

TABLES, LISTINGS AND FIGURES

List of outputs and mock shells

Protocol GWEP1447

EudraCT Number: 2015-002939-18

A PHASE 2, DOUBLE-BLIND, RANDOMIZED, PLACEBO-CONTROLLED PHARMACOKINETIC TRIAL IN TWO PARALLEL GROUPS TO INVESTIGATE POSSIBLE DRUG-DRUG INTERACTIONS BETWEEN STIRIPENTOL OR VALPROATE AND GWP42003-P IN PATIENTS WITH EPILEPSY

Protocol Number:	GWEP1447
(Version Date)	Version 4 (26-Jul-2016) Version 3 (25-Jul-2016) (Sweden Only) Version 5 (28-Jul-2016) (France only)
Name of Test Drug:	Cannabidiol (GWP42003-P)
Phase:	2
Methodology:	Double-Blind, Randomized, Placebo-Controlled
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1. INTRODUCTION

All outputs (tables, listings and figures) will be produced for each cohort (VPA and STP) using the following three treatment groups:

- GWP42003-P
- Placebo
- Overall

For each output, numbering will be the same for both cohorts, reference to the cohort will be indicated in the header (see below).

GW Pharmaceuticals - GWEP1447
Version - - -
- - -

DB Phase Analysis - VPA Cohort - Draft
Confidential

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All mockups

Section 12

Section 12.1 Demographic Data and Subject Characteristics

1. Subject Disposition, Visit Attendance, Protocol Violations					
1.1. Patients Screened by Country and Site					
Screened Population					
Country	Not randomized N=x Subjects n %	Placebo N=x Subjects n %	GWP42003-P N=xx Subjects n %	All patients N=xx Subjects n %	
Site					
All countries	x (100.0)	x (100.0)	xx (100.0)	xx (100.0)	

Country	Site	Not randomized		Placebo		GWP42003-P		All patients	
		N=x	Subjects	N=x	Subjects	N=xx	Subjects	N=xx	Subjects
		n	%	n	%	n	%	n	%
Romania		x (xx.x)		x (xx.x)		x (xx.x)		x (xx.x)	
	1261			x (xx.x)		x (xx.x)		x (xx.x)	
	1289			x (xx.x)		x (xx.x)		x (xx.x)	

...

Source: Listing 1.1

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1. Subject Disposition, Visit Attendance, Protocol Violations

11-1. Patient Disposition

Screened Population

Statistics	Not randomized (N=x)	Placebo (N=x)	GWP42003-P (N=xx)	Total (N=xx)
	n (%)	n (%)	n (%)	n (%)
Screened Subjects	x (100.0)	x (100.0)	xx (100.0)	xx (100.0)
Screen Failure	x (100.0)			x (xx.x)
Withdrew Consent	x (xx.x)			x (xx.x)
...				
Randomized		x (100.0)	xx (100.0)	xx (xx.x)
Randomized and Treated Subjects		x (xx.x)	xx (xx.x)	xx (xx.x)
Completed the DB Period		x (xx.x)	xx (xx.x)	xx (xx.x)
Continued in OLE period				
Continued to the Taper period		x (xx.x)	xx (xx.x)	xx (xx.x)
Did not continue in OLE or Taper				
Reason 1				
...				
Did Not Complete the DB Period		x (xx.x)	xx (xx.x)	xx (xx.x)
Patient/legal representative withdrew consent to participate		x (xx.x)	xx (xx.x)	xx (xx.x)
...		x (xx.x)	xx (xx.x)	xx (xx.x)

Source: Listing 1.1

Percentages are generally based on the number of screened patients except for DB Period status for which percentages are based on randomized patients.

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x

Repeat this table on the safety and the PK populations.

1. Subject Disposition, Visit Attendance, Protocol Violations

11-2. Number of Patients by Visits

Screened Population

Visit	Not randomized (N=x)	Placebo (N=x)	GWP42003-P (N=xx)	Total (N=xx)
	n (%)	n (%)	n (%)	n (%)
V1 (Day -14 to -7)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)
V2 (Day 1)		x (xx.x)	x (xx.x)	x (xx.x)
V2 (Day 2)		x (xx.x)	x (xx.x)	x (xx.x)
V3 (Day 12)		x (xx.x)	x (xx.x)	x (xx.x)
V4 (Day 26)		x (xx.x)	x (xx.x)	x (xx.x)
V4 (Day 27)		x (xx.x)	x (xx.x)	x (xx.x)
...				

Source: Listing 1.3

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2. Analysis Sets

2.1. Summary of Analysis Sets

Screened Population

Population and reason for exclusion	Not randomized	Placebo	GWP42003-P	Total	
	(N=x)	(N=x)	(N=xx)	(N=xx)	
n	(%)	n	(%)	n	(%)
Screened	x (100.0)	x (100.0)	x (100.0)	x (100.0)	
Withdrew Consent	x (xx.x)			x (xx.x)	
Safety Population		x (100.0)	xx (100.0)	xx (xx.x)	
Pharmacokinetic Population*		x (xx.x)	xx (xx.x)	xx (xx.x)	
Reason 1	x (xx.x)	x (xx.x)	x (xx.x)		
Reason 2		x (xx.x)	x (xx.x)		
...		x (xx.x)	x (xx.x)		

Source: Listing 2

* For the pharmacokinetic population, percentages are based on treated subjects.

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2. Analysis Sets

2.2. Summary of Anti-Epileptic Drugs
Safety Population

Population	Anti-Epileptic Drug	Placebo		GWP42003-P		All patients	
		n	%	N=x	N=xx	N=xx	%
Safety Population		x		xx		xx	
	AE Drug 1	x (xx.x)		xx (xx.x)		xx (xx.x)	
	AE Drug 2	x (xx.x)		xx (xx.x)		xx (xx.x)	
	...						
<hr/>		<hr/>		<hr/>		<hr/>	
Pharmacokinetic Population		x		x		xx	
	AE Drug 1	x (xx.x)		xx (xx.x)		xx (xx.x)	
	AE Drug 2	x (xx.x)		xx (xx.x)		xx (xx.x)	
	...						

Source: Listing 6.2

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3. Demographics

3.1. Summary of Demographics Safety Population

Parameters	Statistics	Placebo (N=x)	GWP42003-P (N=xx)	Total (N=xx)
Age (years)	N (missing)	x (x)	xx (xx)	xx (xx)
	Mean (SD)	xx.xx (xx.xx)	xx.xx (xx.xx)	xx.xx (xx.xx)
	Median	xx.xx	xx.xx	xx.xx
	Q1 ; Q3	xx.xx ; xx.xx	xx.xx ; xx.xx	xx.xx ; xx.xx
	Min ; Max	xx.x ; xx.x	xx.x ; xx.x	xx.x ; xx.x
Sex	N (missing)	x	xx	xx
	Male	x (xx.x)	x (xx.x)	xx (xx.x)
	Female	x (xx.x)	x (xx.x)	xx (xx.x)
Race	N (missing)	x	xx	xx
	White/Caucasian	x (xx.x)	xx (xx.x)	xx (xx.x)
	Black/African American	x (xx.x)	xx (xx.x)	xx (xx.x)
	Asian	x (xx.x)	xx (xx.x)	xx (xx.x)
	Native Hawaiian/Other Pacific Islander	x (xx.x)	xx (xx.x)	xx (xx.x)
	Other	x (xx.x)	xx (xx.x)	xx (xx.x)
Height (cm)	N (missing)	x (x)	xx (xx)	xx (xx)
	Mean (SD)	xxx.xx (xx.xx)	xxx.xx (xx.xx)	xxx.xx (xx.xx)
	Median	xxx.xx	xxx.xx	xxx.xx
	Q1 ; Q3	xxx.xx ; xxx.xx	xxx.xx ; xxx.xx	xxx.xx ; xxx.xx
	Min ; Max	xxx.x ; xxx.x	xxx.x ; xxx.x	xxx.x ; xxx.x
Weight (kg)	N (missing)	x (x)	xx (xx)	xx (xx)
	Mean (SD)	xx.xx (xx.xx)	xx.xx (xx.xx)	xx.xx (xx.xx)
	Median	xx.xx	xx.xx	xx.xx
	Q1 ; Q3	xx.xx ; xx.xx	xx.xx ; xx.xx	xx.xx ; xx.xx
	Min ; Max	xx.x ; xxxx.x	xx.x ; xxxx.x	xx.x ; xxxx.x

Source: Listing 3

3. Demographics
3.1. Summary of Demographics
Safety Population

Parameters	Statistics	Placebo (N=x)	GWP42003-P (N=xx)	Total (N=XX)
Body Mass Index (kg/n m ²)		x	xx	xx
	Mean (SD)	xx.xx (x.xx)	xx.xx (xx.x)	xx.xx (xx.x)
	Median	xx.xx	xx.xx	xx.xx
	Q1 ; Q3	xx.xx ; xx.xx	xx.xx ; xx.xx	xx.xx ; xx.xx
	Min ; Max	xx.x ; xx.x	xx.x ; xx.x	xx.x ; xx.x

Source: Listing 3

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4. Baseline Disease Characteristics

4.1. Epilepsy Characteristics

Safety Population

Parameters	Placebo	GWP42003-P	All patients
	N=x	N=xx	N=xx
	Subjects n %	Subjects n %	Subjects n %
Ever Had Abnormal EEG? ->Yes	x (xx.x)	xx (xx.x)	xx (xx.x)
Ever Had Abnormal Neuroimaging History? ->Yes	x (xx.x)	xx (xx.x)	xx (xx.x)
Ever Had Genetic Testing? ->Yes	x (xx.x)	xx (xx.x)	xx (xx.x)
History Of Current Seizures	x (xx.x)	xx (xx.x)	xx (xx.x)
Absence or Atypical absence	x (xx.x)	x (xx.x)	x (xx.x)
Atonic	x (xx.x)	x (xx.x)	x (xx.x)
Complex Partial Seizure (Focal Dyscognitive)	x (xx.x)	x (xx.x)	x (xx.x)
...			
History Of Seizures No Longer Occurring	x (xx.x)	x (xx.x)	x (xx.x)
Atonic	x (xx.x)	x (xx.x)	x (xx.x)
Complex Partial Seizure (Focal Dyscognitive)	x (xx.x)	x (xx.x)	x (xx.x)
...			

Source: Listing 4.1, 4.2, 4.3, 4.4, 4.5

4. Baseline Disease Characteristics

4.2. Previous Use of Cannabis
 Safety Population

Parameters	Statistics	Placebo	GWP42003-P	Total
		(N=x)	(N=xx)	(N=xx)
	n	(%)	n	(%)
Has the patient previously used Cannabis?	n	x	xx	xx
Yes		x (xx.x)	x (xx.x)	x (xx.x)
No		x (xx.x)	x (xx.x)	x (xx.x)
Time since Last of use of Cannabis (Months)	n	x	x	x
Mean (SD)		xxx.x (xxx.x)	xxx.x (xxx.x)	xxx.x (xxx.x)
Median		xxx.x	xxx.x	xxx.x
Q1 ; Q3		xxx.x ; xxx.x	xxx.x ; xxx.x	xxx.x ; xxx.x
Min ; Max		xxx ; xxx	xxx ; xxx	xxx ; xxx
Time since Last of use of Cannabis (Categorical)	n	x	xx	xx
≤3 months		x (xx.x)	xx (xx.x)	xx (xx.x)
>3 months		x (xx.x)	xx (xx.x)	xx (xx.x)
Frequency of use of Cannabis	n	x	xx	xx
Missing		x (xx.x)	x (xx.x)	x (xx.x)
Once per year		x (xx.x)	x (xx.x)	x (xx.x)
Up to 12 times per year		x (xx.x)	x (xx.x)	x (xx.x)
More than 12 times per year		x (xx.x)	x (xx.x)	x (xx.x)

Source: Listing 4.6

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5. Non-Epilepsy Medical History
 Safety Population

System Organ Class Preferred Term	Placebo		GWP42003-P		All patients	
	N=x Subjects n	%	N=xx Subjects n	%	N=xx Subjects n	%
Subject with at least one non-epilepsy medical history	x (xx.x)		xx (xx.x)		xx (xx.x)	
SOC 1	x (xx.x)		xx (xx.x)		xx (xx.x)	
PT 1	x (xx.x)		xx (xx.x)		xx (xx.x)	
PT 2	x (xx.x)		xx (xx.x)		xx (xx.x)	
...						
SOC 2	x (xx.x)		xx (xx.x)		xx (xx.x)	
PT 1	x (xx.x)		xx (xx.x)		xx (xx.x)	
PT 2	x (xx.x)		xx (xx.x)		xx (xx.x)	
...						
...						

Source: Listing 5

If a subject has multiple histories within a system organ class or preferred term, the subject is counted once.

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6. Medications

6.1. Medications Ongoing at Baseline
Safety Population

ATC Level 2 Preferred Term	Placebo		GWP42003-P		All patients	
	N=x	Subjects n %	N=xx	Subjects n %	N=xx	Subjects n %
Subject with at least one medication ongoing at baseline		x (xx.x)	xx (xx.x)	xx (xx.x)		
ATC 2 A		x (xx.x)	xx (xx.x)	xx (xx.x)		
PT 1		x (xx.x)	xx (xx.x)	xx (xx.x)		
PT 2		x (xx.x)	xx (xx.x)	xx (xx.x)		
...						
ATC 2 B		x (xx.x)	xx (xx.x)	xx (xx.x)		
PT 1		x (xx.x)	xx (xx.x)	xx (xx.x)		
PT 2						
...						
...						

Source: Listing 6.3

Clobazam was taken by all patients as planned in the protocol and was excluded from the table.
If a subject has multiple medications within an ATC level 2 or preferred term, the subject is counted once.

6. Medications

6.2. Medications Concomitant to DB Treatment Period
 Safety Population

ATC Level 2 Preferred Term	Placebo	GWP42003-P	All patients
	N=x Subjects n %	N=xx Subjects n %	N=xx Subjects n %
Subject with at least one medication concomitant to DB period	x (xx.x)	xx (xx.x)	xx (xx.x)
ATC 2 A	x (xx.x)	xx (xx.x)	xx (xx.x)
PT 1	x (xx.x)	xx (xx.x)	xx (xx.x)
PT 2	x (xx.x)	xx (xx.x)	xx (xx.x)
...			
ATC 2 B	x (xx.x)	xx (xx.x)	xx (xx.x)
PT 1	x (xx.x)	xx (xx.x)	xx (xx.x)
PT 2			
...			

Source: Listing 6.3

Medications ongoing at baseline or started after baseline are included.

Clobazam was taken by all patients as planned in the protocol and was excluded from the table.

If a subject has multiple medications within an ATC level 2 or preferred term, the subject is counted once.

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Parameters	Statistics	7. Compliance Safety Population		Total (N=xx)
		Placebo (N=x) n (%)	GWP42003-P (N=xx) n (%)	
Compliant?	n	x	xx	xx
No		x (xx.x)	xx (xx.x)	xx (xx.x)
Yes		x (xx.x)	xx (xx.x)	xx (xx.x)

Source: Listing 7

Compliant:

The response to the question 'Did the patient comply with the dosing scheduled' is answered 'Yes' and,
 The response to the question 'Does the actual IMP usage reflect the expected amount used as per the dosing
 scheduled' is answered 'Yes' and,

The response to the question 'Were there some signals of potential abuse since last visit' is answered 'No'.
 Not compliant: if the response to the 2 first questions above was 'No' at least once or the response to the
 third question is 'Yes' at least once.

Unknown otherwise.

Section 12.2 Efficacy

Section 12.2.1 Pharmacokinetics

8. Pharmacokinetics

8.1. PK Values

8.1.1. STP

PK Population

Parameter	Visit	Statistics	Placebo	GWP42003-P	Total
			(N=x)	(N=xx)	(N=xx)
Stiripentol (ng/mL)	D1-Pre-dose	n	x	xx	xx
		Mean (SD)	xxx.xx (xxx.xx)	xxx.xx (xxx.xx)	xxx.xx (xxx.xx)
		Median	xxx.xx	xxx.xx	xxx.xx
		Q1 ; Q3	xxx.xx ; xxx.xx	xxx.xx ; xxx.xx	xxx.xx ; xxx.xx
		Min ; Max	xxx.x ; xxx.x	xxx.x ; xxx.x	xxx.x ; xxx.x
		n*	x	xx	xx
		G-Mean (CV%)	xxx.x (xx.x)	xxx.x (xx.x)	xxx.x (xx.x)
	D1-15 minutes post-dose	n	x	xx	xx
		Mean (SD)	xxx.xx (xxx.xx)	xxx.xx (xxx.xx)	xxx.xx (xxx.xx)
		Median	xxx.xx	xxx.xx	xxx.xx
		Q1 ; Q3	xxx.xx ; xxx.xx	xxx.xx ; xxx.xx	xxx.xx ; xxx.xx
		Min ; Max	xxx.x ; xxx.x	xxx.x ; xxx.x	xxx.x ; xxx.x
		n*	x	xx	xx
		G-Mean (CV%)	xxx.x (xx.x)	xxx.x (xx.x)	xxx.x (xx.x)

...

Source: Listing 8.1

Geometric mean is derived for patients with concentration above LLOQ

* Number of patients with concentration above LLOQ

24 hour kinetic data points excluded from PK analysis and plasma concentration-time profiles (12 hour dosing interval).

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Programmer's note: All blood samples time points will be summarized (pre-dose, 15 minutes, 30 minutes, 1 hour, 1.5 hours, 2 hours, 4 hours, 6 hours, 12 hours, 24 hours post-dose) at Day 1 and Day 26.

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This title is applicable for STP arm. For VPA arm that will be "8.1.1. VPA and Metabolites", and VPA and 4-ene-VPA will be summarized at each timepoint for Day 1 and Day 26.

8. Pharmacokinetics

8.1. PK Values

8.1.2. CBD and Metabolites

PK Population

Parameter	Visit	Statistics (N=x)	Placebo (N=xx)	GWP42003-P (N=xx)	Total (N=xx)
Cannabidiol (ng/mL) D26-Pre-dose		n Mean (SD) Median Q1 ; Q3 Min ; Max	x xxx.xx (xxx.xx) xxx.xx xxx.xx ; xxx.xx xxx.x ; xxx.x	xx xxx.xx (xxx.xx) xxx.xx xxx.xx ; xxx.xx xxx.x ; xxx.x	xx xxx.xx (xxx.xx) xxx.xx xxx.xx ; xxx.xx xxx.x ; xxx.x
		n* G-Mean (CV%)	x xxx.x (xx.x)	xx xxx.x (xx.x)	xx xxx.x (xx.x)
D26-15 minutes post-dose		n Mean (SD) Median Q1 ; Q3 Min ; Max	x xxx.xx (xxx.xx) xxx.xx xxx.xx ; xxx.xx xxx.x ; xxx.x	xx xxx.xx (xxx.xx) xxx.xx xxx.xx ; xxx.xx xxx.x ; xxx.x	xx xxx.xx (xxx.xx) xxx.xx xxx.xx ; xxx.xx xxx.x ; xxx.x
		n* G-Mean (CV%)	x xxx.x (xx.x)	xx xxx.x (xx.x)	xx xxx.x (xx.x)
...					

