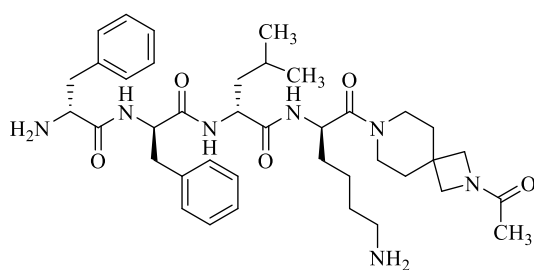


Anrikefon Injection
 Anruikefen Zhusheye

-D-

-2-

-2 7- [3.5]



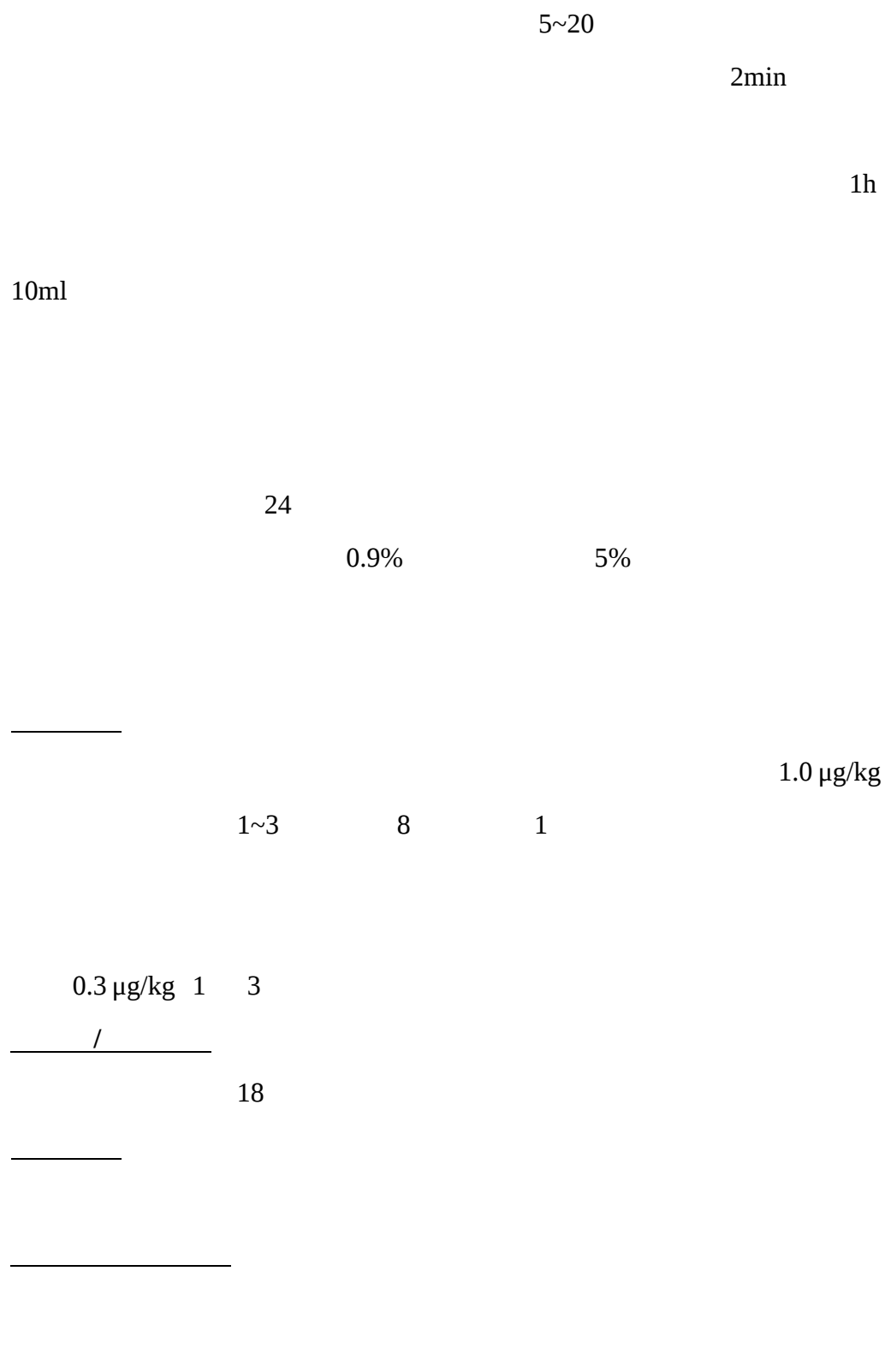
$C_{39}H_{57}N_7O_5$

703.93

1.

2.

