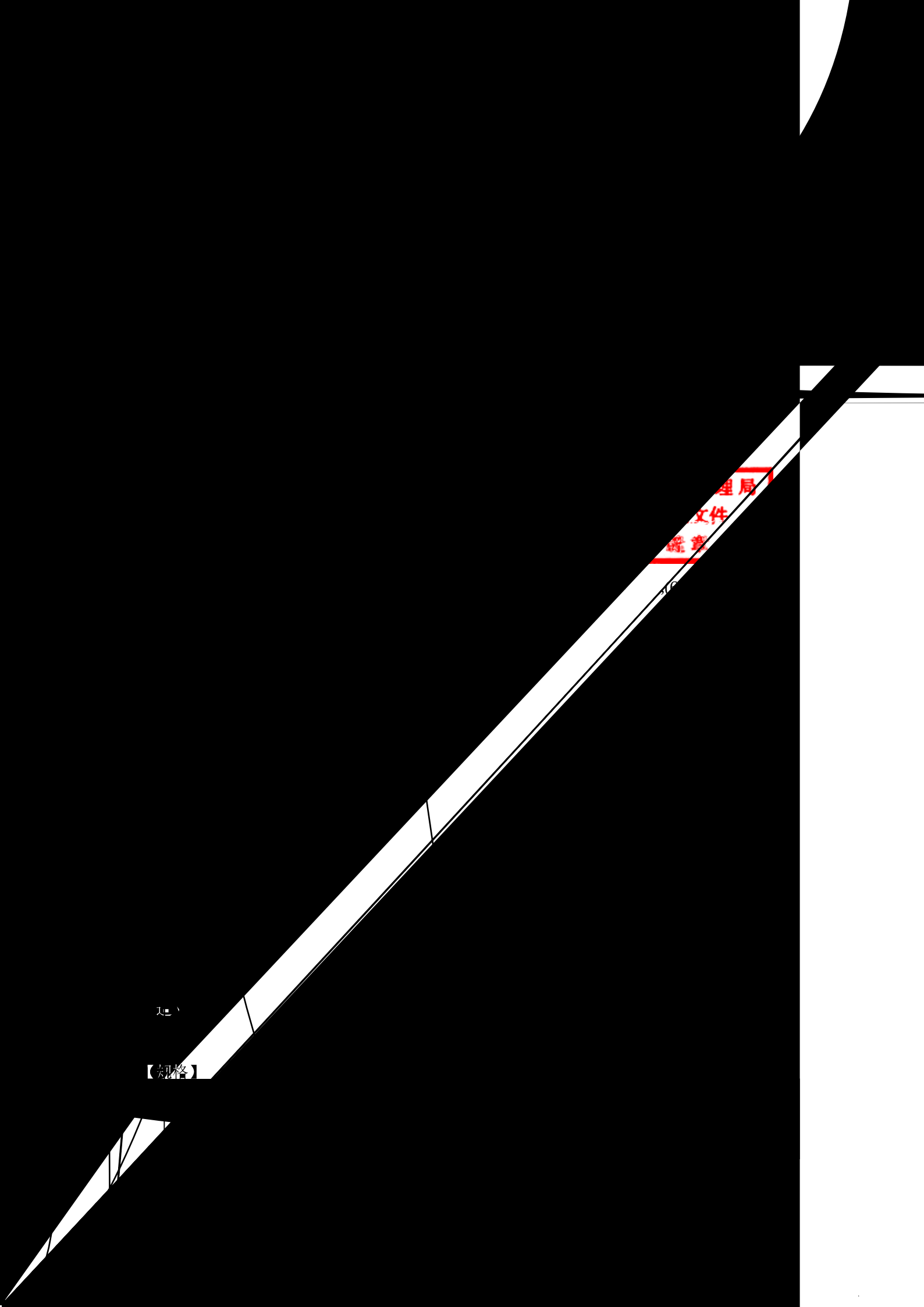
