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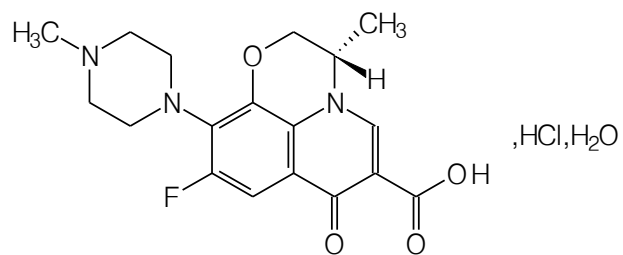
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O**O****O**

Levofloxacin Hydrochloride Tablets

Yansuan Zuoyangfushaxing Pian

()- S -3- -9- -2 3- -10-(4- -1-)-7- -7H-
[1,2,3-de]-[1 4] -6-


$$\text{C}_{18}\text{H}_{20}\text{FN}_3\text{O}_4 \cdot \text{HCl} \cdot \text{H}_2\text{O}$$

415.85

≥ 18

1.

β -

2.

7 14

MDRSP*]

[

MDRSP

MIC ≥ 2 µg/mL

/

5

3.

5

10 14

4.

5.

6.

7.

11.

C₁₈H₂₀FN₃O₄ 0.1g

1

250 mg 500 mg 750 mg 24

1

250 mg 500 mg 60

24

750 mg

90 24

$$\geq 50 \text{ mL/min}$$

50 mL/min
≥ 50 mL/min

1	24	2
	750 mg	7 14
3	500 mg	7 14
4	750 mg	5
	750 mg	5
	500 mg	10 14
	500 mg	7
cSSSI	750 mg	7 14
uSSSI	500 mg	7-10
	500 mg	28
cUTI AP 5	750 mg	5
cUTI AP 6	250 mg	10
	250 mg	3
50 kg ≥ 6 7 8	500 mg	60 ⁸
50 kg ≥ 6 7 8	2	60 ⁸

[MDRSP]

[MDRSP]

cUTI

CUTI

on the basis of the

28

14

9% PAAD

2

18

≥ 6

2

2

≥ 6

1				2
3, 4				
50 kg	≥ 6	500 mg	24	60 ⁴
50 kg	≥ 6	8 mg/kg 250 mg	12	60 ⁴

1.

•

•

•

•

QT

•

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•

•

•

•

•

•

/

•

QT

/

/

/

2.

29

7537

50

74%

65

50%

71%

17%

750 mg

250 mg

500 mg

1

2

3 14

10

750 mg

250 mg

500 mg

1

2

4.3%

250 mg

500 mg

3.8%

750 mg

5.4%

250 mg

500 mg

1.4%

0.6%

0.4%

0.3%

0.2%

750 mg

5

6

≥ 1%

0.1

1%

≥ 3%

5	≥ 1%
/	% N=7537
	1
	4
	6
	3
	1
	7
	5
	3
	2
	2
	2
	2
	1
	1 ^b
	1
	1
	1

a. N = 7274

b. N=3758

6	0.1	1%	N=7537
/			
			a
		a	
			/

a. N = 7274

3.

7

7

/	
	/
	EEG
	QT
	Stevens-Johnson /

1.

2.

3.

4. QT

QT

QT

IA

QT

5.

/

/

/

6.

Stevens-Johnson

A B

CDAD

CDAD

10.

/

11.

/

/

“ V ”

12.

7,000

14

6

≥ 65

13.

≥ 6

14.

C

810 mg/kg/

9.4

160 mg/kg/

1.9

50 mg/kg/

810 mg/kg/

1.1

25 mg/kg/

0.5

/

18

-

14

6

16

mg/kg

1534

6

16

6

5

10 mg/kg

2

5

10 mg/kg

500 mg

10

1340

893

60

1

8

8

	N = 1340		N = 893 ^a		p ^b
60	28	2.1%	8	0.9%	p = 0.038
1 ^c	46	3.4%	16	1.8%	p = 0.025

a.