Source: Listing 8.1

Geometric mean is derived for patients with concentration above LLOQ

* Number of patients with concentration above LLOQ

24 hour kinetic data points excluded from PK analysis and plasma concentration-time profiles (12 hour dosing interval).

Programmer's note: All blood samples time points will be summarized (pre-dose, 15 minutes, 30 minutes, 1 hour, 1.5 hours, 2 hours, 4 hours, 6 hours, 12 hours, 24 hours post-dose) at Day 26 for CBD and his metabolites (6-hydroxy cannabidiol, 7-carboxy cannabidiol, 7-hydroxy cannabidiol).

8. Pharmacokinetics

8.1. PK Values

8.1.3. THC and metabolites

PK Population

Parameter	Visit	Statistics	Placebo (N=x)	GWP42003-P (N=xx)	Total (N=xx)
Tetrahydrocannabinol (ng/mL)	D26-Pre-dose	n	x	xx	xx
		Mean (SD)	xxx.xx (xxx.xx)	xxx.xx (xxx.xx)	xxx.xx (xxx.xx)
		Median	xxx.xx	xxx.xx	xxx.xx
		Q1 ; Q3	xxx.xx ; xxx.xx	xxx.xx ; xxx.xx	xxx.xx ; xxx.xx
		Min ; Max	xxx.x ; xxx.x	xxx.x ; xxx.x	xxx.x ; xxx.x
		n*	x	xx	xx
		G-Mean (CV%)	xxx.x (xx.x)	xxx.x (xx.x)	xxx.x (xx.x)
	D26-15 minutes post-dose	n	x	xx	xx
		Mean (SD)	xxx.xx (xxx.xx)	xxx.xx (xxx.xx)	xxx.xx (xxx.xx)
		Median	xxx.xx	xxx.xx	xxx.xx
		Q1 ; Q3	xxx.xx ; xxx.xx	xxx.xx ; xxx.xx	xxx.xx ; xxx.xx
		Min ; Max	xxx.x ; xxx.x	xxx.x ; xxx.x	xxx.x ; xxx.x
		n*	x	xx	xx
		G-Mean (CV%)	xxx.x (xx.x)	xxx.x (xx.x)	xxx.x (xx.x)
	...				

Source: Listing 8.1

Geometric mean is derived for patients with concentration above LLOQ

* Number of patients with concentration above LLOQ

24 hour kinetic data points excluded from PK analysis and plasma concentration-time profiles (12 hour dosing interval).

Page 1 of x

Programmer's note: All blood samples time points will be summarized (pre-dose, 15 minutes, 30 minutes, 1 hour, 1.5 hours, 2 hours, 4 hours, 6 hours, 12 hours, 24 hours post-dose) at Day 26 for THC and his metabolites (11-OH Tetrahydrocannabinol, 11-COOH Tetrahydrocannabinol).

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8. Pharmacokinetics

8.1. PK Values

8.1.4. CLB and Metabolites

PK Population

Parameter	Visit	Statistics	Placebo	GWP42003-P	Total
			(N=x)	(N=xx)	(N=xx)
Clobazam (ng/mL)	D1-Pre-dose	n	x	xx	xx
		Mean (SD)	xxx.xx (xxx.xx)	xxx.xx (xxx.xx)	xxx.xx (xxx.xx)
		Median	xxx.xx	xxx.xx	xxx.xx
		Q1 ; Q3	xxx.xx ; xxxx.xx	xxx.xx ; xxxx.xx	xxx.xx ; xxxx.xx
		Min ; Max	xxx.x ; xxxx.x	xxx.x ; xxxx.x	xxx.x ; xxxx.x
		n*	x	xx	xx
		G-Mean (CV%)	xxx.x (xx.x)	xxx.x (xx.x)	xxx.x (xx.x)
	D1-15 minutes post-dose	n	x	xx	xx
		Mean (SD)	xxx.xx (xxx.xx)	xxx.xx (xxx.xx)	xxx.xx (xxx.xx)
		Median	xxx.xx	xxx.xx	xxx.xx
		Q1 ; Q3	xxx.xx ; xxxx.xx	xxx.xx ; xxxx.xx	xxx.xx ; xxxx.xx
		Min ; Max	xxx.x ; xxxx.x	xxx.x ; xxxx.x	xxx.x ; xxxx.x
		n*	x	xx	xx
		G-Mean (CV%)	xxx.x (xx.x)	xxx.x (xx.x)	xxx.x (xx.x)
	...				

Source: Listing 8.1

Geometric mean is derived for patients with concentration above LLOQ

* Number of patients with concentration above LLOQ

24 hour kinetic data points excluded from PK analysis and plasma concentration-time profiles (12 hour dosing interval).

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Programmer's note: All blood samples time points will be summarized (pre-dose, 15 minutes, 30 minutes, 1 hour, 1.5 hours, 2 hours, 4 hours, 6 hours, 12 hours, 24 hours post-dose) at Day 1 and Day 26 for CLB and his metabolite (N-Desmethylclobazam).

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8. Pharmacokinetics

8.1. PK Values

8.1.5. Others AEDs

PK Population

Parameter	Visit	Statistics	Placebo (N=x)	GWP42003-P (N=xx)	Total (N=xx)
Levetiracetam (ng/mL)	D26-Pre-dose	n	x	xx	xx
		Mean (SD)	xxx.xx (xxx.xx)	xxx.xx (xxx.xx)	xxx.xx (xxx.xx)
		Median	xxx.xx	xxx.xx	xxx.xx
		Q1 ; Q3	xxx.xx ; xxxx.xx	xxx.xx ; xxxx.xx	xxx.xx ; xxxx.xx
		Min ; Max	xxx.x ; xxxx.x	xxx.x ; xxxx.x	xxx.x ; xxxx.x
		n*	x	xx	xx
		G-Mean (CV%)	xxx.x (xx.x)	xxx.x (xx.x)	xxx.x (xx.x)
	D26-15 minutes post-dose	n	x	xx	xx
		Mean (SD)	xxx.xx (xxx.xx)	xxx.xx (xxx.xx)	xxx.xx (xxx.xx)
		Median	xxx.xx	xxx.xx	xxx.xx
		Q1 ; Q3	xxx.xx ; xxxx.xx	xxx.xx ; xxxx.xx	xxx.xx ; xxxx.xx
		Min ; Max	xxx.x ; xxxx.x	xxx.x ; xxxx.x	xxx.x ; xxxx.x
		n*	x	xx	xx
		G-Mean (CV%)	xxx.x (xx.x)	xxx.x (xx.x)	xxx.x (xx.x)
	...				

Source: Listing 8.1

For each drug, the subset of patients that took the drug is used.

Geometric mean is derived for patients with concentration above LLOQ

* Number of patients with concentration above LLOQ

24 hour kinetic data points excluded from PK analysis and plasma concentration-time profiles (12 hour dosing interval).

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Programmer's note: All blood samples time points will be summarized (pre-dose, 15 minutes, 30 minutes, 1 hour, 1.5 hours, 2 hours, 4 hours, 6 hours, 12 hours, 24 hours post-dose) at Day 1 and Day 26 for levetiracetam (LEV) and topiramate (TPM).

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8. Pharmacokinetics

8.1. PK Values

8.1.6. Summary

PK Population

Parameter	Visit	Placebo			GWP42003-P		
		N	Mean (SD)	Median	N	Mean (SD)	Median
Stiripentol (ng/mL)	D1-Pre-dose	x	xxx.xx (xxxx.xx)	(xxxx.xx)	xx	xxx.xx (xxxx.xx)	xxx.xx
	D1-15 minutes post-dose	x	xxx.xx (xxxx.xx)	(xxxx.xx)	xx	xxx.xx (xxxx.xx)	xxx.xx
	D1-30 minutes post-dose	x	xxx.xx (xxxx.xx)	(xxxx.xx)	xx	xxx.xx (xxxx.xx)	xxx.xx
	...	x	xxx.xx (xxxx.xx)	(xxxx.xx)	xx	xxx.xx (xxxx.xx)	xxx.xx
Cannabidiol (ng/mL)	D26-Pre-dose	x	xxx.xx (xxxx.xx)	(xxxx.xx)	xx	xxx.xx (xxxx.xx)	xxx.xx
	D26-15 minutes post-dose	x	xxx.xx (xxxx.xx)	(xxxx.xx)	xx	xxx.xx (xxxx.xx)	xxx.xx
	...						

Source: Listing 8.1

24 hour kinetic data points excluded from PK analysis and plasma concentration-time profiles (12 hour dosing interval).

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Programmer's note: All parameters and all blood samples time points from tables 8.1.1 to 8.1.5 will be summarized.
 Stiripentol is applicable for STP arm. For VPA arm, VPA and 4-ene-VPA will be summarized.

8. Pharmacokinetics

8.2. PK Parameters

8.2.1. STP

PK Population

Parameter	PK parameter	Visit	Statistics	Placebo	GWP42003-P	Total	
				(N=x)	(N=xx)	(N=xx)	
Stiripentol	TMax (h)	Day 1	n	x	xx	xx	
			Mean (SD)	x.xx (x.xx)	x.xx (x.xx)	x.xx (x.xx)	
			Median	x.xx	x.xx	x.xx	
			Q1 ; Q3	x.xx ; x.xx	x.xx ; x.xx	x.xx ; x.xx	
			Min ; Max	x.x ; x.x	x.x ; x.x	x.x ; x.x	
	Day 26		n*	x	xx	xx	
			G-Mean (CV%)	x.x (xx.x)	x.x (xx.x)	x.x (xx.x)	
			n	x	xx	xx	
			Mean (SD)	x.xx (x.xx)	x.xx (x.xx)	x.xx (x.xx)	
			Median	x.xx	x.xx	x.xx	
	Cmax (ng/mL)		Q1 ; Q3	x.xx ; x.xx	x.xx ; x.xx	x.xx ; x.xx	
			Min ; Max	x.x ; x.x	x.x ; x.x	x.x ; x.x	
			n*	x	xx	xx	
			G-Mean (CV%)	x.x (xx.x)	x.x (xx.x)	x.x (xx.x)	
			...				

Source: Listing 8.2

AUCtau and Cmax have been dose normalized by dividing the parameters by the dose expressed in mg/kg.

* Number of patients with parameter value above 0

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Programmer's note: The following PK parameters: TMax, Cmax, Cmax normalized, AUCtau, AUCtau normalized, CLss/F and Vss/F will be summarized at Day 1 and Day 26.

This title is applicable for STP arm. For VPA arm that will be "8.2.1. VPA and Metabolites", and the above PK parameters will be summarized for VPA and 4-ene-VPA at Day 1 and Day 26.

8. Pharmacokinetics

8.2. PK Parameters

8.2.2. CBD and Metabolites

PK Population

Parameter	PK parameter	Visit	Statistics	Placebo	GWP42003-P	Total
				(N=x)	(N=xx)	(N=xx)
Cannabidiol	TMax (h)	Day 26	n	x	xx	xx
			Mean (SD)	xxx.xx (xx.xx)	xxx.xx (xx.xx)	xxx.xx (xx.xx)
			Median	xxx.xx	xxx.xx	xxx.xx
			Q1 ; Q3	xx.xx ; xxxx.xx	xx.xx ; xxxx.xx	xx.xx ; xxxx.xx
			Min ; Max	xx.x ; xxxx.x	xx.x ; xxxx.x	xx.x ; xxxx.x
			n*	x	xx	xx
			G-Mean (CV%)	xxx.x (xx.x)	xxx.x (xx.x)	xxx.x (xx.x)
		...				

Source: Listing 8.2

AU_{tau} and C_{max} have been dose normalized by dividing the parameters by the dose expressed in mg/kg.

* Number of patients with parameter value above 0

Page 1 of x

Programmer's note: The following PK parameters: TMax, Cmax, Cmax normalized, AU_{tau}, AU_{tau} normalized, CLss/F and Vss/F will be summarized at Day 26 for CBD and his metabolites (6-hydroxy cannabidiol, 7-carboxy cannabidiol, 7-hydroxy cannabidiol).

8. Pharmacokinetics

8.2. PK Parameters

8.2.3. THC and Metabolites

PK Population

Parameter	PK parameter	Visit	Statistics	Placebo (N=x)	GWP42003-P (N=xx)	Total (N=xx)
Tetrahydrocannabinol	TMax (h)	Day 26	n	x	xx	xx
			Mean (SD)	xxx.xx (xx.xx)	xxx.xx (xx.xx)	xxx.xx (xx.xx)
			Median	xxx.xx	xxx.xx	xxx.xx
			Q1 ; Q3	xx.xx ; xxx.xx	xx.xx ; xxx.xx	xx.xx ; xxx.xx
			Min ; Max	xx.x ; xxx.x	xx.x ; xxx.x	xx.x ; xxx.x
			n*	x	xx	xx
			G-Mean (CV%)	xxx.x (xx.x)	xxx.x (xx.x)	xxx.x (xx.x)
		...				

Source: Listing 8.2

AUCtau and Cmax have been dose normalized by dividing the parameters by the dose expressed in mg/kg.

* Number of patients with parameter value above 0

Page 1 of x

Programmer's note: The following PK parameters: TMax, Cmax, Cmax normalized, AUCtau, AUCtau normalized, CLss/F and Vss/F will be summarized at Day 26 for THC and his metabolites (11-OH Tetrahydrocannabinol, 11-COOH Tetrahydrocannabinol).

8. Pharmacokinetics

8.2. PK Parameters

8.2.4. CLB and Metabolites

PK Population

Parameter	PK parameter	Visit	Statistics	Placebo	GWP42003-P	Total
				(N=x)	(N=xx)	(N=xx)
Clobazam	TMax (h)	Day 1	n	x	xx	xx
			Mean (SD)	xxx.xx (xx.xx)	xxx.xx (xx.xx)	xxx.xx (xx.xx)
			Median	xxx.xx	xxx.xx	xxx.xx
			Q1 ; Q3	xx.xx ; xxx.xx	xx.xx ; xxxx.xx	xx.xx ; xxxx.xx
			Min ; Max	xx.x ; xxx.x	xx.x ; xxxx.x	xx.x ; xxxx.x
			n*	x	xx	xx
			G-Mean (CV%)	xxx.x (xx.x)	xxx.x (xx.x)	xxx.x (xx.x)
		...				

Source: Listing 8.2

AUCtau and Cmax have been dose normalized by dividing the parameters by the dose expressed in mg/kg.

* Number of patients with parameter value above 0

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x

Programmer's note: The following PK parameters: TMax, Cmax, Cmax normalized, AUCtau, AUCtau normalized, CLss/F and Vss/F will be summarized at Day 1 and Day 26 for CLB and his metabolite (N-Desmethylclobazam).

8. Pharmacokinetics

8.2. PK Parameters

8.2.5. Other AEDs

PK Population

Parameter	PK parameter	Visit	Statistics	Placebo (N=x)	GWP42003-P (N=xx)	Total (N=xx)
Levetiracetam	TMax (h)	Day 1	n	x	xx	xx
			Mean (SD)	xxx.xx (xx.xx)	xxx.xx (xx.xx)	xxx.xx (xx.xx)
			Median	xxx.xx	xxx.xx	xxx.xx
			Q1 ; Q3	xx.xx ; xxxx.xx	xx.xx ; xxxx.xx	xx.xx ; xxxx.xx
			Min ; Max	xx.x ; xxxx.x	xx.x ; xxxx.x	xx.x ; xxxx.x
			n*	x	xx	xx
			G-Mean (CV%)	xxx.x (xx.x)	xxx.x (xx.x)	xxx.x (xx.x)
		...				

Source: Listing 8.2

* Number of patients with parameter value above 0

Page 1 of x

Programmer's note: The following PK parameters: TMax, Cmax, Cmax normalized, AUctau, AUctau normalized, CLss/F and Vss/F will be summarized at Day 1 and Day 26 for levetiracetam (LEV) and topiramate (TPM).

8. Pharmacokinetics

8.2. PK Parameters

8.2.6. Summary

PK Population

Parameter	Summary	Visit	Placebo			GWP42003-P		
			N	Mean (SD)	Median	N	Mean (SD)	Median
Stiripentol	TMax (h)	D1	x	xx.x (x.xx)	x.xx	xx	xx.x (x.xx)	x.xx
		D26	x	xx.x (x.xx)	x.xx	xx	xx.x (x.xx)	x.xx
	Cmax (ng/mL)	D1	x	xx.xx (x.xx)	xx.xx	xx	xx.xx (x.xx)	xx.xx
		D26	x	xx.xx (x.xx)	xx.xx	xx	xx.xx (x.xx)	xx.xx
...								
Cannabidiol	TMax (h)	D26	x	xx.xx (x.xx)	xx.xx	xx	xx.xx (x.xx)	xx.xx
...								

Source: Listing 8.2

For STP or VPA and Metabolites, AUCTau and Cmax have been dose normalized by dividing the parameters by the dose expressed in mg/kg.

For each drug, the subset of patients that took the drug is used.

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Programmer's note: All parameters and PK parameters from tables 8.2.1 to 8.2.5 will be summarized at both visits Day 1 and Day 26 if applicable.

Stiripentol is applicable for STP arm. For VPA arm, VPA and 4-ene-VPA will be summarized.

8. Pharmacokinetics
 8.3. Drug Drug Interaction
 8.3.1. STP
 PK Population

Parameter	Visit	Statistics	Placebo (N=x)	GWP42003-P (N=xx)	Total (N=xx)
Cmax (ng/mL)	Visit 2 Day 1	n	x	x	x
		Mean (SD)	xxx.xx (xxx.xx)	xxx.xx (xxx.xx)	xxx.xx (xxx.xx)
		G-Mean (CV%)	xxx.xx (xx.xx)	xxx.xx (xx.xx)	xxx.xx (xx.xx)
	Visit 4 Day 26	n	x	x	x
		Mean (SD)	xxx.xx (xxx.xx)	xxx.xx (xxx.xx)	xxx.xx (xxx.xx)
		G-Mean (CV%)	xxx.xx (xx.xx)	xxx.xx (xx.xx)	xxx.xx (xx.xx)
	Day 26 to Day 1 ratio	Ratio	x.xxx	x.xxx	
		90%CI	[x.xxx - x.xxx]	[x.xxx - x.xxx]	
AUCtau (h*ng/mL)	Visit 2 Day 1	n	x	x	x
		Mean (SD)	xxx.xx (xxx.xx)	xxx.xx (xxx.xx)	xxx.xx (xxx.xx)
		G-Mean (CV%)	xxx.xx (xx.xx)	xxx.xx (xx.xx)	xxx.xx (xx.xx)
	Visit 4 Day 26	n	x	x	x
		Mean (SD)	xxx.xx (xxx.xx)	xxx.xx (xxx.xx)	xxx.xx (xxx.xx)
		G-Mean (CV%)	xxx.xx (xx.xx)	xxx.xx (xx.xx)	xxx.xx (xx.xx)
	Day 26 to Day 1 ratio	Ratio	x.xxx	x.xxx	
		90%CI	[x.xxx - x.xxx]	[x.xxx - x.xxx]	

Source: Listing 8.2

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Programmer's note: This title is applicable for STP arm. For VPA arm that will be "8.3.1. VPA", and the two above PK parameters will be summarized for VPA at Day 1 and Day 26, and the ratio as well.

