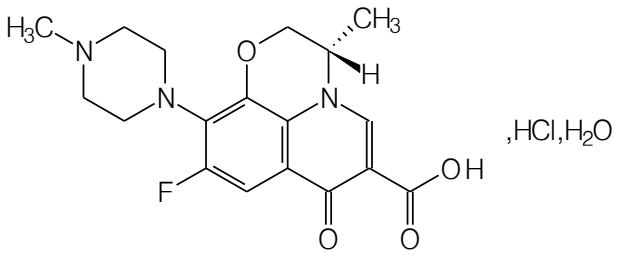
2006 10 26
2013 3 1 2015 6 8 2015 11 30 2017 8 16

60

- o
- o
- o
- 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-



$C_{18}H_{20}FN_3O_4 . HCl . H_2O$
415.85

≥ 18

1.

β -

2.

7 14 [

MDRSP*]

MDRSP

MIC ≥ 2 µg/mL /

5

3.

5

10 14

4.

5.

6.

7.

!

10

9.
5
10
10.

11.

28

$C_{18}H_{20}FN_3O_4$ 0.1g

1.
1
250 mg 500 mg 750 mg 24
1
250 mg 500 mg 60
24 750 mg 90 24
1
≥ 50 mL/min 50 mL/min
1 ≥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

28 14

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
-
-
-
-
-
-
-
-
- /
-

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 /

18

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/

1.9 810 mg/kg/

50 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

1,945 26 ≥ 65 1081
14 65 74 864 12 75

65

QT
QT IA
QT

1.

2.
R- S- AUC

INR
3.

4.
CNS

5.
14 AUC

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} 10^{-10}

:

4 5
10mg/kg/ 7 4 mg/kg/ 14
300mg/kg/ 7 60mg/kg/
4 3 14
40mg/kg/ 8 ≥ 2.5mg/kg
AUC 0.2
10 40mg/kg 0.7 2.4
18

CNS
6mg/kg

Mean ± SD 9
9 PK Mean ± SD

	C_{max} (μg/mL)	T_{max} (h)	AUC (μg·h/mL)	CL/F^1 (mL/min)	Vd/F^2 (L)	$t_{1/2}$ (h)	CL_R (mL/min)

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

00130011/3/LT EMC /P <MCID 365/Lang (en-US)>BDC BT/F3 10.56 Tf1 0 0 4 Tm[(n)] TJ13/LT EMC /

18 53

250 mg 500 mg 60 750 mg 90

18 54

48h 500 mg CL_{CR} 20 50 mL/min

500 mg

22 75

18 80

18 36

⑪ 66 80

⑫ 19 55

⑬ 500 mg F 0.99 ± 0.08 750 mg F=0.99 ± 0.06 ND =

1 2

500 mg 750 mg 99

500 mg 60

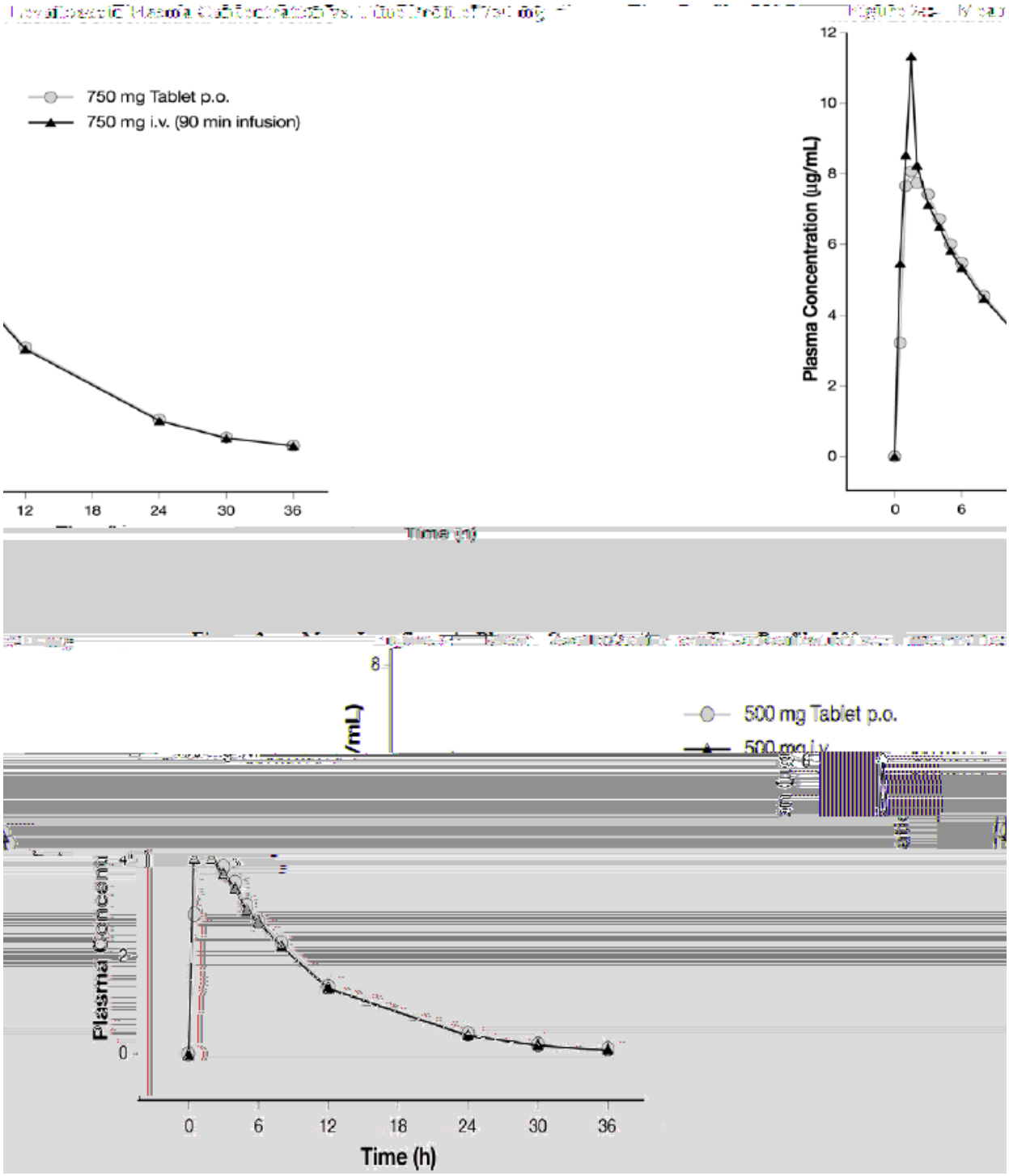
Mean ± SD 6.2 ± 1.0 μg/mL 750 mg 90

Mean ± SD 11.5 ± 4.0 μg/mL

500 mg 750 mg 48

500 mg Mean ± SD 5.7 ± 1.4

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

D-

87 48

4 72 5

N-

6 8 144 226 mL/min

96 142mL/min

24 35

66 80 500 mg

7.6 6

6 16 7mg/kg

6

17 8mg/kg 12 1 250mg AUC_{0-24}

C_{max} 500mg 24 1

500 mg

7.5 6.1

72

48 24

50 mL/min

CAPD

CAPD

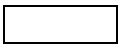
6 1 12 1

10 2

24

2015

H20057797



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