/

b. Fisher ' s

c. 1199

804

1

1

8/46 17%

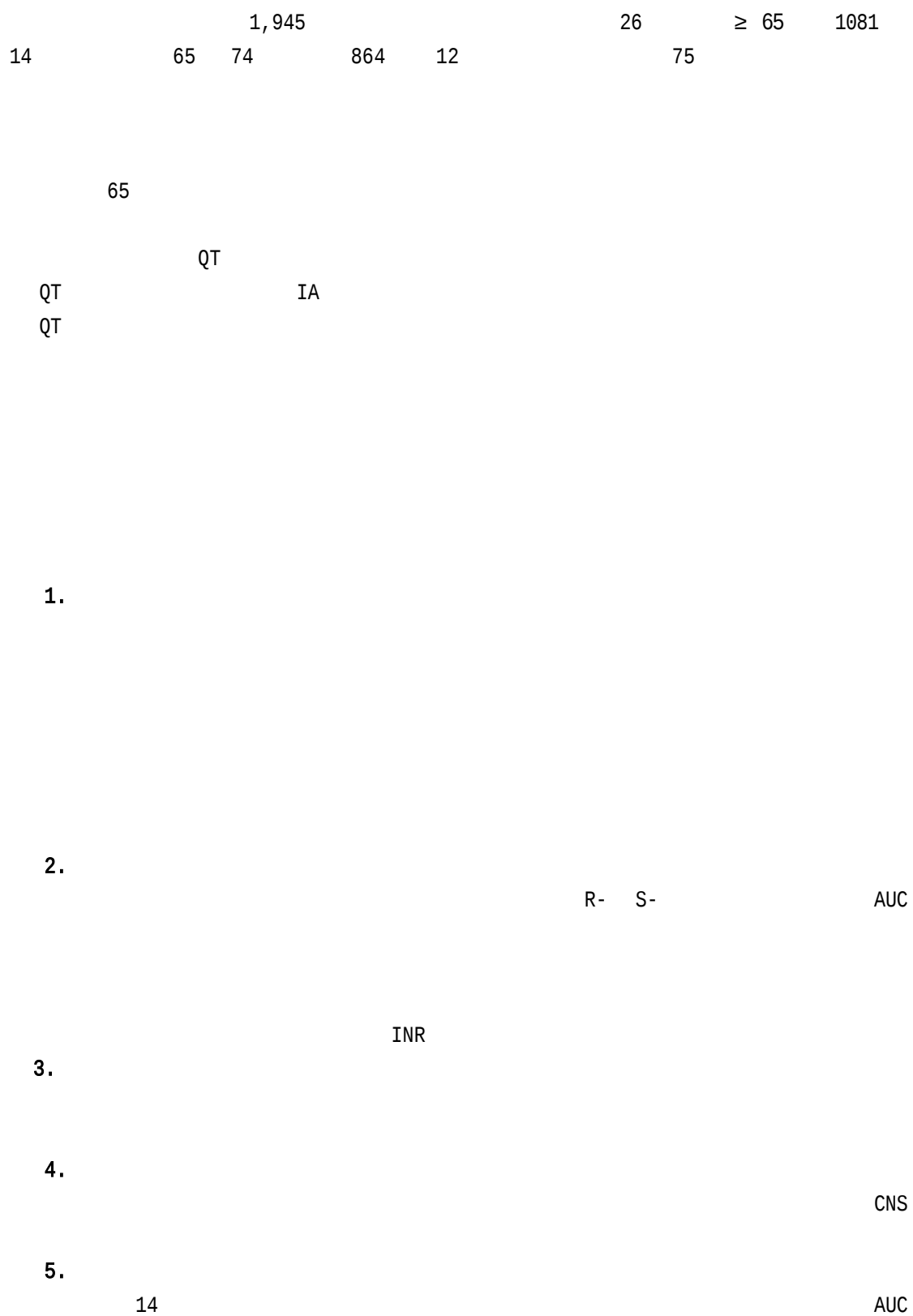
35/46 76%

7

9

80%

2



6.

AUC

C_{max} k_e T_{max} $t_{1/2}$

7.

AUC

8.

AUC $t_{1/2}$ 27% 38 30 CL/F CL_R 21% 35

9.

1500 mg/kg 250 mg/kg

GOT/GPT/ALP
/

1

2

3

1.

(

DNA

$$10^{-9} \quad 10^{-10}$$

:

[illegible]

500 mg p.o.							
500 mg p.o.							