8. Pharmacokinetics

8.3. Drug Drug Interaction
 8.3.2. STP - Dose Normalized
 PK Population

Parameter	Visit	Statistics	Placebo (N=xx)	GWP42003-P (N=xx)	Total (N=xx)
Cmax (ng/mL)	Visit 2 Day 1	n	x	x	x
		Mean (SD)	xxx.xx (xxx.xx)	xxx.xx (xxx.xx)	xxx.xx (xxx.xx)
		G-Mean (CV%)	xxx.xx (xx.xx)	xxx.xx (xx.xx)	xxx.xx (xx.xx)
	Visit 4 Day 26	n	x	x	x
		Mean (SD)	xxx.xx (xxx.xx)	xxx.xx (xxx.xx)	xxx.xx (xxx.xx)
		G-Mean (CV%)	xxx.xx (xx.xx)	xxx.xx (xx.xx)	xxx.xx (xx.xx)
	Day 26 to Day 1 ratio	Ratio	x.xxx	x.xxx	
		90%CI	[x.xxx - x.xxx]	[x.xxx - x.xxx]	
AUCtau (h*ng/mL)	Visit 2 Day 1	n	x	x	x
		Mean (SD)	xxx.xx (xxx.xx)	xxx.xx (xxx.xx)	xxx.xx (xxx.xx)
		G-Mean (CV%)	xxx.xx (xx.xx)	xxx.xx (xx.xx)	xxx.xx (xx.xx)
	Visit 4 Day 26	n	x	x	x
		Mean (SD)	xxx.xx (xxx.xx)	xxx.xx (xxx.xx)	xxx.xx (xxx.xx)
		G-Mean (CV%)	xxx.xx (xx.xx)	xxx.xx (xx.xx)	xxx.xx (xx.xx)
	Day 26 to Day 1 ratio	Ratio	x.xxx	x.xxx	
		90%CI	[x.xxx - x.xxx]	[x.xxx - x.xxx]	

Source: Listing 8.2

AUCtau and Cmax have been dose normalized by dividing the parameters by the dose expressed in mg/kg.

Page 1 of 1

Programmer's note: This title is applicable for STP arm. For VPA arm that will be "8.3.2. VPA - Dose Normalized", and the two above PK parameters will be summarized for VPA at Day 1 and Day 26, and the ratio as well.

8. Pharmacokinetics
 8.3. Drug Drug Interaction
 8.3.3. 4-ene-VPA
 PK Population

Parameter	Visit	Statistics	Placebo (N=x)	GWP42003-P (N=xx)	Total (N=xx)
Cmax (ng/mL)	Visit 2 Day 1	n	x	x	x
		Mean (SD)	xxx.xx (xxx.xx)	xxx.xx (xxx.xx)	xxx.xx (xxx.xx)
		G-Mean (CV%)	xxx.xx (xx.xx)	xxx.xx (xx.xx)	xxx.xx (xx.xx)
	Visit 4 Day 26	n	x	x	x
		Mean (SD)	xxx.xx (xxx.xx)	xxx.xx (xxx.xx)	xxx.xx (xxx.xx)
		G-Mean (CV%)	xxx.xx (xx.xx)	xxx.xx (xx.xx)	xxx.xx (xx.xx)
	Day 26 to Day 1 ratio	Ratio	x.xxx	x.xxx	
		90%CI	[x.xxx - x.xxx]	[x.xxx - x.xxx]	
AUCtau (h*ng/mL)	Visit 2 Day 1	n	x	x	x
		Mean (SD)	xxx.xx (xxx.xx)	xxx.xx (xxx.xx)	xxx.xx (xxx.xx)
		G-Mean (CV%)	xxx.xx (xx.xx)	xxx.xx (xx.xx)	xxx.xx (xx.xx)
	Visit 4 Day 26	n	x	x	x
		Mean (SD)	xxx.xx (xxx.xx)	xxx.xx (xxx.xx)	xxx.xx (xxx.xx)
		G-Mean (CV%)	xxx.xx (xx.xx)	xxx.xx (xx.xx)	xxx.xx (xx.xx)
	Day 26 to Day 1 ratio	Ratio	x.xxx	x.xxx	
		90%CI	[x.xxx - x.xxx]	[x.xxx - x.xxx]	

Source: Listing 8.2

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Programmer's note: This table is only applicable for VPA arm.

8. Pharmacokinetics

8.3. Drug Drug Interaction

8.3.4. 4-ene-VPA - Dose Normalized
 PK Population

Parameter	Visit	Statistics	Placebo (N=x)	GWP42003-P (N=xx)	Total (N=xx)
Cmax (ng/mL)	Visit 2 Day 1	n	x	x	x
		Mean (SD)	xxx.xx (xxx.xx)	xxx.xx (xxx.xx)	xxx.xx (xxx.xx)
		G-Mean (CV%)	xxx.xx (xx.xx)	xxx.xx (xx.xx)	xxx.xx (xx.xx)
	Visit 4 Day 26	n	x	x	x
		Mean (SD)	xxx.xx (xxx.xx)	xxx.xx (xxx.xx)	xxx.xx (xxx.xx)
		G-Mean (CV%)	xxx.xx (xx.xx)	xxx.xx (xx.xx)	xxx.xx (xx.xx)
	Day 26 to Day 1 ratio	Ratio	x.xxx	x.xxx	
		90%CI	[x.xxx - x.xxx]	[x.xxx - x.xxx]	
AUCtau (h*ng/mL)	Visit 2 Day 1	n	x	x	x
		Mean (SD)	xxx.xx (xxx.xx)	xxx.xx (xxx.xx)	xxx.xx (xxx.xx)
		G-Mean (CV%)	xxx.xx (xx.xx)	xxx.xx (xx.xx)	xxx.xx (xx.xx)
	Visit 4 Day 26	n	x	x	x
		Mean (SD)	xxx.xx (xxx.xx)	xxx.xx (xxx.xx)	xxx.xx (xxx.xx)
		G-Mean (CV%)	xxx.xx (xx.xx)	xxx.xx (xx.xx)	xxx.xx (xx.xx)
	Day 26 to Day 1 ratio	Ratio	x.xxx	x.xxx	
		90%CI	[x.xxx - x.xxx]	[x.xxx - x.xxx]	

Source: Listing 8.2

AUCtau and Cmax have been dose normalized by dividing the parameters by the dose expressed in mg/kg.

Page 1 of 1

Programmer's note: This table is only applicable for VPA arm.

Section 12.3 Safety

Section 12.3.1 Exposure to Study Medication

10. Exposure
Safety Population

Parameters	Statistics	Placebo (N=xx)	GWP42003-P (N=xx)	Total (N=xx)
Treatment Duration (Days)	n	x	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x	xx.x
	Q1 ; Q3	xx.x ; xx.x	xx.x ; xx.x	xx.x ; xx.x
	Min ; Max	xx ; xx	xx ; xx	xx ; xx

Source: Listing 10.1

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Section 12.3.2 Adverse Events

11. Adverse Events

11.1. Treatment-Emergent AEs Safety Population

System Organ Class Preferred Term	Placebo	GWP42003-P	All patients
	N=x Subjects n %	N=xx Subjects n %	N=xx Subjects n %
Subject with at least one treatment-emergent AE	x (xx.x)	xx (xx.x)	xx (xx.x)
SOC 1	x (xx.x)	xx (xx.x)	xx (xx.x)
PT 1	x (xx.x)	xx (xx.x)	xx (xx.x)
PT 2	x (xx.x)	xx (xx.x)	xx (xx.x)
...			
SOC 2	x (xx.x)	xx (xx.x)	xx (xx.x)
PT 1	x (xx.x)	xx (xx.x)	xx (xx.x)
PT 2	x (xx.x)	xx (xx.x)	xx (xx.x)
...			
...			

Source: Listing 11.1

If a subject has multiple events within a system organ class or preferred term, the subject is counted once.
 Events are sorted by decreased SOCs, PTs frequencies on the total column. In case of equal frequency, alphabetic order is used.

Page 1 of x

11. Adverse Events

11.2. Treatment-Emergent Related AEs

Safety Population

System Organ Class Preferred Term	Placebo		GWP42003-P		All patients	
	N=x	Subjects n %	N=xx	Subjects n %	N=xx	Subjects n %
Subject with at least one treatment-emergent related AE		x (xx.x)		xx (xx.x)		xx (xx.x)
SOC 1		x (xx.x)		xx (xx.x)		xx (xx.x)
PT 1		x (xx.x)		xx (xx.x)		xx (xx.x)
PT 2		x (xx.x)		xx (xx.x)		xx (xx.x)
...						
SOC 2		x (xx.x)		xx (xx.x)		xx (xx.x)
PT 1		x (xx.x)		xx (xx.x)		xx (xx.x)
PT 2		x (xx.x)		xx (xx.x)		xx (xx.x)
...						

Source: Listing 11.1

If a subject has multiple events within a system organ class or preferred term, the subject is counted once.
 Events are sorted by decreased SOCs, PTs frequencies on the total column. In case of equal frequency, alphabetic order is used.

Page 1 of x

11. Adverse Events

11.3. Treatment-Emergent AEs by Maximum Severity
 Safety Population

System Organ Class Preferred Term	Placebo			GWP42003-P		
	N=x		Subjects n %	N=xx		Subjects n %
	Mild	Moderate		Severe	Mild	
Subject with at least one treatment-emergent AE	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)
SOC 1	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)
PT 1	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)
PT2	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)
...						
SOC 2	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)
PT 1	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)
PT 2	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)
...						
...						

Source: Listing 11.1

For each SOC/PT, maximum severity is used.

If a subject has multiple events within a system organ class or preferred term, the subject is counted once.

Events are sorted by decreased SOCs, PTs frequencies on all subjects without taking into account the severity. In case of equal frequency, alphabetic order is used.

11. Adverse Events

11.4. Pre-Study AEs

Safety Population

System Organ Class Preferred Term	Placebo		GWP42003-P		All patients	
	N=x	Subjects n %	N=xx	Subjects n %	N=xx	Subjects n %
Subject with at least one pre-study AE		x (xx.x)	xx (xx.x)	xx (xx.x)		
SOC 1		x (xx.x)	xx (xx.x)	xx (xx.x)		
PT 1		x (xx.x)	xx (xx.x)	xx (xx.x)		
PT 2		x (xx.x)	xx (xx.x)	xx (xx.x)		
...						
SOC 2		x (xx.x)	xx (xx.x)	xx (xx.x)		
PT 1		x (xx.x)	xx (xx.x)	xx (xx.x)		
PT 2						
...						

Source: Listing 11.1

If a subject has multiple events within a system organ class or preferred term, the subject is counted once.
 Events are sorted by decreased SOCs, PTs frequencies on the total column. In case of equal frequency, alphabetic order is used.

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Section 12.3.3 Deaths, Other Serious And Significant Adverse Events

12. Serious Adverse Events
 12.1. SAEs
 Safety Population

Actual Treatment for DB Phase	Unique Subject Identifier	Period	SOC/ PT/ Reported Term*	Start Date (Day)/ End Date (Day)/ Duration	Severity/ Serious Event	Causality/ Outcome	Action Taken with Study Treatment
GWP42003-P	GWEP1428-W-xxxx-xxx	DB Period	Nervous system disorders / Seizure / Decompensated Epilepsy	2016-09-28 (211) / Y 2016-10-17 (230) / * 20		Severe/ Related / RECOVERED/RESOLVED	Drug Withdrawn
		OLE Period	Investigations / Alanine aminotransferase abnormal / Abnormal Alt Ast And Ggt Values	2016-05-05 (92) / Y 2016-06-16 (134) / * 43		Severe/ Related / RECOVERED/RESOLVED	Drug Withdrawn
...							

* Treatment-emergent SAE.

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12. Serious and Other Significant Adverse Events

12.1. Treatment-Emergent SAEs

Safety Population

System Organ Class Preferred Term	Placebo		GWP42003-P		All patients	
	Subjects		Subjects		Subjects	
	n	%	n	%	n	%
Subject with at least one treatment-emergent SAE		x (xx.x)		xx (xx.x)		xx (xx.x)
SOC 1						
PT 1		x (xx.x)		xx (xx.x)		xx (xx.x)
PT 2		x (xx.x)		xx (xx.x)		xx (xx.x)
...						
SOC 1						
PT 1		x (xx.x)		xx (xx.x)		xx (xx.x)
PT 2		x (xx.x)		xx (xx.x)		xx (xx.x)
...						
...						

Source: Listing 12.1

If a subject has multiple events within a system organ class or preferred term, the subject is counted once.

Events are sorted by decreased SOCs, PTs frequencies on the total column. In case of equal frequency, alphabetic order is used.

Page 1 of x

12. Serious and Other Significant Adverse Events

12.2. Treatment-Emergent Related SAEs

Safety Population

System Organ Class Preferred Term	Placebo		GWP42003-P		All patients	
	n	%	n	%	n	%
Subject with at least one treatment-emergent related SAE	x (xx.x)		xx (xx.x)		xx (xx.x)	
SOC 1						
PT 1	x (xx.x)		xx (xx.x)		xx (xx.x)	
PT 2	x (xx.x)		xx (xx.x)		xx (xx.x)	
...						
SOC 1						
PT 1	x (xx.x)		xx (xx.x)		xx (xx.x)	
PT 2	x (xx.x)		xx (xx.x)		xx (xx.x)	
...						
...						

Source: Listing 12.1

If a subject has multiple events within a system organ class or preferred term, the subject is counted once.

Events are sorted by decreased SOCs, PTs frequencies on the total column. In case of equal frequency, alphabetic order is used.

Page 1 of x

12. Serious and Other Significant Adverse Events

12.3. Treatment-Emergent AEs Reported as Leading to Permanent Cessation of Study Treatment
Safety Population

System Organ Class Preferred Term	Placebo		GWP42003-P		All patients	
	N=x	Subjects n %	N=xx	Subjects n %	N=xx	Subjects n %
Subject with at least one treatment-emergent AE reported as leading to permanent cessation of study treatment		x (xx.x)		xx (xx.x)		xx (xx.x)
SOC 1						
PT 1		x (xx.x)		xx (xx.x)		xx (xx.x)
PT 2		x (xx.x)		xx (xx.x)		xx (xx.x)
...						
SOC 1						
PT 1		x (xx.x)		xx (xx.x)		xx (xx.x)
PT 2		x (xx.x)		xx (xx.x)		xx (xx.x)
...						
...						

Source: Listing 11.1

If a subject has multiple events within a system organ class or preferred term, the subject is counted once. Events are sorted by decreased SOCs, PTs frequencies on the total column. In case of equal frequency, alphabetic order is used.

12. Serious and Other Significant Adverse Events

12.4. Treatment-Emergent AEs Reported as Leading to Reduction of Study Treatment
Safety Population

System Organ Class Preferred Term	Placebo		GWP42003-P		All patients	
	N=x	Subjects n %	N=xx	Subjects n %	N=xx	Subjects n %
Subject with at least one treatment-emergent AE reported as leading to reduction of study treatment		x (xx.x)		xx (xx.x)		xx (xx.x)
SOC 1						
PT 1		x (xx.x)		xx (xx.x)		xx (xx.x)
PT 2		x (xx.x)		xx (xx.x)		xx (xx.x)
...						
SOC 1						
PT 1		x (xx.x)		xx (xx.x)		xx (xx.x)
PT 2		x (xx.x)		xx (xx.x)		xx (xx.x)
...						
...						

Source: Listing 11.1

If a subject has multiple events within a system organ class or preferred term, the subject is counted once. Events are sorted by decreased SOCs, PTs frequencies on the total column. In case of equal frequency, alphabetic order is used.

12. Serious and Other Significant Adverse Events

12.5. All Fatal AEs
Safety Population

System Organ Class Preferred Term	Placebo		GWP42003-P		All patients	
	N=x	Subjects n %	N=xx	Subjects n %	N=xx	Subjects n %
Subject with at least one treatment-emergent AE reported as Fatal			x (xx.x)	xx (xx.x)	xx (xx.x)	
<hr/>						
SOC 1						
PT 1			x (xx.x)	xx (xx.x)	xx (xx.x)	
PT 2			x (xx.x)	xx (xx.x)	xx (xx.x)	
...						
SOC 2						
PT 1			x (xx.x)	xx (xx.x)	xx (xx.x)	
PT 2			x (xx.x)	xx (xx.x)	xx (xx.x)	
...						
...						

Source: Listing 11.1

If a subject has multiple events within a system organ class or preferred term, the subject is counted once. Events are sorted by decreased SOCs, PTs frequencies on the total column. In case of equal frequency, alphabetic order is used.

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12. Serious and Other Significant Adverse Events

12.6. Triggering Adverse Events
 Safety Population

System Organ Class Preferred Term	Placebo		GWP42003-P		All patients	
	N=x	Subjects n %	N=xx	Subjects n %	N=xx	Subjects n %
Subject with at least one treatment-emergent AE reported as triggering		x (xx.x)	xx (xx.x)	xx (xx.x)		
SOC 1		x (xx.x)	xx (xx.x)	xx (xx.x)		
PT 1		x (xx.x)	xx (xx.x)	xx (xx.x)		
PT 2		x (xx.x)	xx (xx.x)	xx (xx.x)		
...						
SOC 2						
PT 1		x (xx.x)	xx (xx.x)	xx (xx.x)		
PT 2		x (xx.x)	xx (xx.x)	xx (xx.x)		
...						
...						

Source: Listing 11.1

Triggering events of interest are defined in the statistical analysis plan in section 4.8.
 If a subject has multiple events within a system organ class or preferred term, the subject is counted once.
 Events are sorted by decreased SOCs, PTs frequencies on the total column. In case of equal frequency,
 alphabetic order is used.

