Figure 1

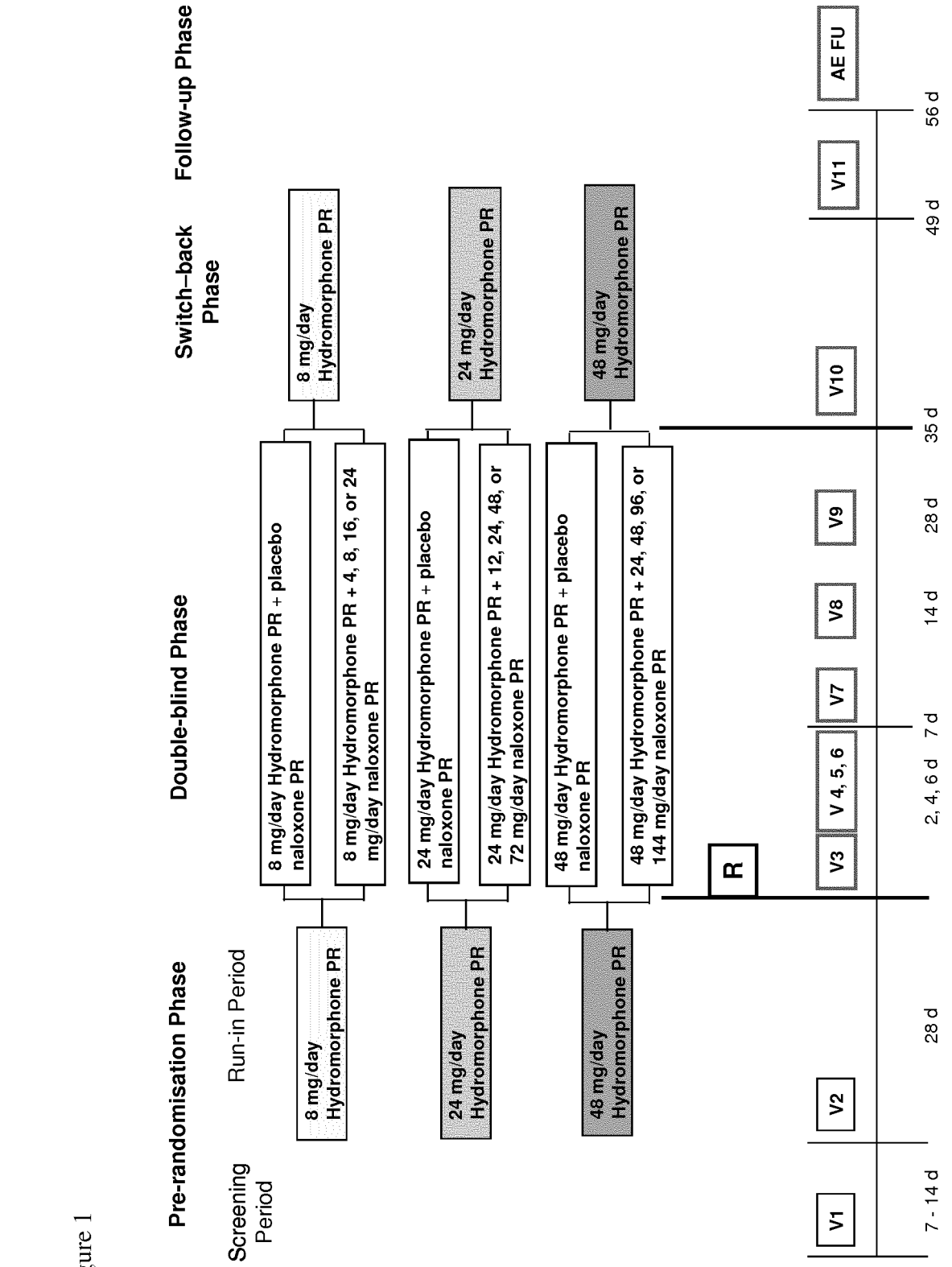
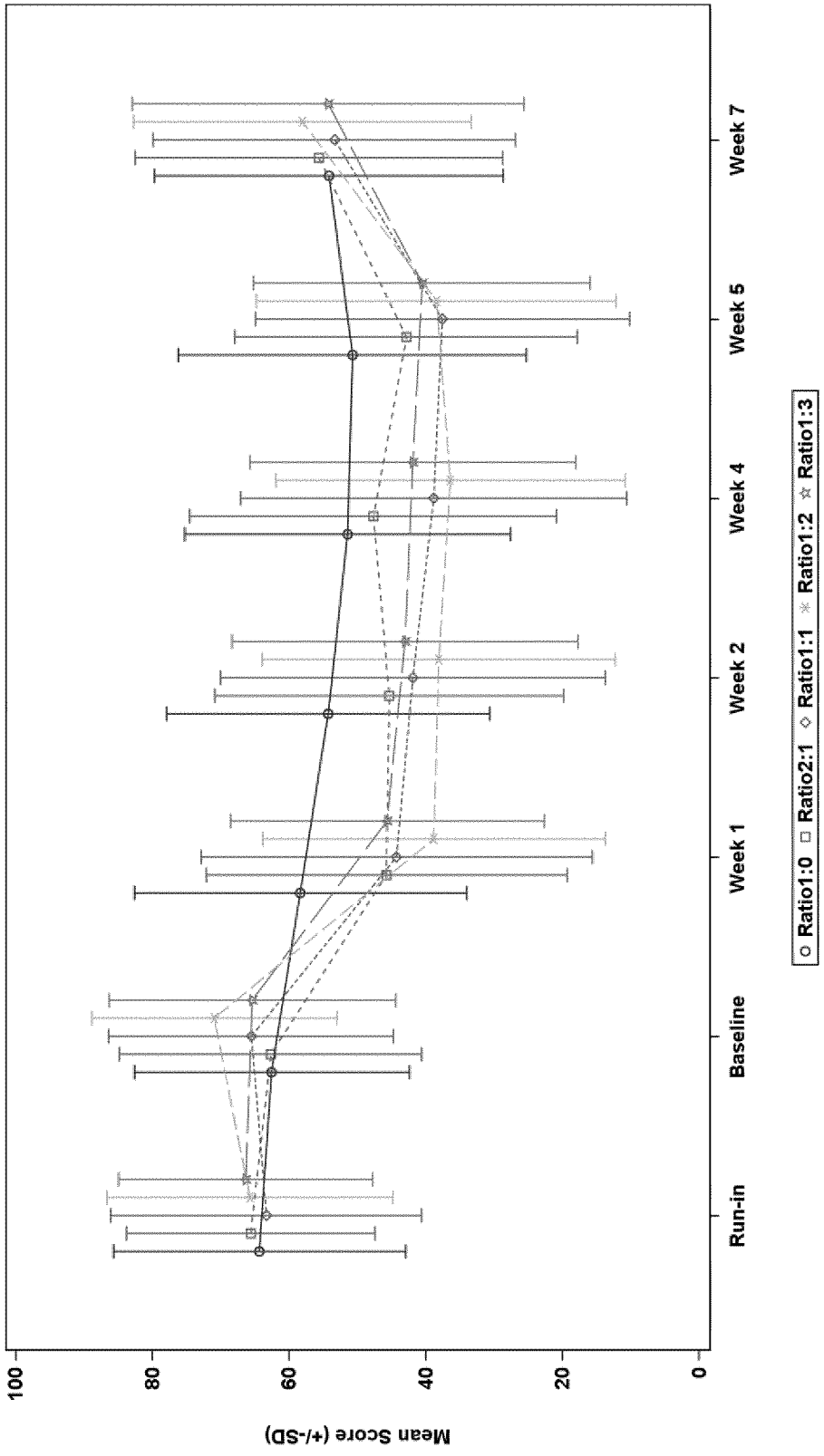