/
/

18 53
250 mg 500 mg

60
18 54

750 mg 90

48h 500 mg CL_{CR} 2

mL/min

500 mg

22 75
18 80

18 36
66 80

11
12
13

19 55
500 mg

F 0.99 ± 0.08 750 mg

F=0.99 ± 0

ND =

1 2

500 mg 750 mg

99

500 mg 60

750 mg 90

Mean ± SD 6.2 ± 1.0 µg/mL

Mean ± SD 11.5 ± 4.0 µg/mL

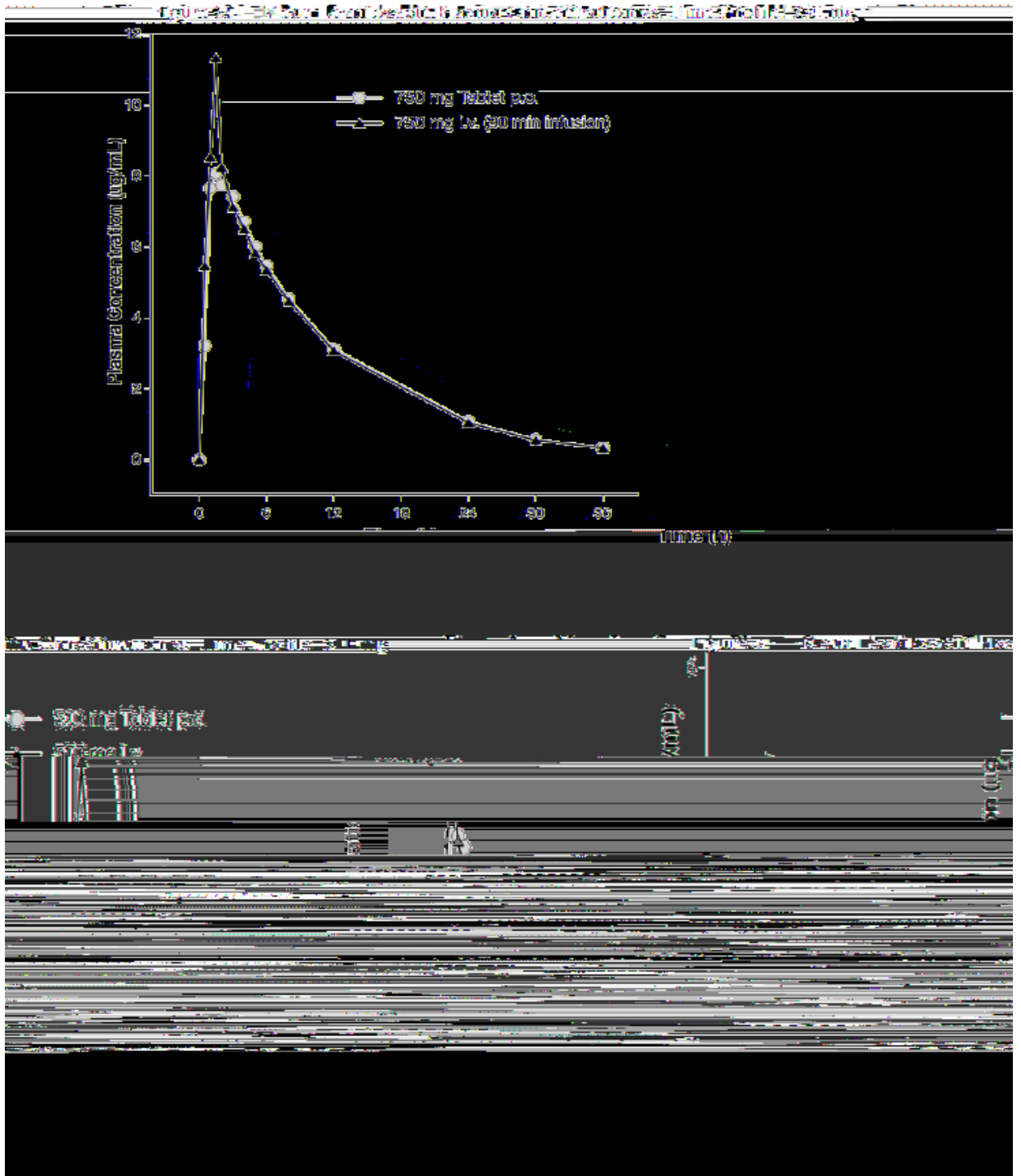
500 mg 750 mg 48

Mean ± SD 5.7 ± 1.4

500 mg

0.5 ± 0.2 µg/mL

1



		500 mg	750 mg	74	112
L				3	
		750 mg	500 mg	AUC	
2	AUC	1			
500 mg	24			2	5
2.4	11.3 µg/g				
1	10 µg/mL	24%	38	/	

96 142mL/min

6 8

144 226 mL/min

24 35

500 mg

6 16

7mg/kg

6 80

7.6

6

17 8mg/kg 12 1 250mg

C_{max} 500mg 24 1

6

AUC₀₋₂₄

7.5 6.1

500 mg

72

48 24

50 mL/min

CAPD

4 72

87 5

D-

48

N-

6

1

12

1

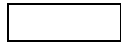
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24

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