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Section 12.3.4 Laboratory Data

13. Laboratory Evaluations
 13.1. Biochemistry
 13.1.1. Value by Visit
 Safety Population

Parameter (Unit)	Visit	Statistics	Placebo (N=x)	GWP42003-P (N=xx)	Total (N=xx)
Alanine aminotransferase V1 (Day -14 to -7) (U/L)		n	x	xx	xx
		Mean (SD)	xx.xx (xx.xx)	xx.xx (xx.xx)	xx.xx (xx.xx)
		Median	xx.xx	xx.xx	xx.xx
		Q1 ; Q3	xx.xx ; xx.xx	xx.xx ; xx.xx	xx.xx ; xx.xx
		Min ; Max	xx.x ; xx.x	xx.x ; xx.x	xx.x ; xx.x
V2 (Day 1)		n	x	xx	xx
		Mean (SD)	xx.xx (xx.xx)	xx.xx (xx.xx)	xx.xx (xx.xx)
		Median	xx.xx	xx.xx	xx.xx
		Q1 ; Q3	xx.xx ; xx.xx	xx.xx ; xx.xx	xx.xx ; xx.xx
		Min ; Max	xx.x ; xx.x	xx.x ; xx.x	xx.x ; xx.x
Baseline		n	x	xx	xx
		Mean (SD)	xx.xx (xx.xx)	xx.xx (xx.xx)	xx.xx (xx.xx)
		Median	xx.xx	xx.xx	xx.xx
		Q1 ; Q3	xx.xx ; xx.xx	xx.xx ; xx.xx	xx.xx ; xx.xx
		Min ; Max	xx.x ; xx.x	xx.x ; xx.x	xx.x ; xx.x
V3 (Day 12)		n	x	xx	xx
		Mean (SD)	xx.xx (xx.xx)	xx.xx (xx.xx)	xx.xx (xx.xx)
		Median	xx.xx	xx.xx	xx.xx
		Q1 ; Q3	xx.xx ; xx.xx	xx.xx ; xx.xx	xx.xx ; xx.xx
		Min ; Max	xx.x ; xx.x	xx.x ; xx.x	xx.x ; xx.x

Source: Listing 13.1

Baseline is defined as the last available measurements obtained during the screening period, prior to first IMP dose administration.

13. Laboratory Evaluations

13.1. Biochemistry

13.1.1. Value by Visit

Safety Population

Parameter (Unit)	Visit	Statistics	Placebo (N=x)	GWP42003-P (N=xx)	Total (N=xx)
Alanine aminotransferase (U/L)	V4 (Day 26)	n	x	xx	xx
		Mean (SD)	xx.xx (xx.xx)	xx.xx (xx.xx)	xx.xx (xx.xx)
		Median	xx.xx	xx.xx	xx.xx
		Q1 ; Q3	xx.xx ; xx.xx	xx.xx ; xx.xx	xx.xx ; xx.xx
		Min ; Max	xx.x ; xx.x	xx.x ; xx.x	xx.x ; xx.x
Albumin (g/L)	V1 (Day -14 to -7)	n	x	xx	xx
		Mean (SD)	xx.xx (xx.xx)	xx.xx (xx.xx)	xx.xx (xx.xx)
		Median	xx.xx	xx.xx	xx.xx
		Q1 ; Q3	xx.xx ; xx.xx	xx.xx ; xx.xx	xx.xx ; xx.xx
		Min ; Max	xx.x ; xx.x	xx.x ; xx.x	xx.x ; xx.x
...					

Source: Listing 13.1

Baseline is defined as the last available measurements obtained during the screening period, prior to first IMP dose administration.

Page 2 of x

Programmer's note: All biochemistry parameters will be summarized in this table. Visits according to the studied period will be summarized. For DB period, visits up to V4 (Day 26) will be included; for OLE period, visits from V5 (Week 2) will be included.

13. Laboratory Evaluations

13.1. Biochemistry

13.1.2. Change from Baseline by Visit

Safety Population

Parameter (Unit)	Visit	Statistics	Placebo (N=x)	GWP42003-P (N=xx)	Total (N=xx)
Alanine aminotransferase V3 (Day 12) (U/L)		n	x	xx	xx
		Mean (SD)	xx.xx (xx.xx)	xx.xx (xx.xx)	xx.xx (xx.xx)
		Median	xx.xx	xx.xx	xx.xx
		Q1 ; Q3	xx.xx ; xx.xx	xx.xx ; xx.xx	xx.xx ; xx.xx
		Min ; Max	xx.x ; xx.x	xx.x ; xx.x	xx.x ; xx.x
V4 (Day 26)		n	x	xx	xx
		Mean (SD)	xx.xx (xx.xx)	xx.xx (xx.xx)	xx.xx (xx.xx)
		Median	xx.xx	xx.xx	xx.xx
		Q1 ; Q3	xx.xx ; xx.xx	xx.xx ; xx.xx	xx.xx ; xx.xx
		Min ; Max	xx.x ; xx.x	xx.x ; xx.x	xx.x ; xx.x
...					

Source: Listing 13.1

Baseline is defined as the last available measurements obtained during the screening period, prior to first IMP dose administration.

Page 1 of x

Programmer's note: All biochemistry parameters will be summarized in this table. Visits according to the studied period will be summarized. Only post-baseline visits will be displayed. For DB period, visits up to V4 (Day 26) will be included; for OLE period, visits from V5 (Week 2) will be included.

13. Laboratory Evaluations

13.1. Biochemistry

13.1.3. Shift from Baseline Based on Reference Ranges

Safety Population

Parameter (Unit)	Visit	Statistics	Placebo	GWP42003-P	Total
			(N=x)	(N=xx)	(N=xx)
Alanine aminotransferase (U/L)	V3 (Day 12)	n	x	xx	xx
		Low to Low	x (xx.x)	xx (xx.x)	xx (xx.x)
		Low to Normal	x (xx.x)	xx (xx.x)	xx (xx.x)
		Low to High	x (xx.x)	xx (xx.x)	xx (xx.x)
		Normal to Low	x (xx.x)	xx (xx.x)	xx (xx.x)
		Normal to	x (xx.x)	xx (xx.x)	xx (xx.x)
		Normal			
		Normal to High	x (xx.x)	xx (xx.x)	xx (xx.x)
		High to Low	x (xx.x)	xx (xx.x)	xx (xx.x)
		High to Normal	x (xx.x)	xx (xx.x)	xx (xx.x)
		High to High	x (xx.x)	xx (xx.x)	xx (xx.x)
	V4 (Day 26)	n	x	xx	xx
		Low to Low	x (xx.x)	xx (xx.x)	xx (xx.x)
		Low to Normal	x (xx.x)	xx (xx.x)	xx (xx.x)
		...			
		...			
		...			

Source: Listing 13.1

Baseline is defined as the last available measurements obtained during the screening period, prior to first IMP dose administration.

Page 1 of x

Programmer's note: All biochemistry parameters with available normal range indicators will be summarized in this table. Visits according to the studied period will be summarized. Only post-baseline visits will be displayed. For DB period, visits up to V4 (Day 26) will be included; for OLE period, visits from V5 (Week 2) will be included.

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13. Laboratory Evaluations
 13.1. Biochemistry
 13.1.4. Shift from Baseline Based on Toxicity Limits
 Safety Population

Parameter (Unit)	Visit	Statistics	Placebo	GWP42003-P	Total
			(N=x)	(N=xx)	(N=xx)
Alanine aminotransferase (U/L)	V3 (Day 12)	n	x	xx	xx
		No tox to No tox	x (xx.x)	xx (xx.x)	xx (xx.x)
		No tox to Tox increased	x (xx.x)	xx (xx.x)	xx (xx.x)
		...			
	V4 (Day 26)	n	x	xx	xx
		No tox to No tox	x (xx.x)	xx (xx.x)	xx (xx.x)
		...			
		...			

Source: Listing 13.1

Baseline is defined as the last available measurements obtained during the screening period, prior to first IMP dose administration.

Page 1 of x

Programmer's note: All biochemistry parameters included in Table 4 in the SAP will be summarized in this table. Visits according to the studied period will be summarized. Only post-baseline visits will be displayed. For DB period, visits up to V4 (Day 26) will be included; for OLE period, visits from V5 (Week 2) will be included.

13. Laboratory Evaluations

13.2. Hematology

13.2.1. Value by Visit

Safety Population

Parameter (Unit)	Visit	Statistics	Placebo (N=4)	GWP42003-P (N=16)	Total (N=20)	
Absolute basophil count (10/L)	V1 (Day -14 to -7)	n	x	xx	xx	
		Mean (SD)	xx.xx (xx.xx)	xx.xx (xx.xx)	xx.xx (xx.xx)	
		Median	xx.xx	xx.xx	xx.xx	
		Q1 ; Q3	xx.xx ; xx.xx	xx.xx ; xx.xx	xx.xx ; xx.xx	
		Min ; Max	xx.x ; xx.x	xx.x ; xx.x	xx.x ; xx.x	
	V2 (Day 1)	n	x	xx	xx	
		Mean (SD)	xx.xx (xx.xx)	xx.xx (xx.xx)	xx.xx (xx.xx)	
		Median	xx.xx	xx.xx	xx.xx	
		Q1 ; Q3	xx.xx ; xx.xx	xx.xx ; xx.xx	xx.xx ; xx.xx	
		Min ; Max	xx.x ; xx.x	xx.x ; xx.x	xx.x ; xx.x	
	Baseline	n	xx.xx (xx.xx)	xx.xx (xx.xx)	xx.xx (xx.xx)	
		Mean (SD)	xx.xx	xx.xx	xx.xx	
		Median	xx.xx ; xx.xx	xx.xx ; xx.xx	xx.xx ; xx.xx	
		Q1 ; Q3	xx.x ; xx.x	xx.x ; xx.x	xx.x ; xx.x	
		Min ; Max	x	xx	xx	
<hr/>						
...						

Source: Listing 13.1

Baseline is defined as the last available measurements obtained during the screening period, prior to first IMP dose administration.

Page 1 of x

Programmer's note: All hematology parameters will be summarized in this table. Visits according to the studied period will be summarized. For DB period, visits up to V4 (Day 26) will be included; for OLE period, visits from V5 (Week 2) will be included.

13. Laboratory Evaluations

13.2. Hematology

13.2.2. Change from Baseline by Visit

Safety Population

Parameter (Unit)	Visit	Statistics	Placebo (N=x)	GWP42003-P (N=xx)	Total (N=xx)
Absolute basophil count (10/L)	V3 (Day 12)	n	x	xx	xx
		Mean (SD)	xx.xx (xx.xx)	xx.xx (xx.xx)	xx.xx (xx.xx)
		Median	xx.xx	xx.xx	xx.xx
		Q1 ; Q3	xx.xx ; xx.xx	xx.xx ; xx.xx	xx.xx ; xx.xx
		Min ; Max	xx.x ; xx.x	xx.x ; xx.x	xx.x ; xx.x
	V4 (Day 26)	n	x	xx	xx
		Mean (SD)	xx.xx (xx.xx)	xx.xx (xx.xx)	xx.xx (xx.xx)
		Median	xx.xx	xx.xx	xx.xx
		Q1 ; Q3	xx.xx ; xx.xx	xx.xx ; xx.xx	xx.xx ; xx.xx
		Min ; Max	xx.x ; xx.x	xx.x ; xx.x	xx.x ; xx.x
...					

Source: Listing 13.1

Baseline is defined as the last available measurements obtained during the screening period, prior to first IMP dose administration.

Page 1 of x

Programmer's note: All hematology parameters will be summarized in this table. Visits according to the studied period will be summarized. Only post-baseline visits will be displayed. For DB period, visits up to V4 (Day 26) will be included; for OLE period, visits from V5 (Week 2) will be included.

13. Laboratory Evaluations

13.2. Hematology

13.2.3. Shift from Baseline Based on Reference Ranges

Safety Population

Parameter (Unit)	Visit	Statistics	Placebo	GWP42003-P	Total
			(N=x)	(N=xx)	(N=xx)
Absolute basophil count (10/L)	V3 (Day 12)	n	x	xx	xx
		Low to Low	x (xx.x)	xx (xx.x)	xx (xx.x)
		Low to Normal	x (xx.x)	xx (xx.x)	xx (xx.x)
		Low to High	x (xx.x)	xx (xx.x)	xx (xx.x)
		Normal to Low	x (xx.x)	xx (xx.x)	xx (xx.x)
		Normal to Normal	x (xx.x)	xx (xx.x)	xx (xx.x)
		Normal to High	x (xx.x)	xx (xx.x)	xx (xx.x)
		High to Low	x (xx.x)	xx (xx.x)	xx (xx.x)
		High to Normal	x (xx.x)	xx (xx.x)	xx (xx.x)
		High to High	x (xx.x)	xx (xx.x)	xx (xx.x)
	V4 (Day 26)	n	x	xx	xx
		Low to Low	x (xx.x)	xx (xx.x)	xx (xx.x)
		...			
		...			

Source: Listing 13.1

Baseline is defined as the last available measurements obtained during the screening period, prior to first IMP dose administration.

Page 1 of ...

Programmer's note: All hematology parameters with available normal range indicators will be summarized in this table. Visits according to the studied period will be summarized. Only post-baseline visits will be displayed. For DB period, visits up to V4 (Day 26) will be included; for OLE period, visits from V5 (Week 2) will be included.

13. Laboratory Evaluations

13.2. Hematology

13.2.4. Shift from Baseline Based on Toxicity Limits

Safety Population

Parameter (Unit)	Visit	Statistics	Placebo	GWP42003-P	Total
			(N=x)	(N=xx)	(N=xx)
		n	n (%)	n (%)	n (%)
Absolute basophil count (10/L)	V3 (Day 12)	n	x	xx	xx
		No tox to No tox	x (xx.x)	xx (xx.x)	xx (xx.x)
		No tox to Tox increased	x (xx.x)	xx (xx.x)	xx (xx.x)
		...			
	V4 (Day 26)	n	x	xx	xx
		No tox to No tox	x (xx.x)	xx (xx.x)	xx (xx.x)
		...			

Source: Listing 13.1

Baseline is defined as the last available measurements obtained during the screening period, prior to first IMP dose administration.

Page 1 of x

Programmer's note: All hematology parameters included in Table 5 in the SAP will be summarized in this table. Visits according to the studied period will be summarized. Only post-baseline visits will be displayed. For DB period, visits up to V4 (Day 26) will be included; for OLE period, visits from V5 (Week 2) will be included.

13. Laboratory Evaluations

13.3. Urinalysis

13.3.1. Value by Visit

Safety Population

Parameter (Unit)	Visit	Statistics	Placebo (N=x)	GWP42003-P (N=xx)	Total (N=xx)
Epithelial renal (/hpf)	V1 (Day -14 to -7)	n	x	xx	xx
		Mean (SD)	xx.xx (xx.xx)	xx.xx (xx.xx)	xx.xx (xx.xx)
		Median	xx.xx	xx.xx	xx.xx
		Q1 ; Q3	xx.xx ; xx.xx	xx.xx ; xx.xx	xx.xx ; xx.xx
		Min ; Max	xx.x ; xx.x	xx.x ; xx.x	xx.x ; xx.x
	V2 (Day 1)	n	x	xx	xx
		Mean (SD)	xx.xx (xx.xx)	xx.xx (xx.xx)	xx.xx (xx.xx)
		Median	xx.xx	xx.xx	xx.xx
		Q1 ; Q3	xx.xx ; xx.xx	xx.xx ; xx.xx	xx.xx ; xx.xx
		Min ; Max	xx.x ; xx.x	xx.x ; xx.x	xx.x ; xx.x
	Baseline	n	xx.xx (xx.xx)	xx.xx (xx.xx)	xx.xx (xx.xx)
		Mean (SD)	xx.xx	xx.xx	xx.xx
		Median	xx.xx ; xx.xx	xx.xx ; xx.xx	xx.xx ; xx.xx
		Q1 ; Q3	xx.x ; xx.x	xx.x ; xx.x	xx.x ; xx.x
		Min ; Max	x	xx	xx
	...				

Source: Listing 13.1

Baseline is defined as the last available measurements obtained during the screening period, prior to first IMP dose administration.

Page 1 of x

Programmer's note: All urinalysis parameters will be summarized in this table. Visits according to the studied period will be summarized. For DB period, visits up to V4 (Day 26) will be included; for OLE period, visits from V5 (Week 2) will be included.

13. Laboratory Evaluations

13.3. Urinalysis

13.3.2. Change from Baseline by Visit

Safety Population

Parameter (Unit)	Visit	Statistics	Placebo (N=x)	GWP42003-P (N=xx)	Total (N=xx)
Epithelial renal (/hpf)	V3 (Day 12)	n	x	xx	xx
		Mean (SD)	xx.xx (xx.xx)	xx.xx (xx.xx)	xx.xx (xx.xx)
		Median	xx.xx	xx.xx	xx.xx
		Q1 ; Q3	xx.xx ; xx.xx	xx.xx ; xx.xx	xx.xx ; xx.xx
		Min ; Max	xx.x ; xx.x	xx.x ; xx.x	xx.x ; xx.x
	V4 (Day 26)	n	x	xx	xx
		Mean (SD)	xx.xx (xx.xx)	xx.xx (xx.xx)	xx.xx (xx.xx)
		Median	xx.xx	xx.xx	xx.xx
		Q1 ; Q3	xx.xx ; xx.xx	xx.xx ; xx.xx	xx.xx ; xx.xx
		Min ; Max	xx.x ; xx.x	xx.x ; xx.x	xx.x ; xx.x
...					

Source: Listing 13.1

Baseline is defined as the last available measurements obtained during the screening period, prior to first IMP dose administration.

Page 1 of x

Programmer's note: All urinalysis parameters will be summarized in this table. Visits according to the studied period will be summarized. Only post-baseline visits will be displayed. For DB period, visits up to V4 (Day 26) will be included; for OLE period, visits from V5 (Week 2) will be included.

13. Laboratory Evaluations

13.3. Urinalysis

13.3.3. Shift from Baseline Based on Reference Ranges

Safety Population

Parameter (Unit)	Visit	Statistics	Placebo (N=4)	GWP42003-P (N=16)	Total (N=20)
Epithelial renal (/hpf)	V3 (Day 12)	n	x	xx	xx
		Normal to	x (xx.x)	xx (xx.x)	xx (xx.x)
		Normal			
		...			
	V4 (Day 26)	n	x	xx	xx
		Normal to	x (xx.x)	xx (xx.x)	xx (xx.x)
		Normal			
		...			

Source: Listing 13.1

Baseline is defined as the last available measurements obtained during the screening period, prior to first IMP dose administration.

Page 1 of x

Programmer's note: All urinalysis parameters with available normal range indicators will be summarized in this table. Visits according to the studied period will be summarized. Only post-baseline visits will be displayed. For DB period, visits up to V4 (Day 26) will be included; for OLE period, visits from V5 (Week 2) will be included.