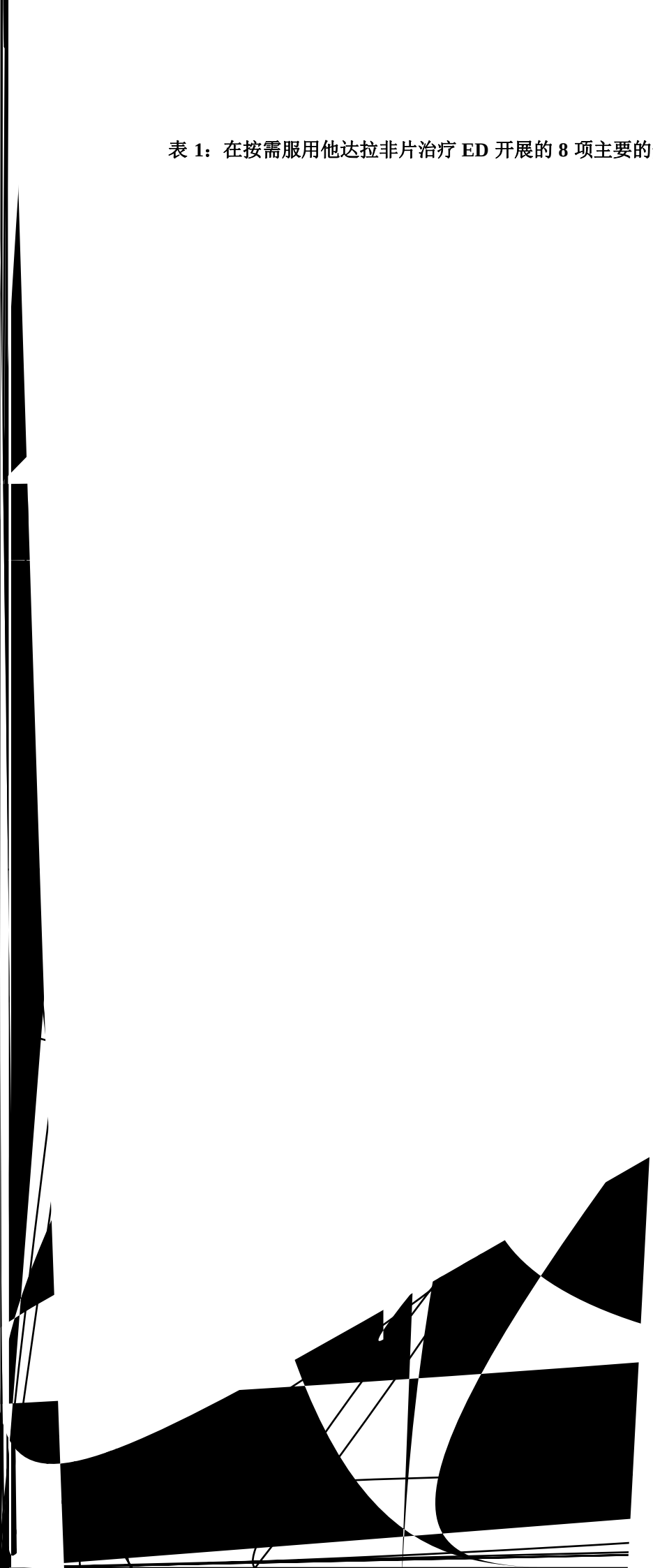

