2	0.24	35.9	36.10	36.7

### 14.5 Summary Statistics for Vital Signs (continued)

Race	Parameter	Scheduled Time	Number of Subjects	Mean	SD	Minimum	Median	Maximum
Korean	SBP [mmHg]	-1 Hour	19	113.2	10.42	95.0	116.00	128.0
		3 Hours	19	112.5	7.33	95.0	113.00	126.0
		24 Hours	19	113.4	10.18	96.0	112.00	137.0
		48 Hours	19	115.3	8.86	103.0	114.00	136.0
	DBP [mmHg]	-1 Hour	19	69.5	6.32	57.0	69.00	83.0
		3 Hours	19	67.8	7.45	51.0	69.00	78.0
		24 Hours	19	69.1	6.27	58.0	70.00	80.0
		48 Hours	19	69.5	9.46	47.0	68.00	85.0
	Pulse rate [bpm]	-1 Hour	19	66.2	10.83	47.0	64.00	90.0
		3 Hours	19	67.9	6.62	54.0	69.00	79.0
		24 Hours	19	64.0	7.80	47.0	64.00	79.0
		48 Hours	19	63.8	7.29	52.0	64.00	79.0
	Body temperature [°C]	-1 Hour	19	36.1	0.34	35.6	36.10	36.8
		3 Hours	19	36.3	0.30	35.9	36.20	36.9
		24 Hours	19	35.9	0.19	35.5	35.90	36.4
		48 Hours	19	35.9	0.32	35.2	36.00	36.4
Caucasian	SBP [mmHg]	-1 Hour	20	115.8	10.31	101.0	114.00	132.0
		3 Hours	20	115.3	11.58	99.0	116.50	148.0
		24 Hours	20	116.3	11.24	94.0	116.50	142.0
		48 Hours	20	114.4	8.77	99.0	116.50	129.0
	DBP [mmHg]	-1 Hour	20	68.5	9.13	55.0	65.00	85.0
		3 Hours	20	67.4	7.64	56.0	66.00	83.0
		24 Hours	20	68.3	8.50	50.0	66.50	81.0
		48 Hours	20	67.8	9.20	50.0	66.00	84.0
	Pulse rate [bpm]	-1 Hour	20	64.5	6.18	54.0	65.00	73.0
		3 Hours	20	65.6	8.78	56.0	63.00	82.0
		24 Hours	20	68.2	8.81	54.0	67.00	83.0
		48 Hours	20	69.4	9.56	49.0	69.50	87.0
	Body temperature [°C]	-1 Hour	20	36.0	0.36	35.4	36.00	36.7
		3 Hours	20	36.2	0.25	35.6	36.25	36.5
		24 Hours	20	36.1	0.27	35.5	36.05	36.6
		48 Hours	20	36.0	0.48	35.1	36.00	36.9

## 15. REFERENCES

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