Section 12.3.5 Listings of Abnormal Laboratory Values

13. Laboratory Evaluations
13.2. Patients/Parameters with Abnormalities (Values Outside Reference or Toxicity Limits)
Safety Population

Actual Treatment for DB Phase	Unique Subject Identifier	Category/Parameter	Analysis Visit	Date and Time (Day) Assessment	Analysis Value	Change from Baseline	Change/ %	Indicator (RR)	Toxicity Grade
GWP42003-P	GWEP1428-W-xxxx-xxx	Biochemistry/ Alanine aminotransferase (U/L)	Visit x	yyyyymmdd:hh:mm (xx)	xxx	xxx/xxx.xx	H [xx-xx]	Tox increased	
		Biochemistry/ Alkaline phosphatase (U/L)	Visit x	yyyyymmdd:hh:mm (xx)	xxx	xxx/xxx.xx	L [xx-xx]		
		...							

Page 1 of x

Section 12.3.6 Vital Signs, Other Physical Findings and Other Safety Data

14. Vital signs, Other Physical Findings and Other Observations Related to Safety

14.1. Vital Signs

14.1.1. Value by Visit

Safety Population

Parameter (Unit)	Visit	Statistics	Placebo	GWP42003-P	Total
			(N=4)	(N=16)	(N=20)
		n	n (%)	n (%)	n (%)
VS/BP/PE indicative of medical condition?	Anytime post baseline	n	x	xx	xx
	Yes		x (xx.x)	xx (xx.x)	xx (xx.x)
	No		x (xx.x)	xx (xx.x)	xx (xx.x)
Weight (kg)	V1 (Day -14 to -7)	n	x	xx	xx
	Mean (SD)	xx.xx (xx.xx)	xx.xx (xx.xx)	xx.xx (xx.xx)	
	Median	xx.xx	xx.xx	xx.xx	
	Q1 ; Q3	xx.xx ; xx.xx	xx.xx ; xx.xx	xx.xx ; xx.xx	
	Min ; Max	xx.x ; xx.x	xx.x ; xx.x	xx.x ; xx.x	
	V2 (Day 1)	n	x	xx	xx
	Mean (SD)	xx.xx (xx.xx)	xx.xx (xx.xx)	xx.xx (xx.xx)	
	Median	xx.xx	xx.xx	xx.xx	
	Q1 ; Q3	xx.xx ; xx.xx	xx.xx ; xx.xx	xx.xx ; xx.xx	
	Min ; Max	xx.x ; xx.x	xx.x ; xx.x	xx.x ; xx.x	
...					

Source: Listing 14.1

VS=Vital Signs; BP=Blood Pressure; PE=Physical Examination.

Baseline is defined as the last available measurements obtained during the screening period, prior to first IMP dose administration.

Page 1 of x

Programmer's note: Weight, DBP, SBP, pulse rate, temperature and respiratory rate will be summarized in this table. Visits according to the studied period will be summarized. For DB period, visits up to V4 (Day 27) including baseline will be included; for OLE period, visits from V5 (Week 2) will be included.

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14. Vital signs, Other Physical Findings and Other Observations Related to Safety

14.1. Vital Signs

14.1.2. Change from Baseline by Visit

Safety Population

Parameter (Unit)	Visit	Statistics	Placebo (N=4)	GWP42003-P (N=16)	Total (N=20)
Weight (kg)	V2 (Day 2)	n	x	xx	xx
		Mean (SD)	xx.xx (xx.xx)	xx.xx (xx.xx)	xx.xx (xx.xx)
		Median	xx.xx	xx.xx	xx.xx
		Q1 ; Q3	xx.xx ; xx.xx	xx.xx ; xx.xx	xx.xx ; xx.xx
		Min ; Max	xx.x ; xx.x	xx.x ; xx.x	xx.x ; xx.x
	V3 (Day 12)	n	x	xx	xx
		Mean (SD)	xx.xx (xx.xx)	xx.xx (xx.xx)	xx.xx (xx.xx)
		Median	xx.xx	xx.xx	xx.xx
		Q1 ; Q3	xx.xx ; xx.xx	xx.xx ; xx.xx	xx.xx ; xx.xx
		Min ; Max	xx.x ; xx.x	xx.x ; xx.x	xx.x ; xx.x
...					

Source: Listing 14.1

Baseline is defined as the last available measurements obtained during the screening period, prior to first IMP dose administration.

Page 1 of ...

Programmer's note: Weight, DBP, SBP, pulse rate, temperature and respiratory rate will be summarized in this table. Visits according to the studied period will be summarized. Only post-baseline visits will be displayed. For DB period, visits up to V4 (Day 27) including baseline will be included; for OLE period, visits from V5 (Week 2) will be included.

14. Vital signs, Other Physical Findings and Other Observations Related to Safety

14.2. ECG

14.2.1. Value by Visit

Safety Population

Parameter (Unit)	Visit	Statistics	Placebo	GWP42003-P	Total
			(N=x)	(N=xx)	(N=xx)
		n	n (%)	n (%)	n (%)
ECG indicative of medical condition?	Anytime post baseline	n	x	xx	xx
	Yes		x (xx.x)	xx (xx.x)	xx (xx.x)
	No		x (xx.x)	xx (xx.x)	xx (xx.x)
PR Interval (msec)	V1 (Day -14 to -7)	n	x	xx	xx
	Mean (SD)		xx.xx (xx.xx)	xx.xx (xx.xx)	xx.xx (xx.xx)
	Median		xx.xx	xx.xx	xx.xx
	Q1 ; Q3		xx.xx ; xx.xx	xx.xx ; xx.xx	xx.xx ; xx.xx
	Min ; Max		xx.x ; xx.x	xx.x ; xx.x	xx.x ; xx.x
	V2 (Day 1)	n	x	xx	xx
	Mean (SD)		xx.xx (xx.xx)	xx.xx (xx.xx)	xx.xx (xx.xx)
	Median		xx.xx	xx.xx	xx.xx
	Q1 ; Q3		xx.xx ; xx.xx	xx.xx ; xx.xx	xx.xx ; xx.xx
	Min ; Max		xx.x ; xx.x	xx.x ; xx.x	xx.x ; xx.x
...					

Source: Listing 14.2

Baseline is defined as the last available measurements obtained during the screening period, prior to first IMP dose administration.

Page 1 of x

Programmer's note: PR interval, QRS duration, QT interval, QTcB, ventricular rate, rythm, ST or T-wave changes and Infarct pattern/R-wave progression will be summarized in this table. Visits according to the studied period will be summarized. For DB period, visits up to V4 (Day 26) including baseline will be included; for OLE period, visits from V5 (Week 2) will be included.

14. Vital signs, Other Physical Findings and Other Observations Related to Safety

14.2. ECG

14.2.2 Change from Baseline by Visit

Safety Population

Parameter (Unit)	Visit	Statistics	Placebo	GWP42003-P	Total
			(N=x)	(N=xx)	(N=xx)
		n	(%)	n	(%)
PR Interval (msec)	V3 (Day 12)	n	x	xx	xx
		Mean (SD)	xx.xx (xx.xx)	xx.xx (xx.xx)	xx.xx (xx.xx)
		Median	xx.xx	xx.xx	xx.xx
		Q1 ; Q3	xx.xx ; xx.xx	xx.xx ; xx.xx	xx.xx ; xx.xx
		Min ; Max	xx.x ; xx.x	xx.x ; xx.x	xx.x ; xx.x
	V4 (Day 26)	n	x	xx	xx
		Mean (SD)	xx.xx (xx.xx)	xx.xx (xx.xx)	xx.xx (xx.xx)
		Median	xx.xx	xx.xx	xx.xx
		Q1 ; Q3	xx.xx ; xx.xx	xx.xx ; xx.xx	xx.xx ; xx.xx
		Min ; Max	xx.x ; xx.x	xx.x ; xx.x	xx.x ; xx.x
...					

Source: Listing 14.2

Baseline is defined as the last available measurements obtained during the screening period, prior to first IMP dose administration.

Page 1 of x

Programmer's note: PR interval, QRS duration, QT interval, QTcB, ventricular rate, rythm, ST or T-wave changes and Infarct pattern/R-wave progression will be summarized in this table. Only post-baseline visits will be displayed. Visits according to the studied period will be summarized. For DB period, visits up to V4 (Day 26) including baseline will be included; for OLE period, visits from V5 (Week 2) will be included.

14. Vital signs, Other Physical Findings and Other Observations Related to Safety

14.3. C-SSRS

Safety Population

Parameter	Period	Statistics	Placebo	GWP42003-P	Total
			(N=4)	(N=16)	(N=20)
Wish to be dead	Baseline	n	x	xx	xx
		Yes	x (xx.x)	xx (xx.x)	xx (xx.x)
		No	x (xx.x)	xx (xx.x)	xx (xx.x)
	DB period	n	x	xx	xx
		Yes	x (xx.x)	xx (xx.x)	xx (xx.x)
		No	x (xx.x)	xx (xx.x)	xx (xx.x)
Non-Specific Active Suicidal Thoughts	Baseline	n	x	xx	xx
		Yes	x (xx.x)	xx (xx.x)	xx (xx.x)
		No	x (xx.x)	xx (xx.x)	xx (xx.x)
	DB period	n	x	xx	xx
		Yes	x (xx.x)	xx (xx.x)	xx (xx.x)
		No	x (xx.x)	xx (xx.x)	xx (xx.x)
...					

Source: Listing 14.4

Page 1 of x

Programmer's note: All C-SSRS categories including the ones derived in the SAP will be summarized in this table. Baseline, DB and OLE periods will be summarized. For baseline, visits up to V2 (Day 1) will be included; for DB period, visits up to V4 (Day 26) will be included; for OLE period, visits from V5 (Week 2) will be included.

14. Vital signs, Other Physical Findings and Other Observations Related to Safety

14.4. Seizure data

14.4.1. Average Daily Seizures - Descriptive Statistics

Safety Population

Period	Statistics	Placebo (N=4)	GWP42003-P (N=16)	Total (N=20)
Screening	n	x	xx	xx
	Mean (SD)	xx.xx (xx.xx)	xx.xx (xx.xx)	xx.xx (xx.xx)
	Median	xx.xx	xx.xx	xx.xx
	Q1 ; Q3	xx.xx ; xx.xx	xx.xx ; xx.xx	xx.xx ; xx.xx
	Min ; Max	xx.x ; xx.x	xx.x ; xx.x	xx.x ; xx.x
DB Period	n	x	xx	xx
	Mean (SD)	xx.xx (xx.xx)	xx.xx (xx.xx)	xx.xx (xx.xx)
	Median	xx.xx	xx.xx	xx.xx
	Q1 ; Q3	xx.xx ; xx.xx	xx.xx ; xx.xx	xx.xx ; xx.xx
	Min ; Max	xx.x ; xx.x	xx.x ; xx.x	xx.x ; xx.x
OLE Period	n	x	xx	xx
	Mean (SD)	xx.xx (xx.xx)	xx.xx (xx.xx)	xx.xx (xx.xx)
	Median	xx.xx	xx.xx	xx.xx
	Q1 ; Q3	xx.xx ; xx.xx	xx.xx ; xx.xx	xx.xx ; xx.xx
	Min ; Max	xx.x ; xx.x	xx.x ; xx.x	xx.x ; xx.x

Source: Listing 14.5

Average daily seizures is derived, within patients, as the number of seizures divided by the number of days with evaluation.

Page 1 of 1

Programmer's note: For DB period, visits up to V4 (Day 26) will be included; for OLE period, visits from V5 (Week 2) will be included.

14. Vital signs, Other Physical Findings and Other Observations Related to Safety

14.4. Seizure data

14.4.2. Average Daily Seizures - Change from Baseline

Safety Population

Parameters	Statistics	Placebo (N=4)	GWP42003-P (N=16)	Total (N=20)
Change from Baseline	n	x	xx	xx
	Mean (SD)	xx.xx (xx.xx)	xx.xx (xx.xx)	xx.xx (xx.xx)
	Median	xx.xx	xx.xx	xx.xx
	Q1 ; Q3	xx.xx ; xx.xx	xx.xx ; xx.xx	xx.xx ; xx.xx
	Min ; Max	xx.x ; xx.x	xx.x ; xx.x	xx.x ; xx.x
Percent Change from Baseline	n	x	xx	xx
	Mean (SD)	xx.xx (xx.xx)	xx.xx (xx.xx)	xx.xx (xx.xx)
	Median	xx.xx	xx.xx	xx.xx
	Q1 ; Q3	xx.xx ; xx.xx	xx.xx ; xx.xx	xx.xx ; xx.xx
	Min ; Max	xx.x ; xx.x	xx.x ; xx.x	xx.x ; xx.x
% Improvement	n	x	xx	xx
	>25% worsening	x (xx.x)	xx (xx.x)	xx (xx.x)
	-25 to 25%, no change	x (xx.x)	xx (xx.x)	xx (xx.x)
	25-50% improvement	x (xx.x)	xx (xx.x)	xx (xx.x)
	50-75% improvement	x (xx.x)	xx (xx.x)	xx (xx.x)
	>75% improvement	x (xx.x)	xx (xx.x)	xx (xx.x)

Source: Listing 14.5

Negative changes represent a decrease in seizures and thus an improvement.

Baseline is defined as the last available measurements obtained during the screening period, prior to first IMP dose administration.

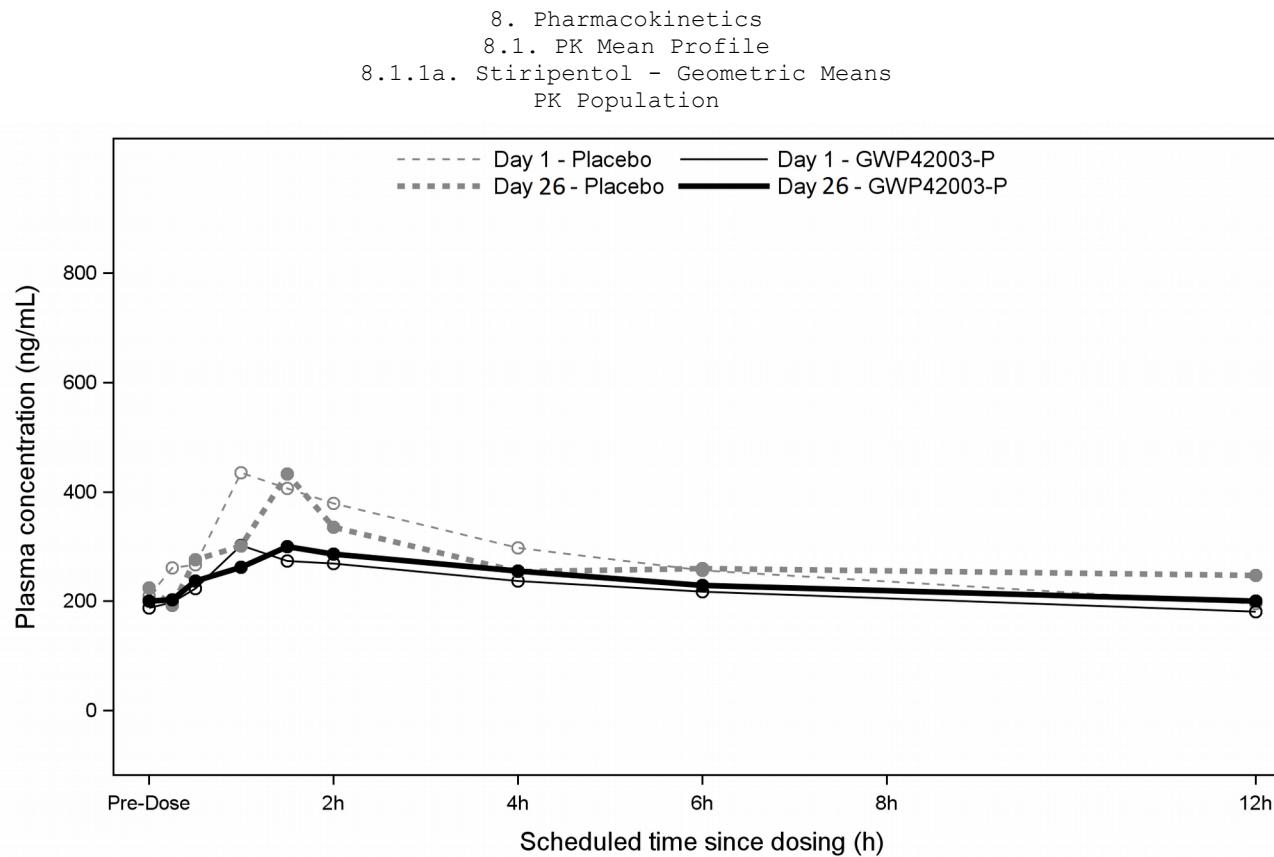
Page 1 of 1

Programmer's note: Table will be produced at DB and OLE analysis.

For DB period, visits up to V4 (Day 26) will be included; for OLE period, visits from V5 (Week 2) will be included.

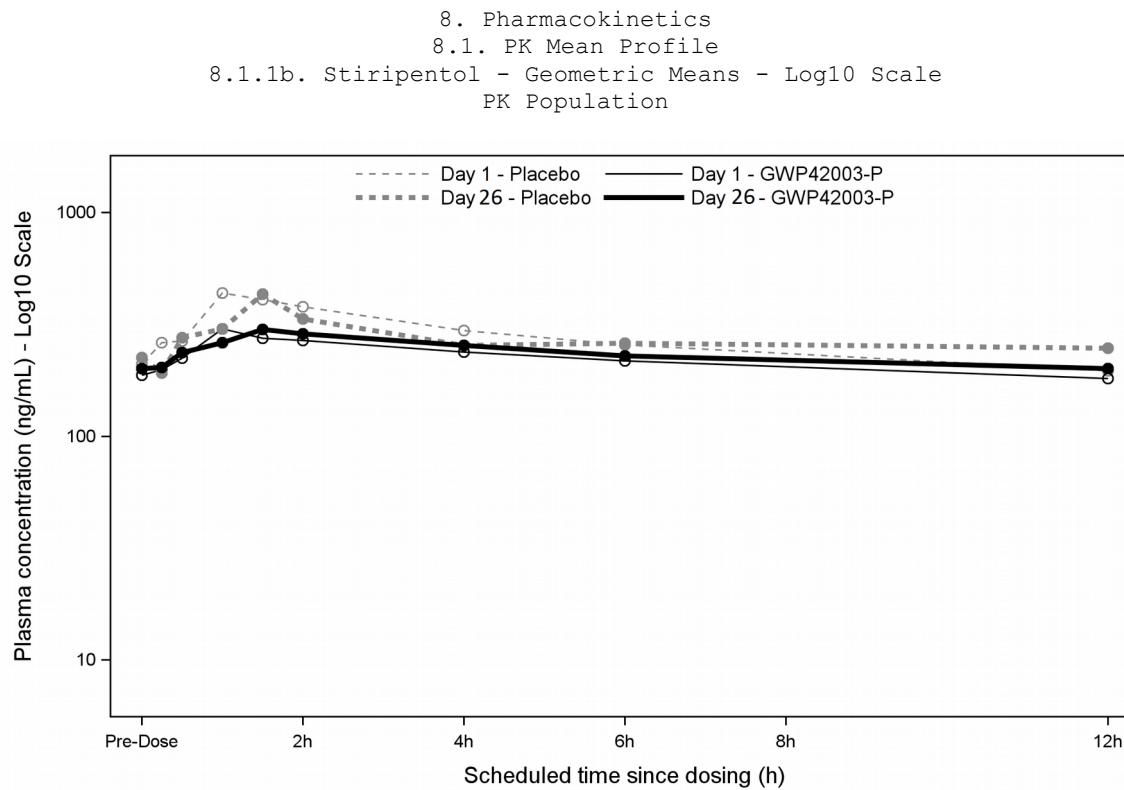
Section 12.4 Figures

Programmer's note: For all plasma concentration (8.1, 8.2 and 8.3) figures, 24h post-dose time point won't be included.