【规格】

勃起功能障碍

- 10mg
- 20mg 5mg
-

表 1：在按需服用他达拉非片治疗 ED 开展的 8 项主要的安慰剂对照 3 期研究中（包括一项



2.5%

<0.1%

<2%

—

—

— GGTP, Gamma Glutamyl Transpeptidase

—

—

—

—

—

—

上市后经验

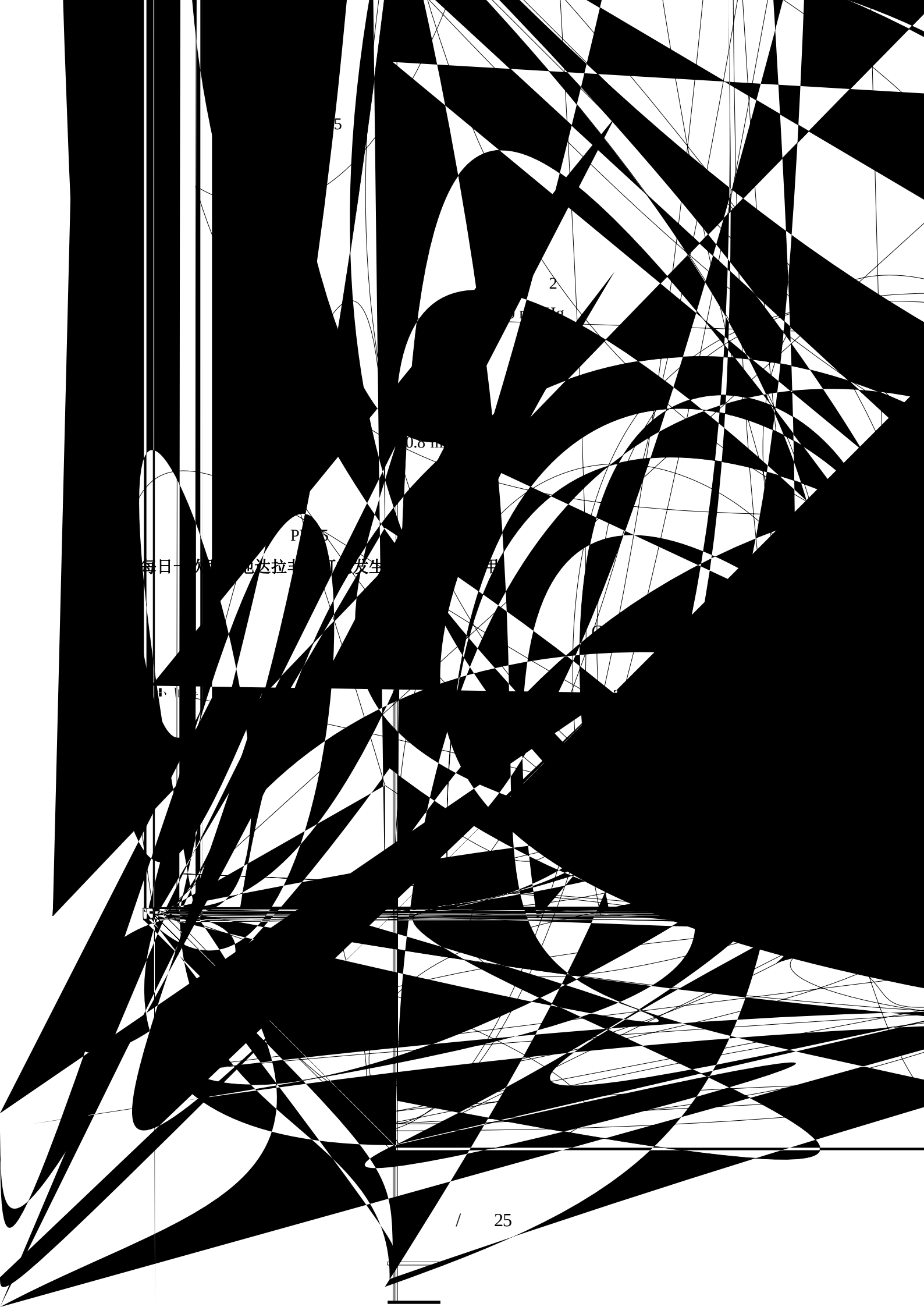
—

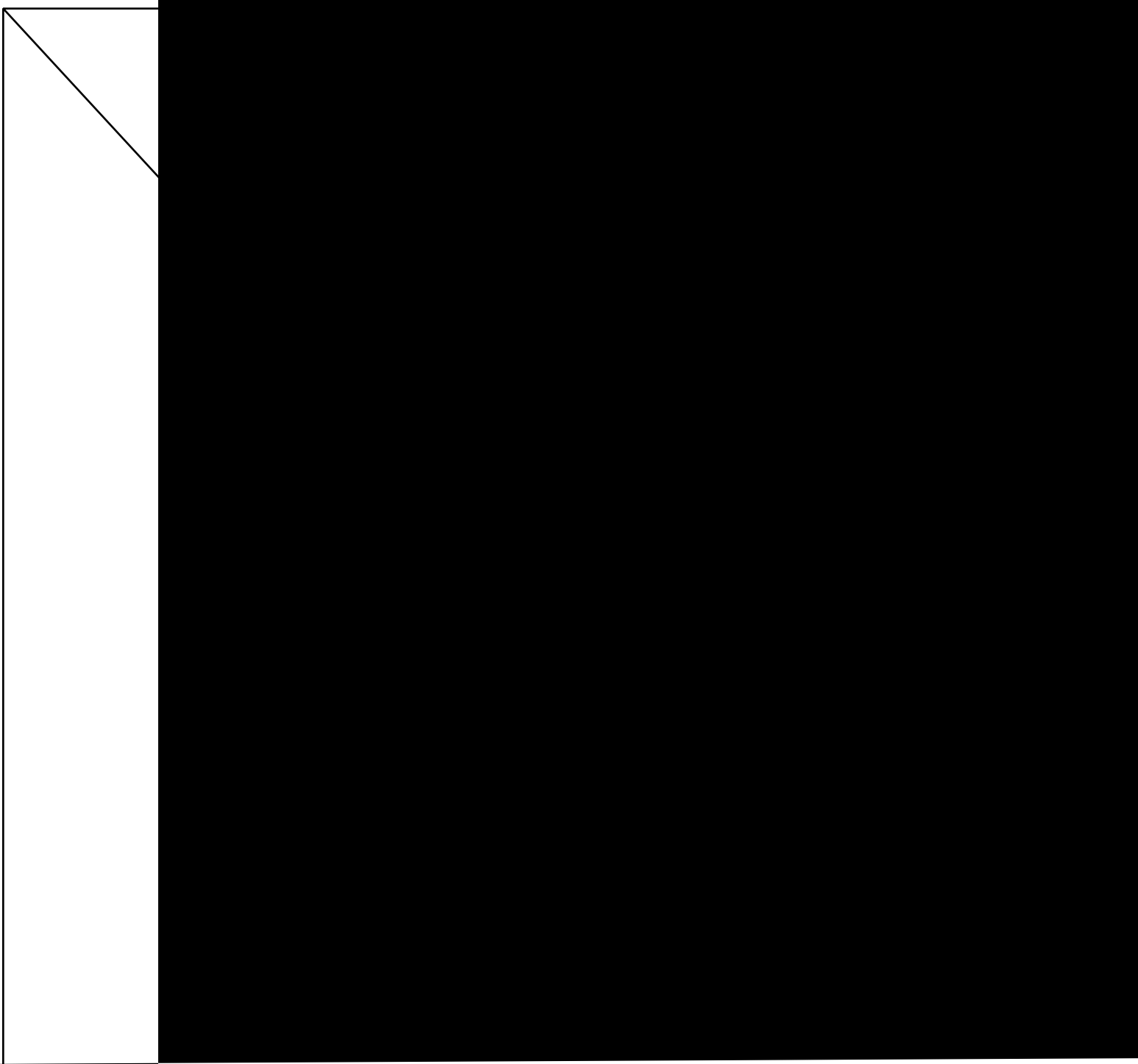
—