Pre-randomisation Phase
Double-blind Phase
Switch–back Phase
Follow-up Phase
Screening Period
Run-in Period
8 mg/day Hydromorphone PR
24 mg/day Hydromorphone PR
48 mg/day Hydromorphone PR
8 mg/day Hydromorphone PR + placebo naloxone PR
8 mg/day Hydromorphone PR + 4, 8, 16, or 24 mg/day naloxone PR
24 mg/day Hydromorphone PR + placebo naloxone PR
24 mg/day Hydromorphone PR + 12, 24, 48, or 72 mg/day naloxone PR
48 mg/day Hydromorphone PR + placebo naloxone PR
48 mg/day Hydromorphone PR + 24, 48, 96, or 144 mg/day naloxone PR
R
V1
V2
V3
V 4, 5, 6
V7
V8
V9
V10
V11
AE FU
7 - 14 d
28 d
2, 4, 6 d
7 d
14 d
28 d
35 d
49 d
56 d

Figure 2


Mean Score (+/-SD)
100
80
60
40
20
0
Run-in
Baseline
Week 1
Week 2
Week 4
Week 5
Week 7
Ratio1:0
Ratio2:1
Ratio1:1
Ratio1:2
Ratio1:3
Cross-reference: Appendix 16.2.3.8
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