Source: Table 8.1.5

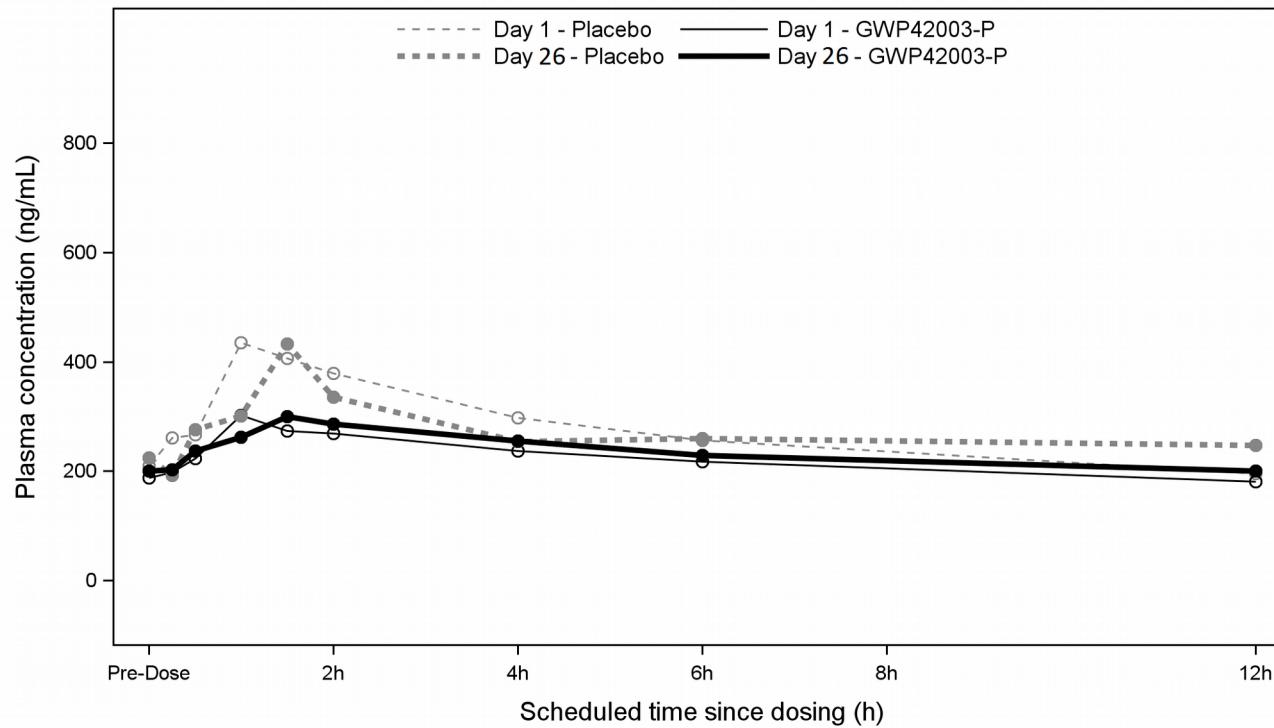
Programmer's note: This title is applicable for STP arm. For VPA arm that will be "8.1.1a. Valproic Acid - Geometric Means".



Source: Table 8.1.5

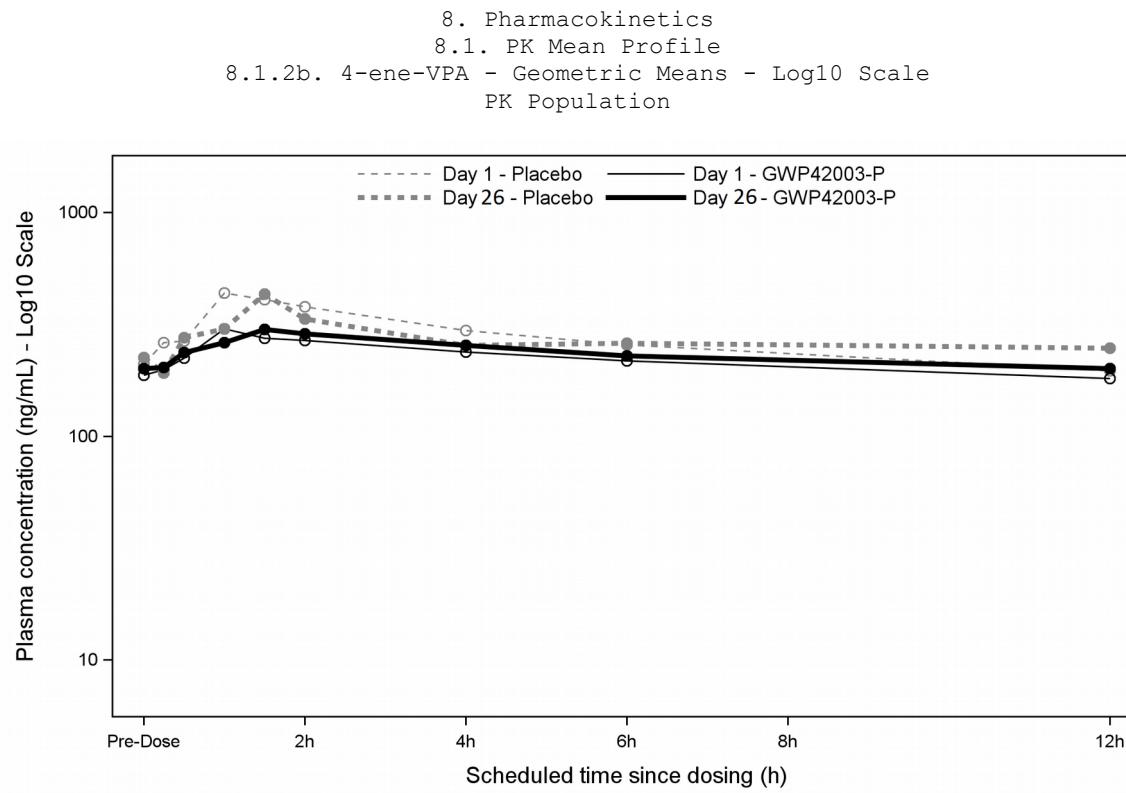
Programmer's note: This title is applicable for STP arm. For VPA arm that will be "8.1.1b. Valproic Acid - Geometric Means - Log10 Scale".

8. Pharmacokinetics
8.1. PK Mean Profile
8.1.2a. 4-ene-VPA - Geometric Means
PK Population



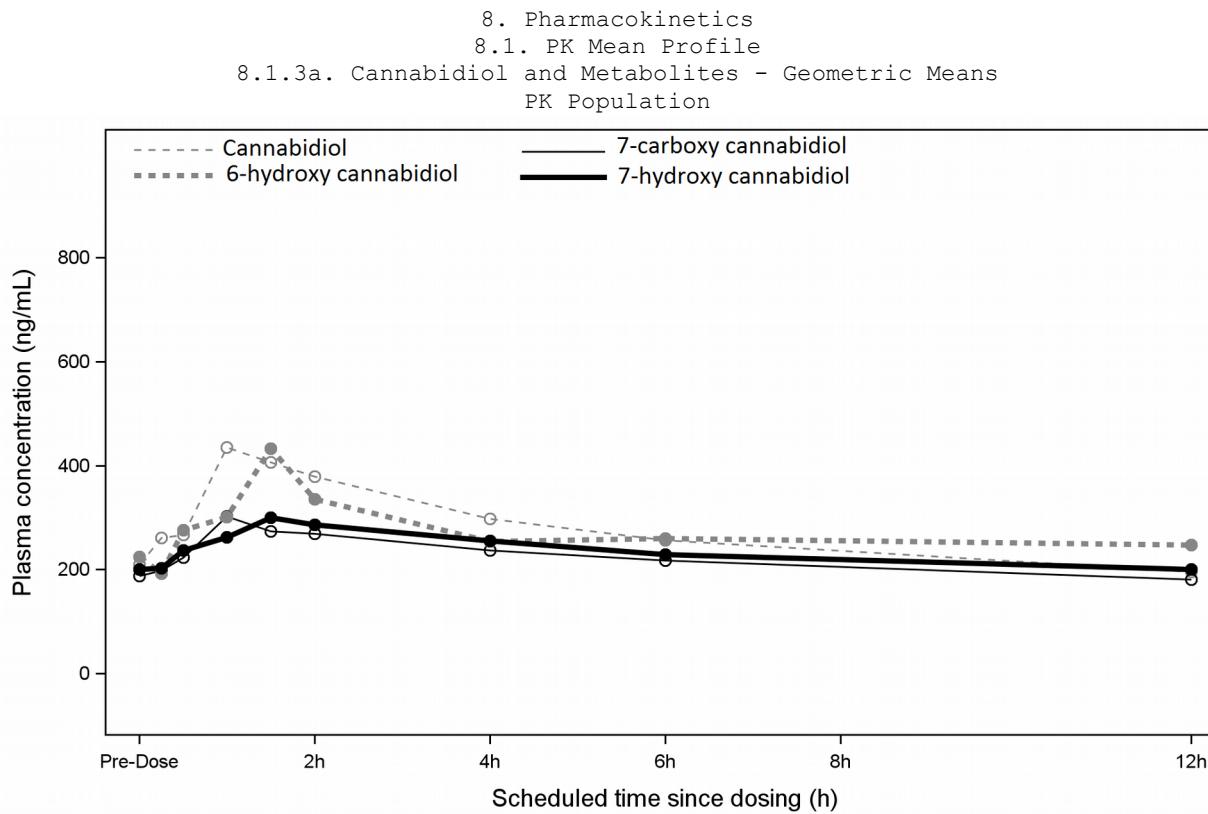
Source: Table 8.1.5

Programmer's note: Only applicable for VPA arm.



Source: Table 8.1.5

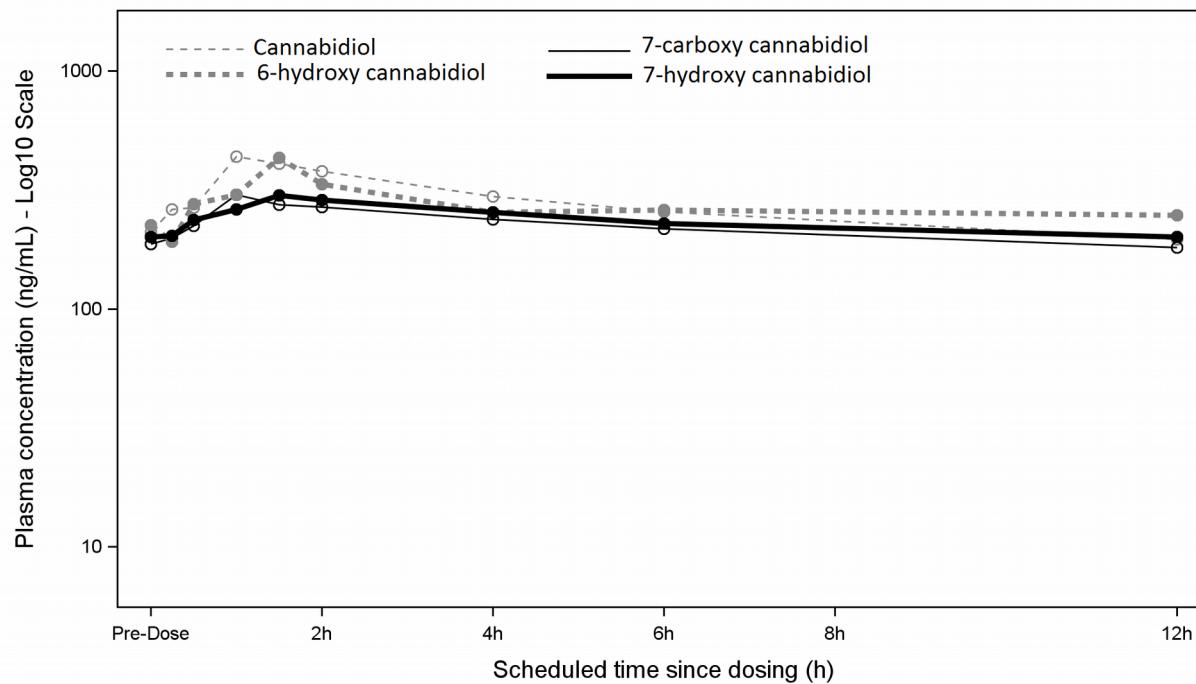
Programmer's note: Only applicable for VPA arm.



Source: Table 8.1.5

Programmer's note: Only Day 26 for GWP42003-P treatment will be plotted. No line for Placebo will be plotted as all values will be LLOQ. CBD and his three metabolites will be plotted on the same plot.

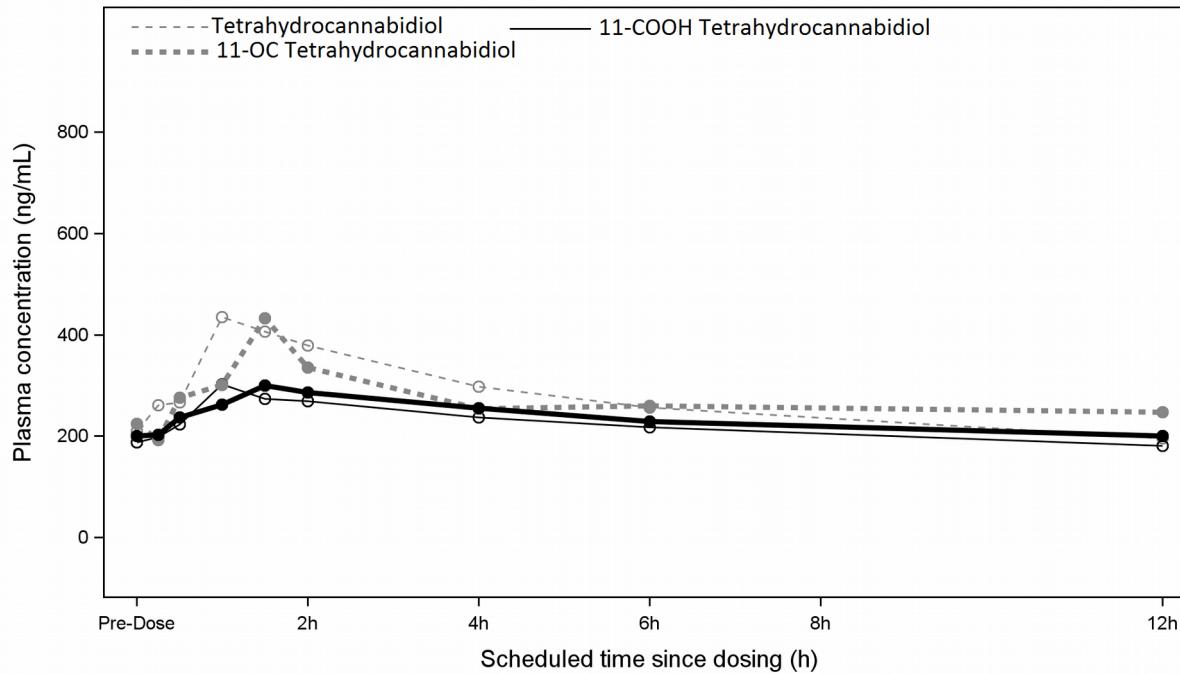
8. Pharmacokinetics
8.1. PK Mean Profile
8.1.3b. Cannabidiol and Metabolites - Geometric Means - Log10 Scale
PK Population



Source: Table 8.1.5

Programmer's note: Only Day 26 for GWP42003-P treatment will be plotted. No line for Placebo will be plotted as all values will be LLOQ. CBD and his three metabolites will be plotted on the same plot.