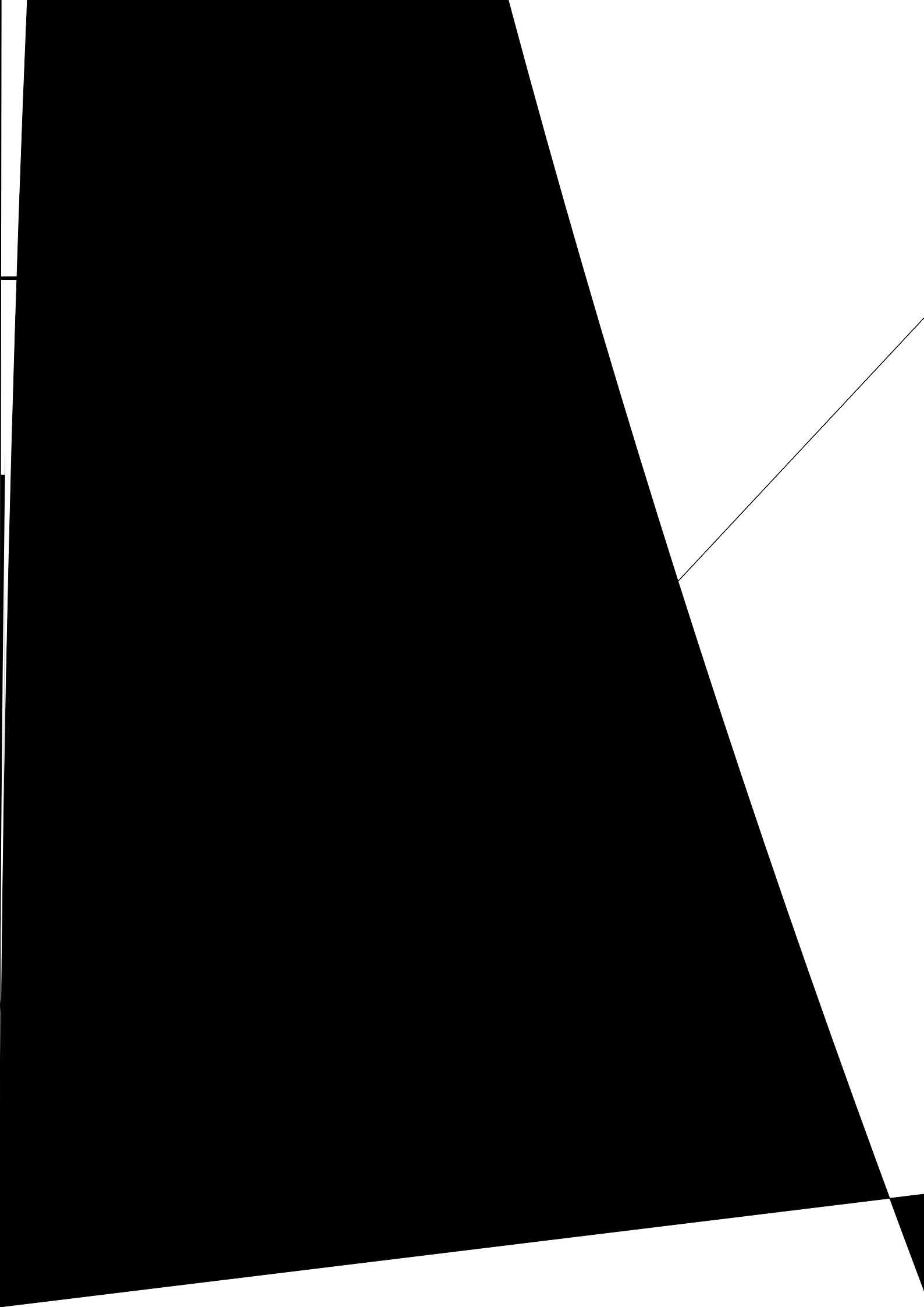
—

—

NAION, Non-arteritic Anterior Ischemic Optic Neuropathy 5 PDE 5, Phosphodiesterase 5