1ml 0.1mg



			2	
		III	HSK21542-301	HSK21542-303
			HSK21542-301	136
1.0µg/kg	135			≥1%
	5.1%	2.2%		3.7%
		1.5%	2.2%	
1				≥1%
	1			
		(N = 136)		(N = 135)
		5.1%		

	0	1.5%

HSK21542-303
 129

1.0µg/kg

129

129

≥1%

7.8%

8.5%

8.5%

3.9%

2.3%

2.3%

2

≥1%

2

	7.8%	41.1%	17.8%
	8.5%	37.2%	13.2%
	8.5%	0	0
	3.9%	0.8%	0.8%
	2.3%	0	0.8%
	2.3%	4.7%	4.7%
	0	2.3%	0

2
 ≥3

	12	40	HSK21542	
/			HSK21542	
502		0.3 µg/kg	1	3
392		24		176
12				
	275		270	
HSK21542		71 (25.8%)	47 (17.4%)	
		HSK21542		0.7%
0.4%	3		≥1%	

	12 (4.4)	5 (1.9)
	7 (2.5)	7 (2.6)
	14 (5.1)	7 (2.6)

	3 (1.1)	3 (1.1)
	3 (1.1)	2 (0.7)

442

92 (20.8%)

0.9% 4

≥1%

	26 (5.9)
	16 (3.6)
	13 (2.9)
	5 (1.1)
	5 (1.1)
	5 (1.1)

38 ≥65

51 ≥65

HSK21542 11 (28.9%) 6 (11.8%)≥65

5 ≥65

	11 (16.9)
	2 (3.1)
	2 (3.1)
	1 (1.5)
	1 (1.5)
Y-	1 (1.5)
Q	1 (1.5)
QT	1 (1.5)
	1 (1.5)
	1 (1.5)
	1 (1.5)
	1 (1.5)

1 IV

2

3

18

	II	III		
≥65	21			
			65	
				III
	HSK21542		≥65	76

CYP1A2	CYP2B6	CYP3A4		CYP1A2	CYP2B6	CYP2C8
CYP2C9	CYP2C19	CYP2D6	CYP3A4/5			
				BCRP	P-	P-gp
		OATP 1B1	OATP1B3			OAT 1
OAT3		OCT 2				MATE
1	MATE2-K					

1

2
0.16 mL 1.888μg
13
I 3.375μg/kg
66.7% 4/6 33.3% 2/6
16.7% 1/6

C-QT QTc
0.2~3.375 μg/kg
2 min 15 min 1μg/kg
C_{max} 10.2 ng/mL 8.13 ng/mL
AUC_{0-t} 10.13 ng*h/mL 9.89 ng*h/mL 2 min
15 min

3 0.3 μg/kg
0.2~3.375 μg/kg
227~274 mL/kg
3 0.3 μg/kg 1.3 L/kg
0.46~0.54 [¹⁴C]
14.3%

[¹⁴C]

≤1.07%

0.2~3.375 µg/kg

t_{1/2} 1.39~2.24 h

46.30±12.02% 35.60±5.66%

3 0.3µg/kg

t_{1/2} 26.3 h

74.7±13.2% 0.621±0.871%

0.119±0.292%

N=159

(N=13)

N=281

AUC

7.88% 73.8% C_{max}

1 µg/kg

90≤GFR<130 mL/min, N=8

60≤GFR<90 mL/min,

N=8

30≤GFR<60 mL/min N=8

15≤GFR<30 mL/min N=9

AUC_{0-∞}

27.02% 62.79% 121.64% C_{max}

N=43

(N=11)

(N=15)

N=447

AUC 13.6% 51.2% 30.5%

AUC

AUC

AUC

33%

78%

PK

≥65

65

AUC

38.5%

≥65

65

AUC

4%

II

18-70

III

ASA

I-

271

136

135

8h

3

1.0μg/kg

2min

FAS

0-

24h

SPID

SPID_{0-24h}

-39.1

*h

-27.4

*h

95%

CI

-11.7 (-17.0

-6.5)