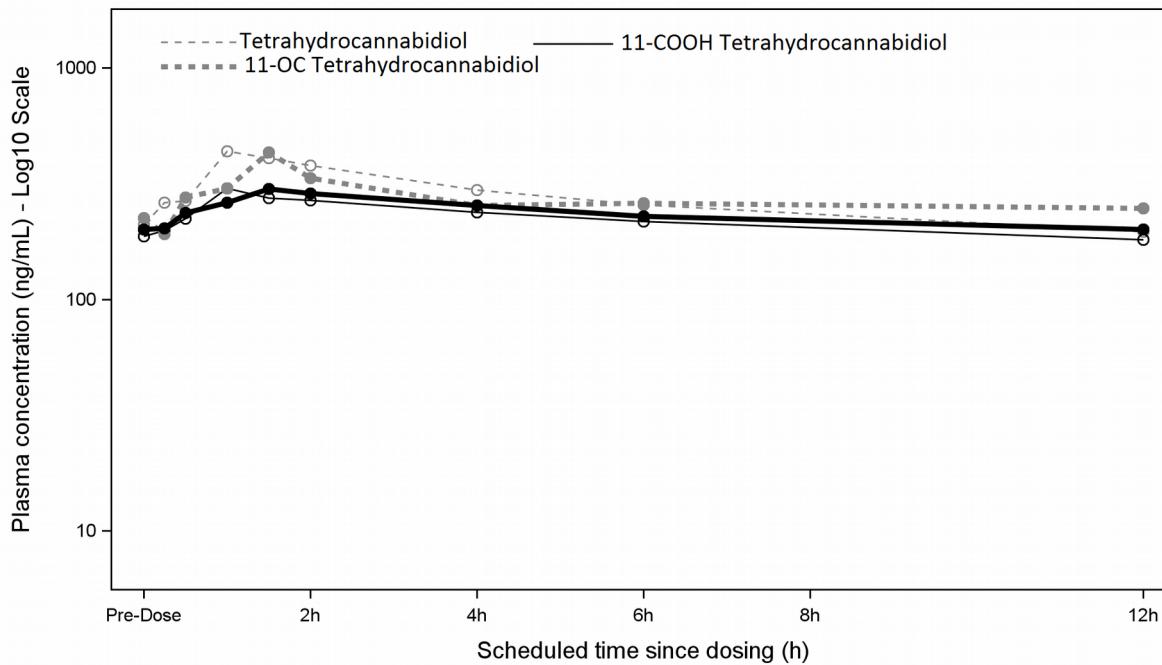
8. Pharmacokinetics
8.1. PK Mean Profile
8.1.4a. Tetrahydrocannabinol and Metabolites - Geometric Means
PK Population



Source: Table 8.1.5

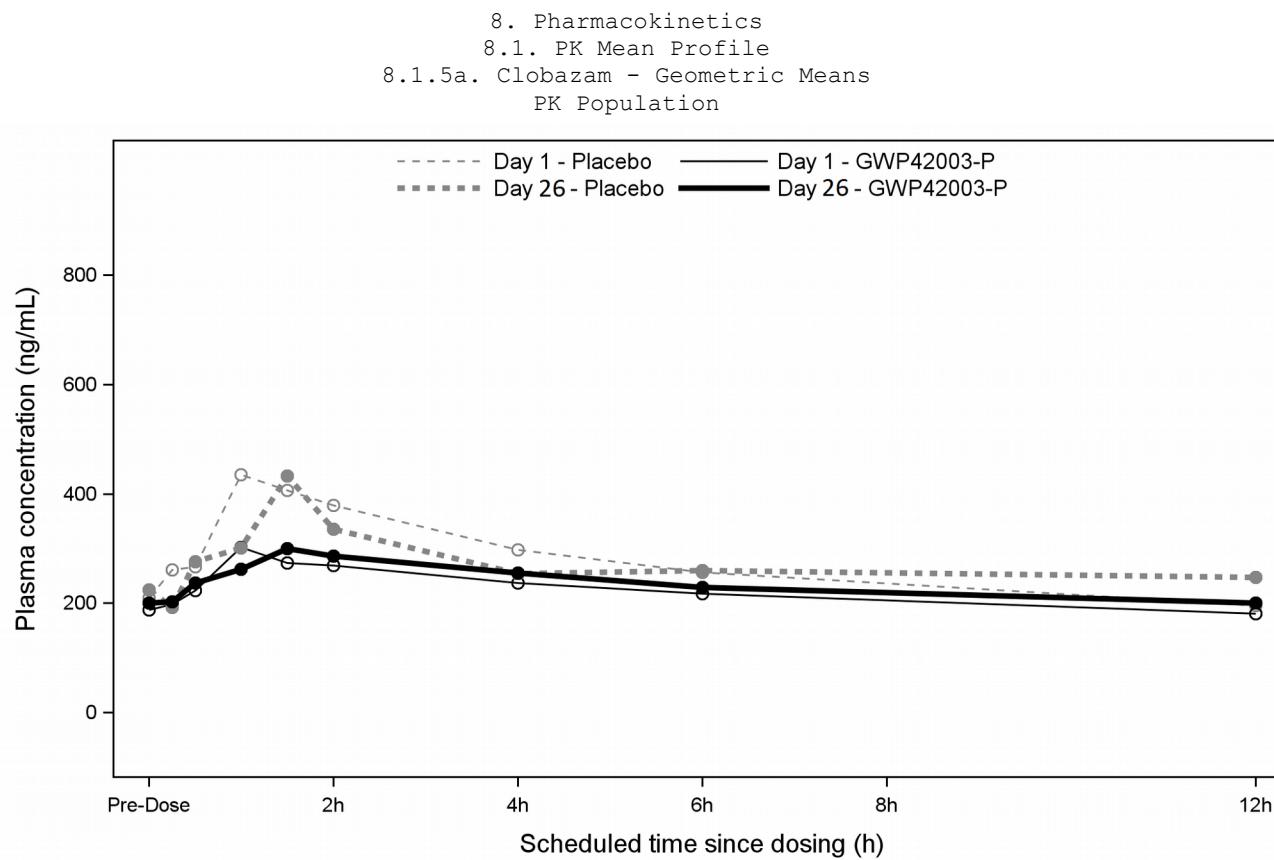
Programmer's note: Only Day 26 for GWP42003-P treatment will be plotted. No line for Placebo will be plotted as all values will be LLOQ. THC and his two metabolites will be plotted on the same plot (so only 3 lines on the plot).

8. Pharmacokinetics
8.1. PK Mean Profile
8.1.4b. Tetrahydrocannabinol and Metabolites - Geometric Means - Log10 Scale
PK Population



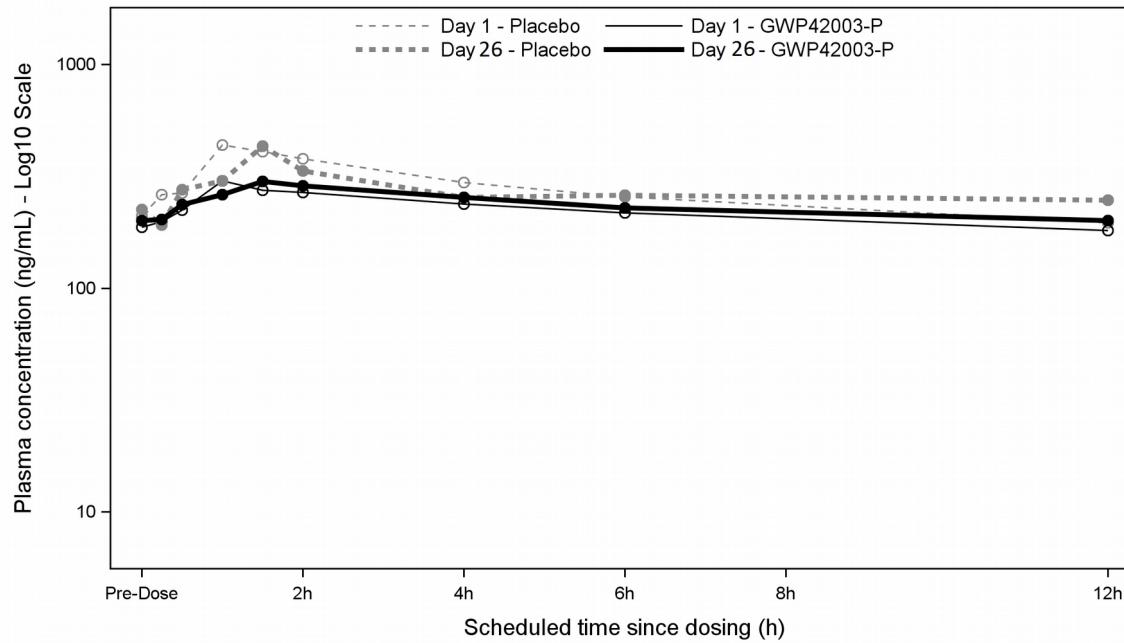
Source: Table 8.1.5

Programmer's note: Only Day 26 for GWP42003-P treatment will be plotted. No line for Placebo will be plotted as all values will be LLOQ. THC and his two metabolites will be plotted on the same plot (so only 3 lines on the plot).