/

哺乳期妇女

/

/

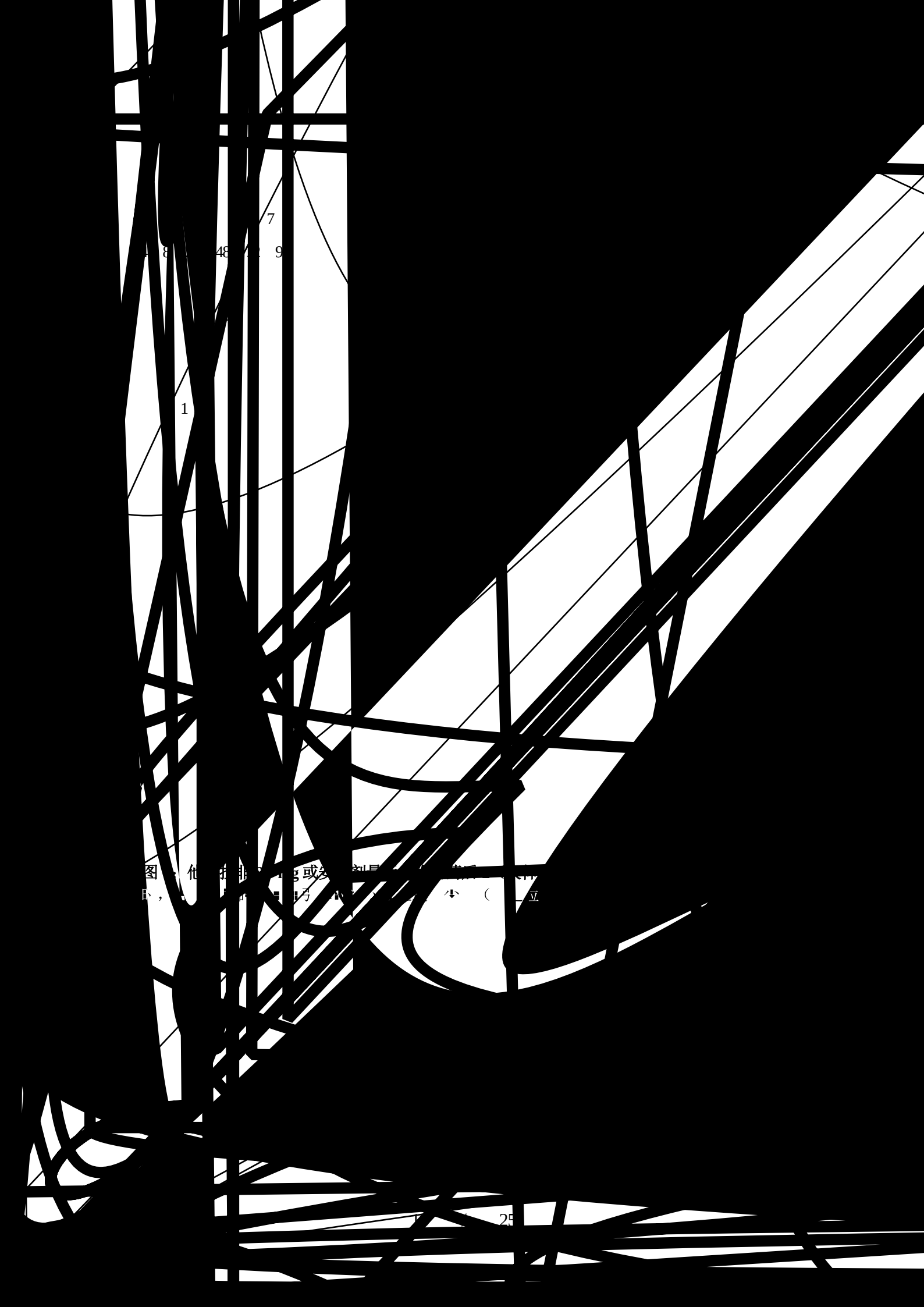
2.4

3 10 mg 6 20 mg

9 20 mg 6

10 mg 20 mg

【儿童用药】



A (N=24) 4 mg 8

8 4 8

B (N=24) 4 mg 8

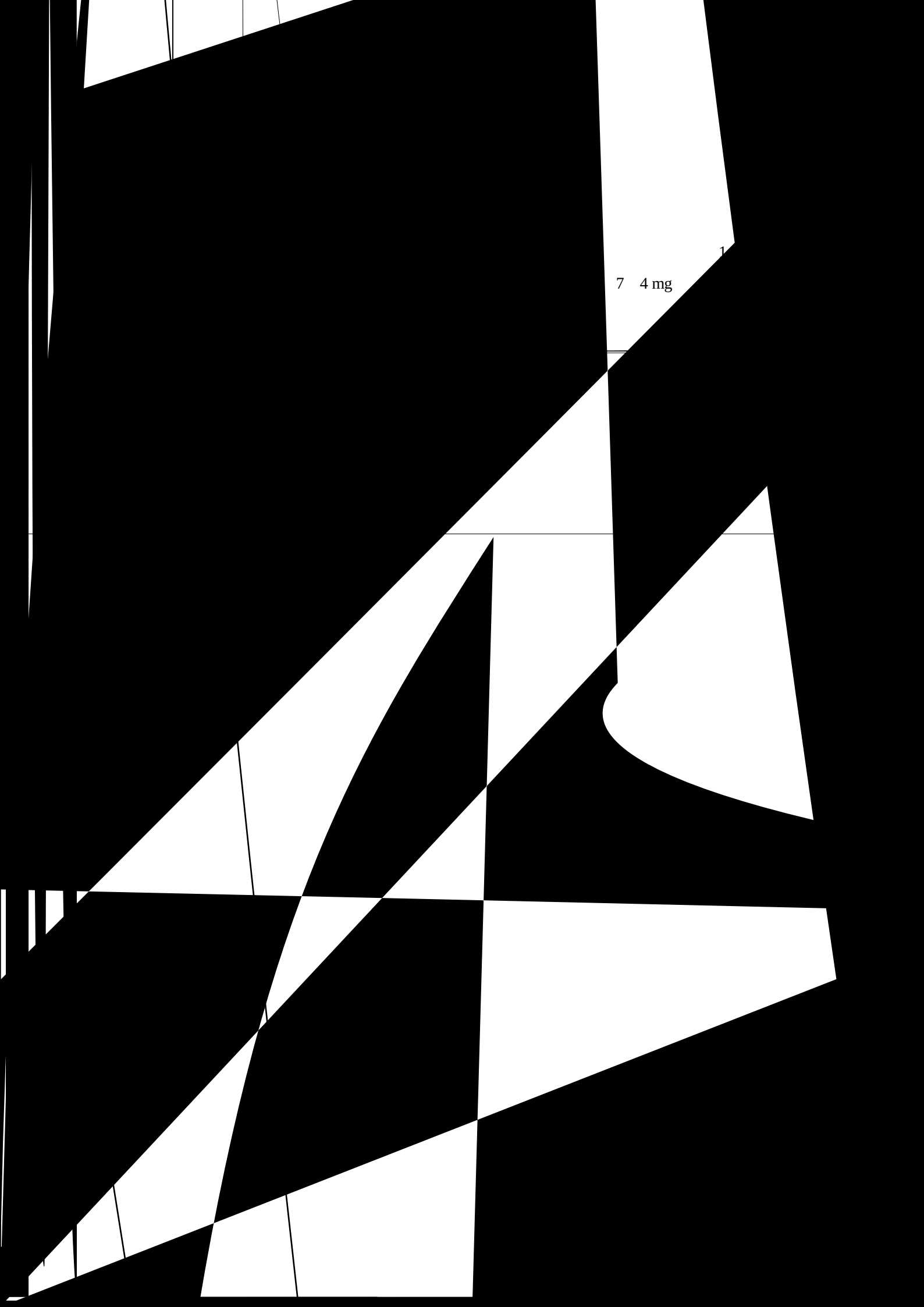
8 4 8

C N=24 8 mg 8

8 8

6 3 C 12

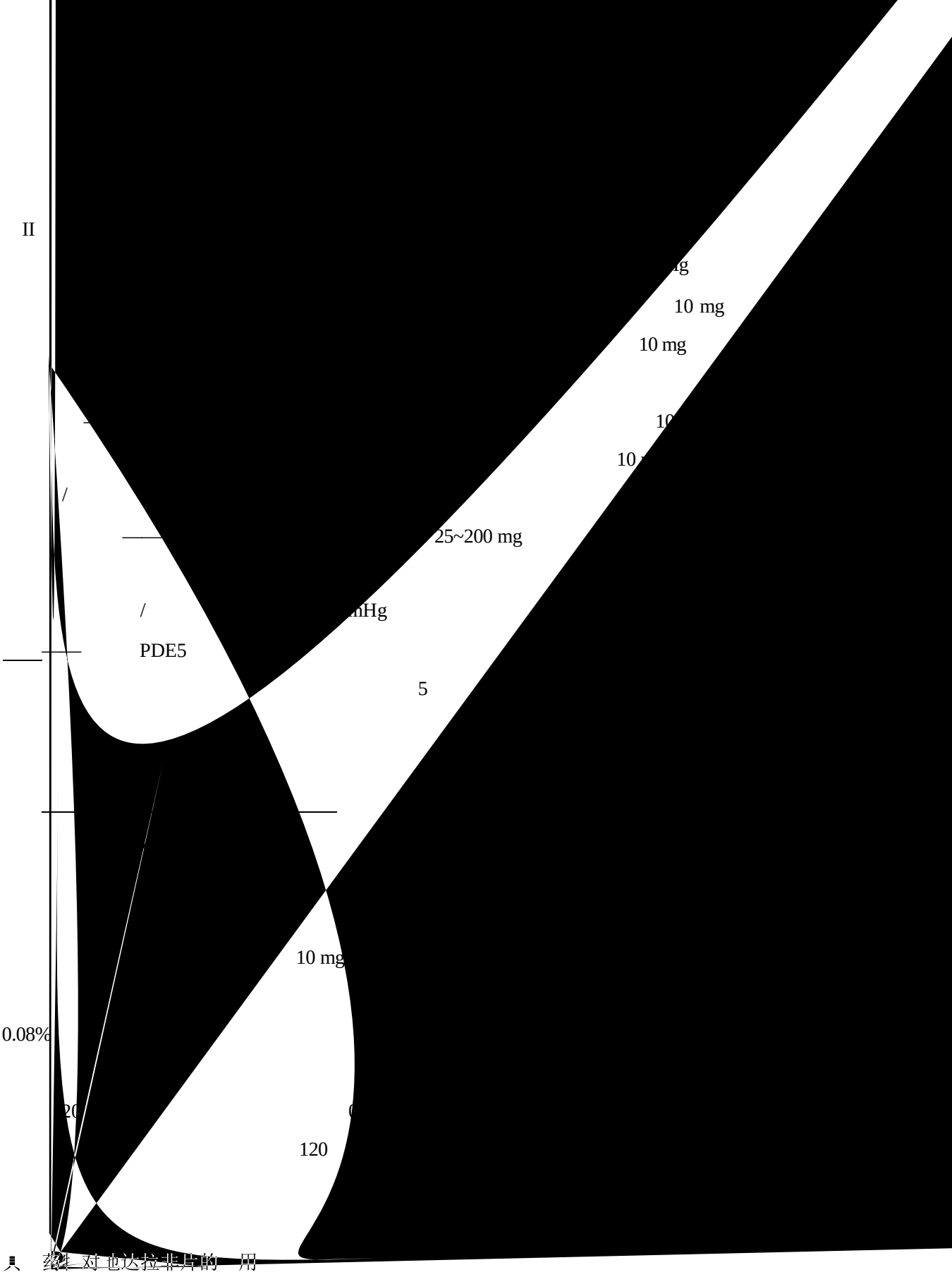
表 6


1
7 4 mg

N=39 35

14 7

平均最大降幅（ ）


II
10 mg
10 mg
25~200 mg
PDE5
5
10 mg
0.08%
120

P450 —— CYP3A4 CYP3A4