FAS

22.0 h vs 20.3 h

9.0

vs 8.4

8.9 vs 7.8

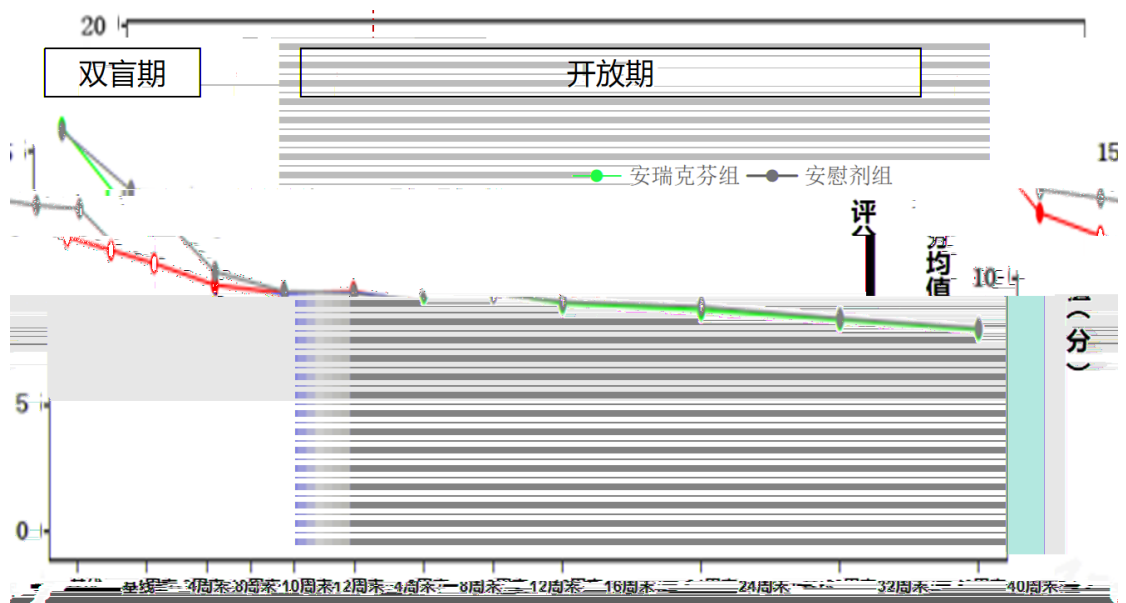
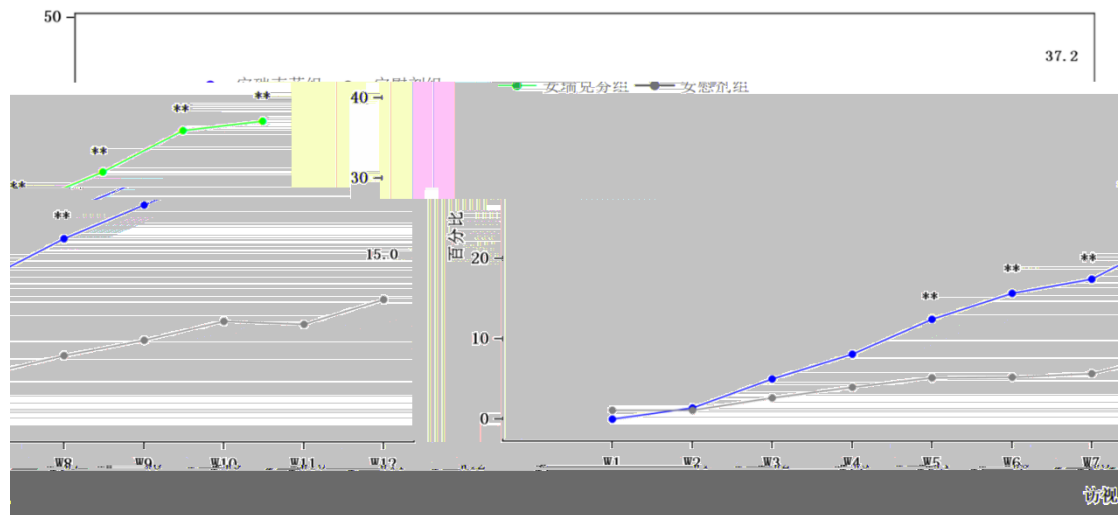
0-24h 33.1% vs 46.7%

2.3 mg vs 2.9 mg PPS

FAS

SPID _{0-24h} *h		
	-39.1	-27.4
95%	-11.7 (-17.0, -6.5)	/
P	<0.0001	/

		/	III	ASA
I-II	18-70			
387				129
129	129			8h
3	1.0µg/kg	2min		
	FAS			SPID _{0-24h}
	-64.0	* h -62.9%	* h -62.9%	* h -64.0%
SPID _{0-24h}	95% CI	-18.1(-24.4	-11.9)	* h
SPID _{0-24h}	95% CI	-17.0 (-23.2	-10.7)	
* h	SPID _{0-24h}	95% CI	-1.1(-	
7.4 5.1)	* h	FAS		
	21.04 h	21.32 h	18.18 h	
8.7	8.5	8.2		8.6 8.4
7.6	0-24h			40.3% 35.7%
71.3%	0-24h	29.8mg	29.3mg	61.6mg
SPID _{0-24h}	*h			



K

KOR

Ames

2 7 1 3 10 mg/kg/ ≥1 mg/kg/

/

- 6~17

0.2 1 4 mg/kg/ [AUC MRHD 1µg/kg

19 82 358] 4 mg/kg/

- NOAEL 1mg/kg/ 7~19

0.3 1 2 µg/kg/ AUC MRHD 0.1 0.3 0.8

2 µg/kg/

6 21

0.2 1 4 mg/kg/ AUC MRHD 17 59 250

1 0.1 0.5 2.5 mg/kg/ AUC

MRHD 16 107 1609 10 60 425 RasH2

1 6 0.4 2 10 mg/kg/ AUC

MRHD 31 142 669 23 112 593

25

4 /

36

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H20250014

17

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