CYP3A4
—— 20 mg CYP3A4
400 mg/ 20 mg AUC 312% C_{max}(Maximum
observed plasma concentration) 22% 10 mg 200 mg/
10 mg AUC 107% C_{max} 15%
CYP3A4

500 mg 600 mg CYP3A4 CYP2C9
CYP2C19 CYP2D6 20 mg 20 mg
AUC 32% C_{max} 30% 200 mg 20 mg
20 mg AUC 124% C_{max}
HIV
P450 —— CYP3A4

—— 600 mg/ CYP3A4 10 mg
AUC 88% C_{max} 46%
CYP3A4
CYP3A4

他达拉非片对其他药物的作用

—
P450 — P450 CYP
P450
CYP1A2 CYP3A4 CYP2C9 CYP2C19 CYP2D6 CYP2E1
—
3 /
— S- R- AUC

— AUC
P- — 40 mg 10
0.25 mg/

【药物过量】

500 mg 100 mg

【临床药理】

药代动力学

玉 证验:据

40 mg

0.1%

10mg 20mg 6

3

6 20 mg 9

20 mg

10 20 mg

18~53

100 mg

QT_c (Fridericia

90% CI=1.9 5.1 QT

90% CI=1.2 4.4 100 mg

CYP3A4

进口药品在 验数据

10m

单剂量口服 10mg

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文号】 H20244073