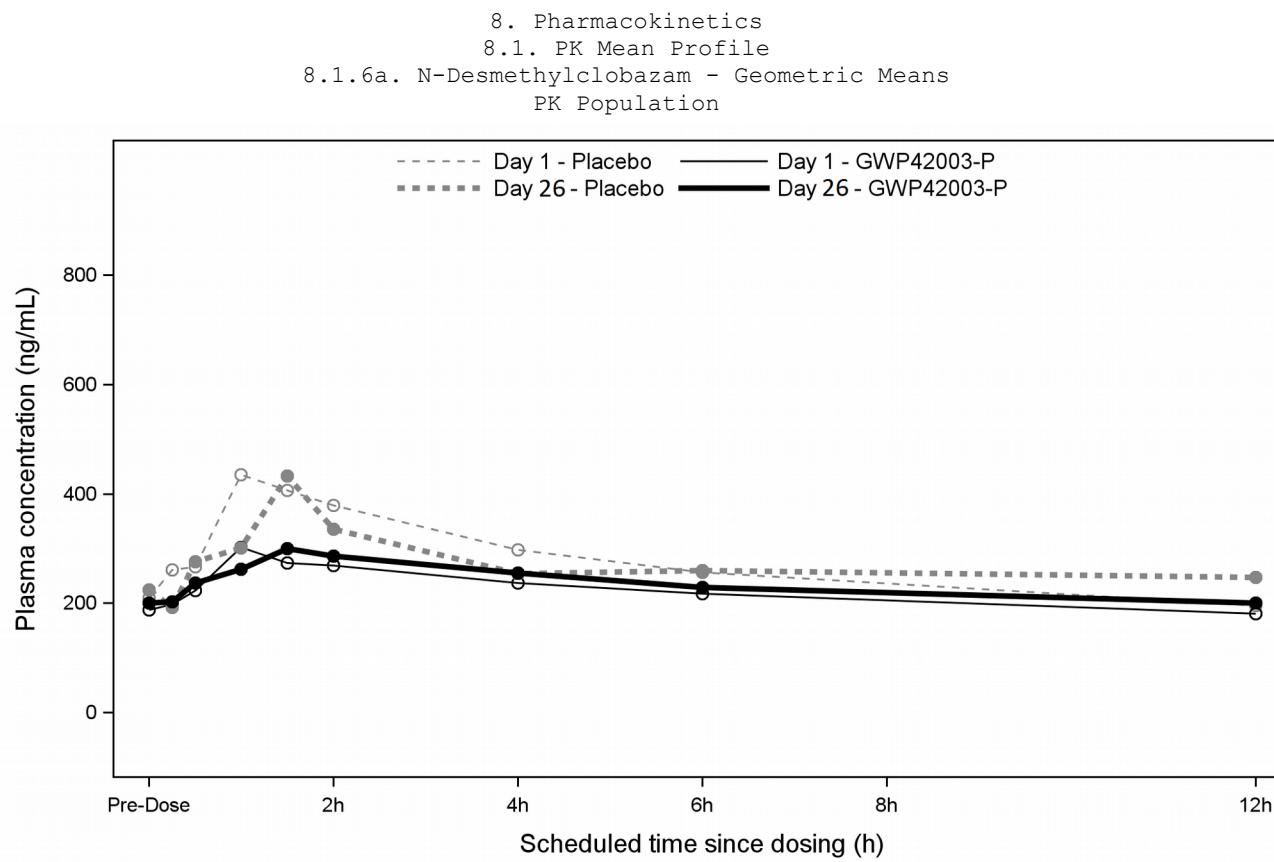


Source: Table 8.1.5

8. Pharmacokinetics
8.1. PK Mean Profile
8.1.5b. Clobazam - Geometric Means - Log10 Scale
PK Population

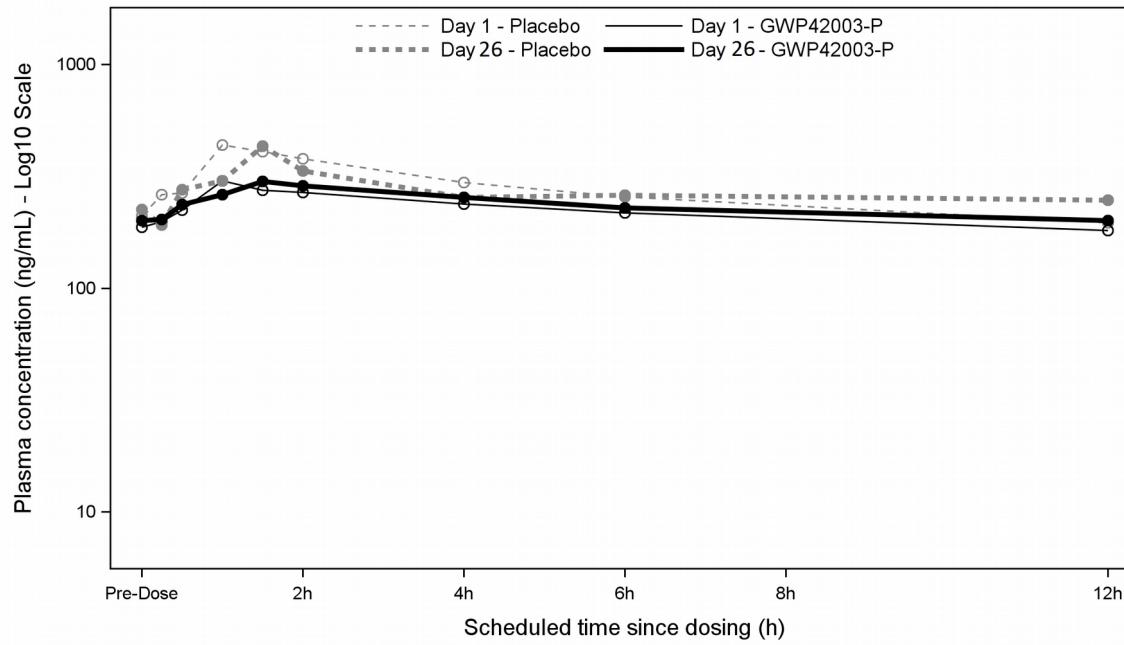


Source: Table 8.1.5



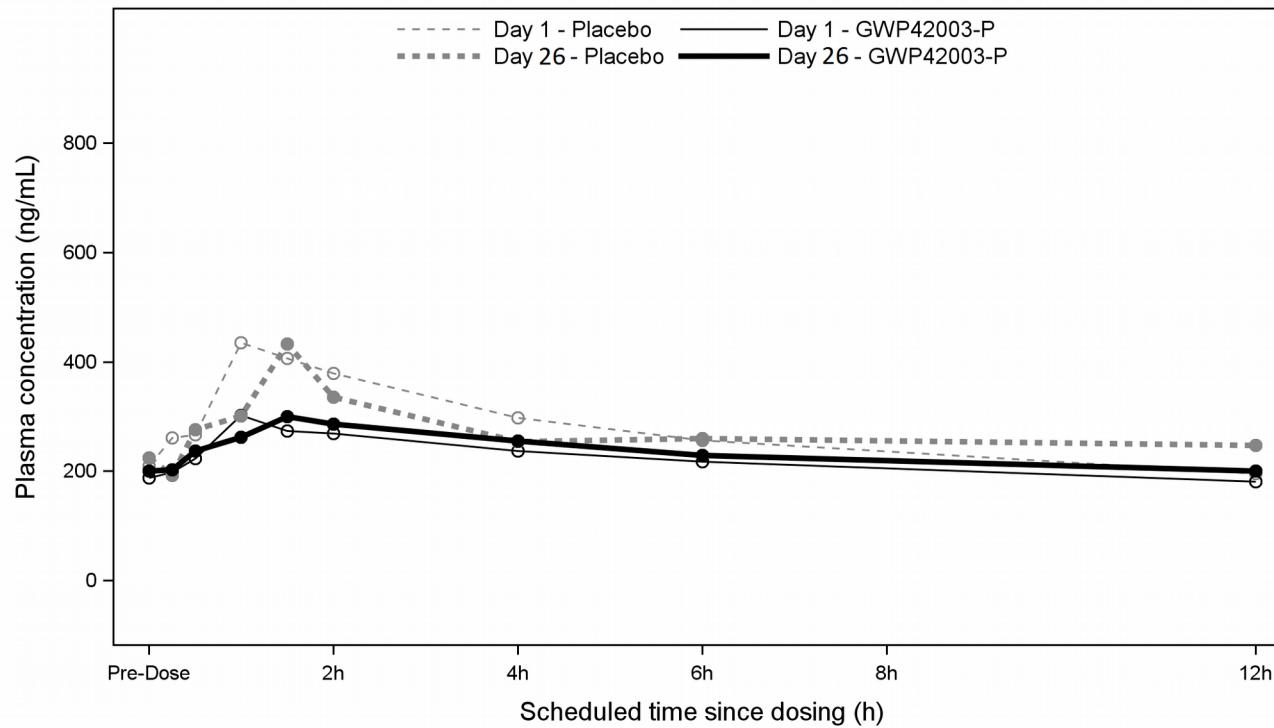
Source: Table 8.1.5

8. Pharmacokinetics
8.1. PK Mean Profile
8.1.6b. N-Desmethylclobazam - Geometric Means - Log10 Scale
PK Population

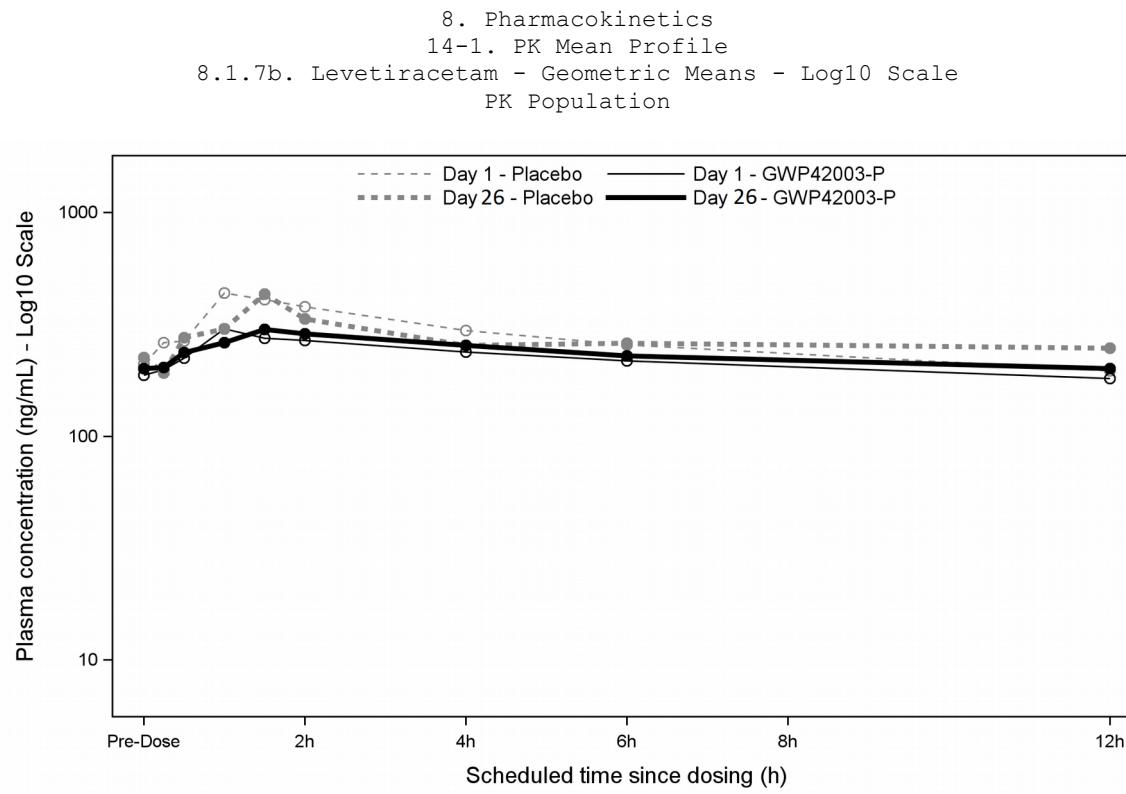


Source: Table 8.1.5

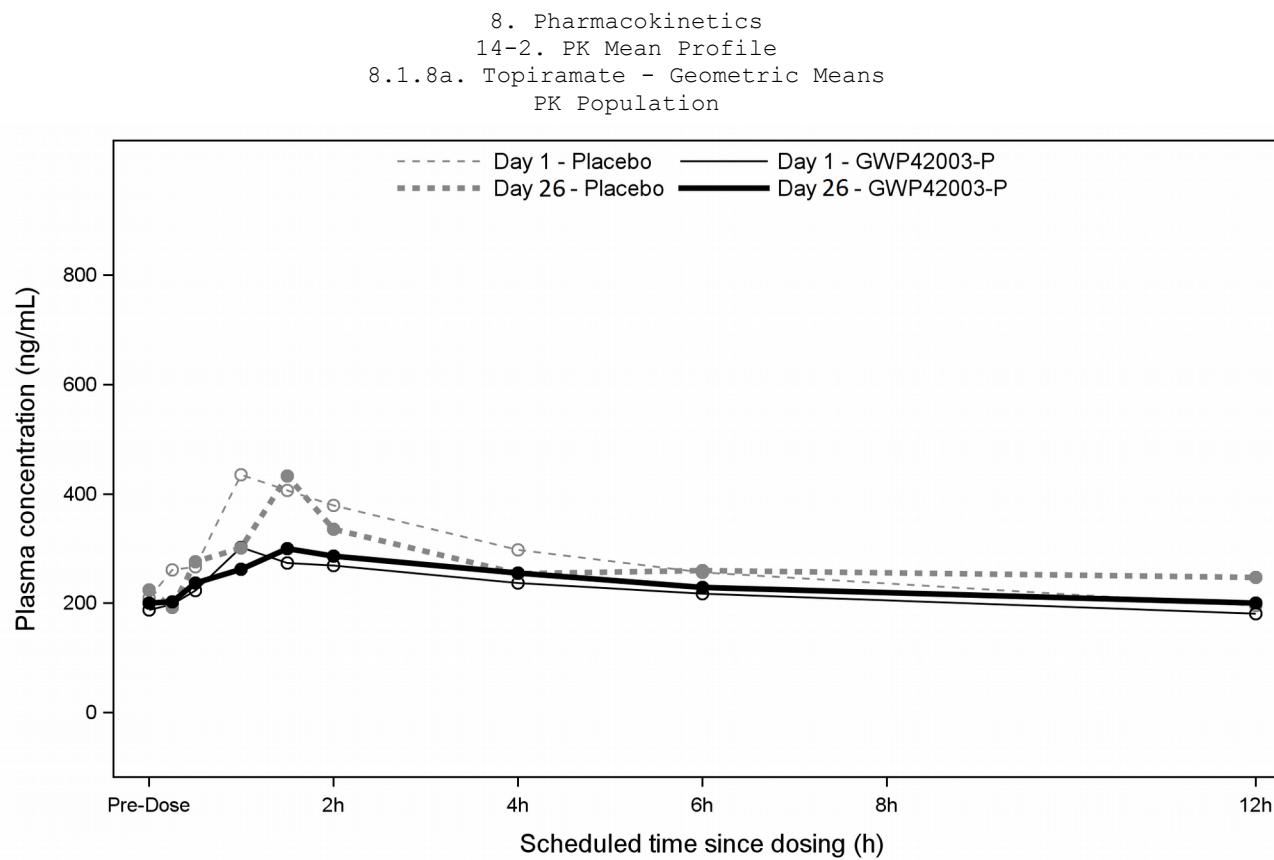
8. Pharmacokinetics
8.1. PK Mean Profile
8.1.7a. Levetiracetam - Geometric Means
PK Population



Source: Table 8.1.5

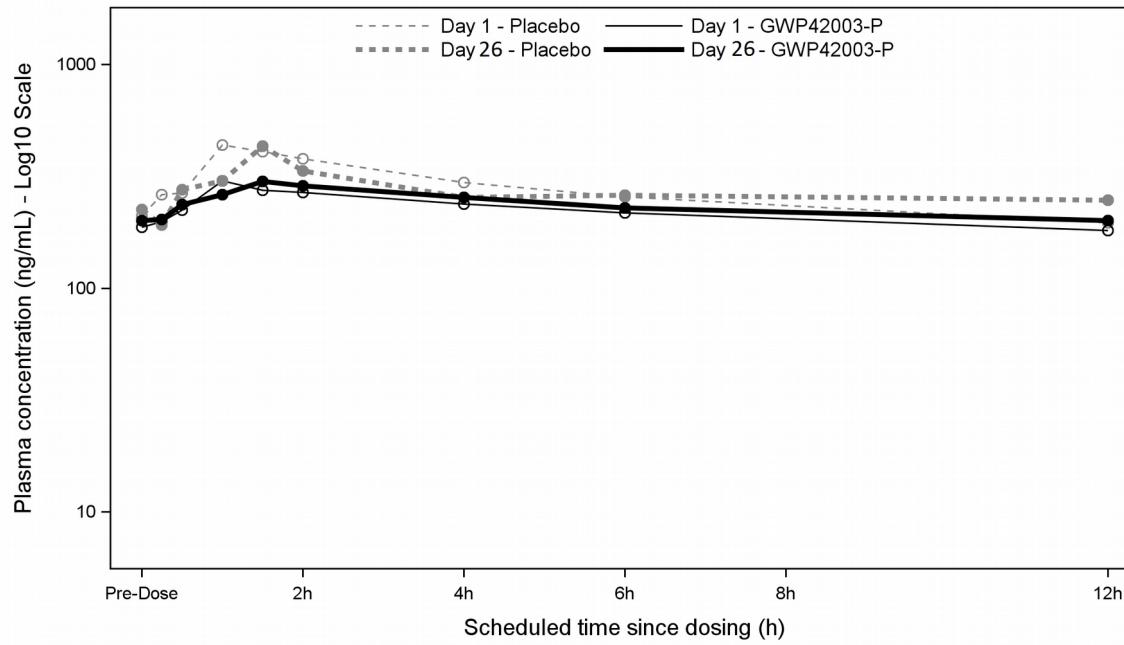


Source: Table 8.1.5

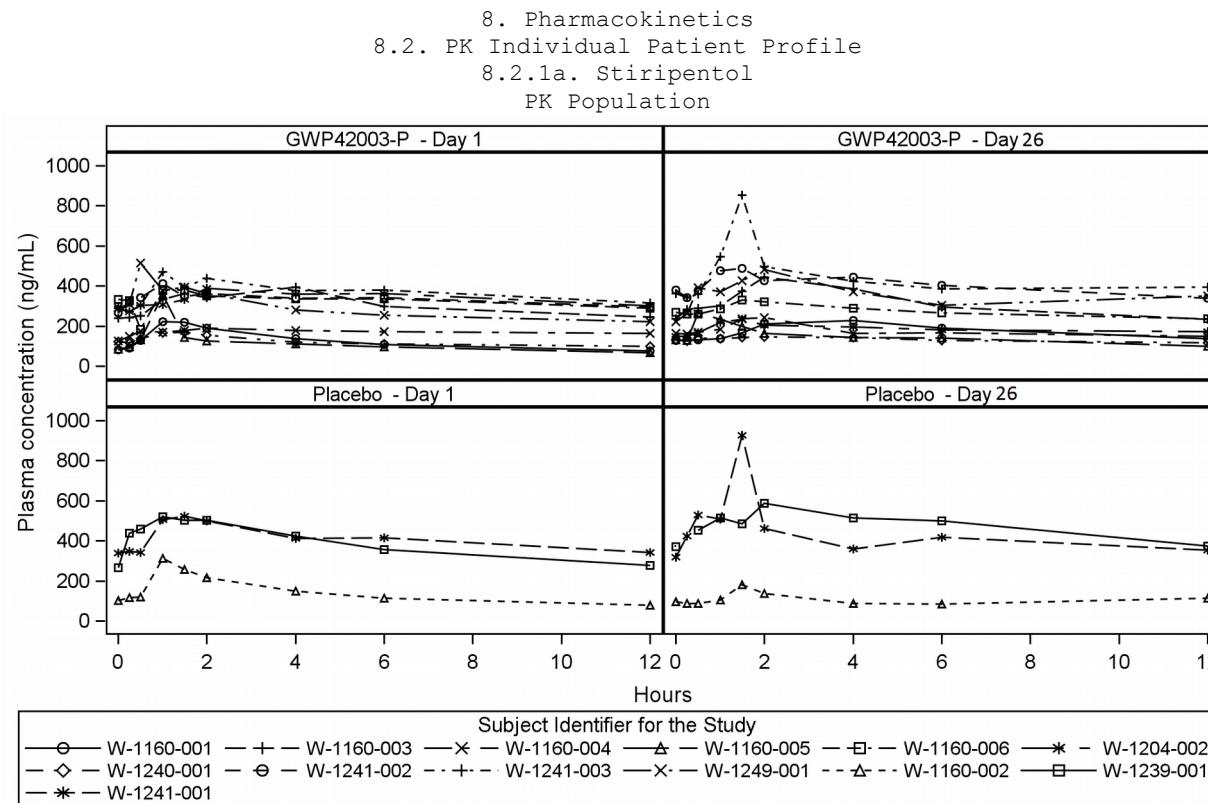


Source: Table 8.1.5

8. Pharmacokinetics
8.1. PK Mean Profile
8.1.8b. Topiramate - Geometric Means - Log10 Scale
PK Population

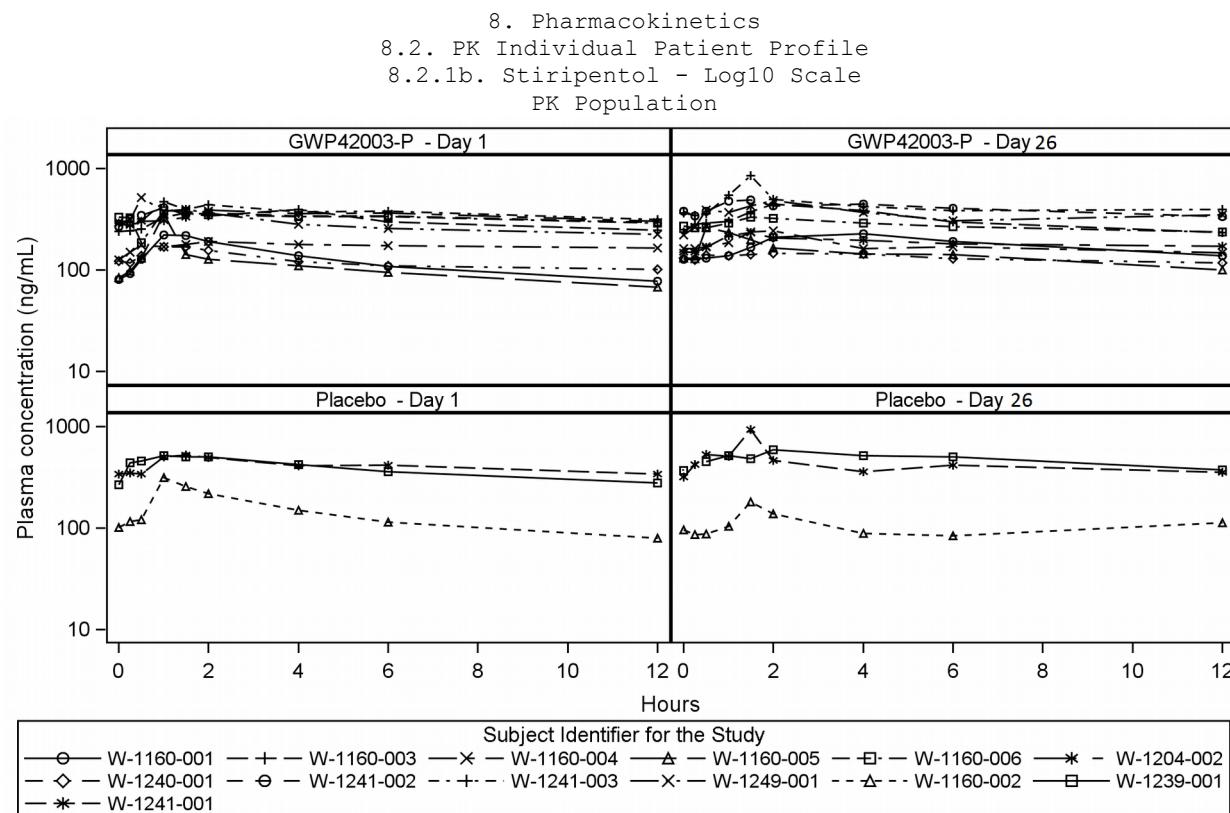


Source: Table 8.1.5



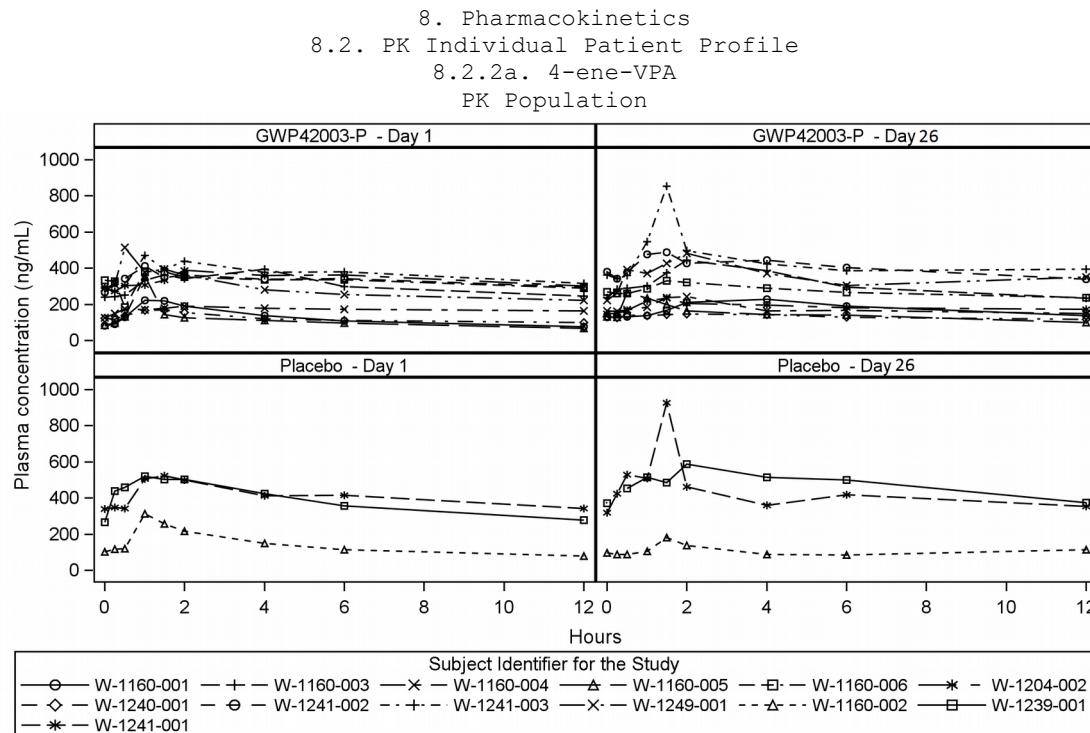
Source: Listing 8.1

Programmer's note: This title is applicable for STP arm. For VPA arm that will be "8.2.1a. Valproic Acid".



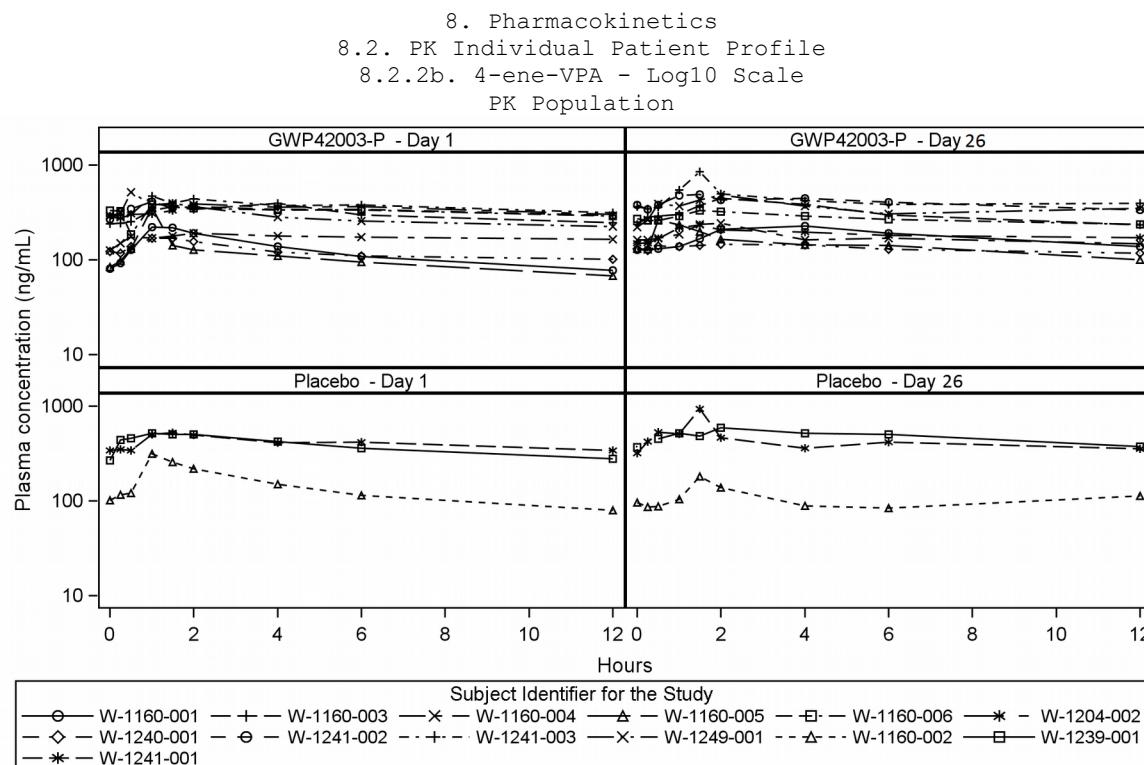
Source: Listing 8.1

Programmer's note: This title is applicable for STP arm. For VPA arm that will be "8.2.1b. Valproic Acid - Log10 Scale".



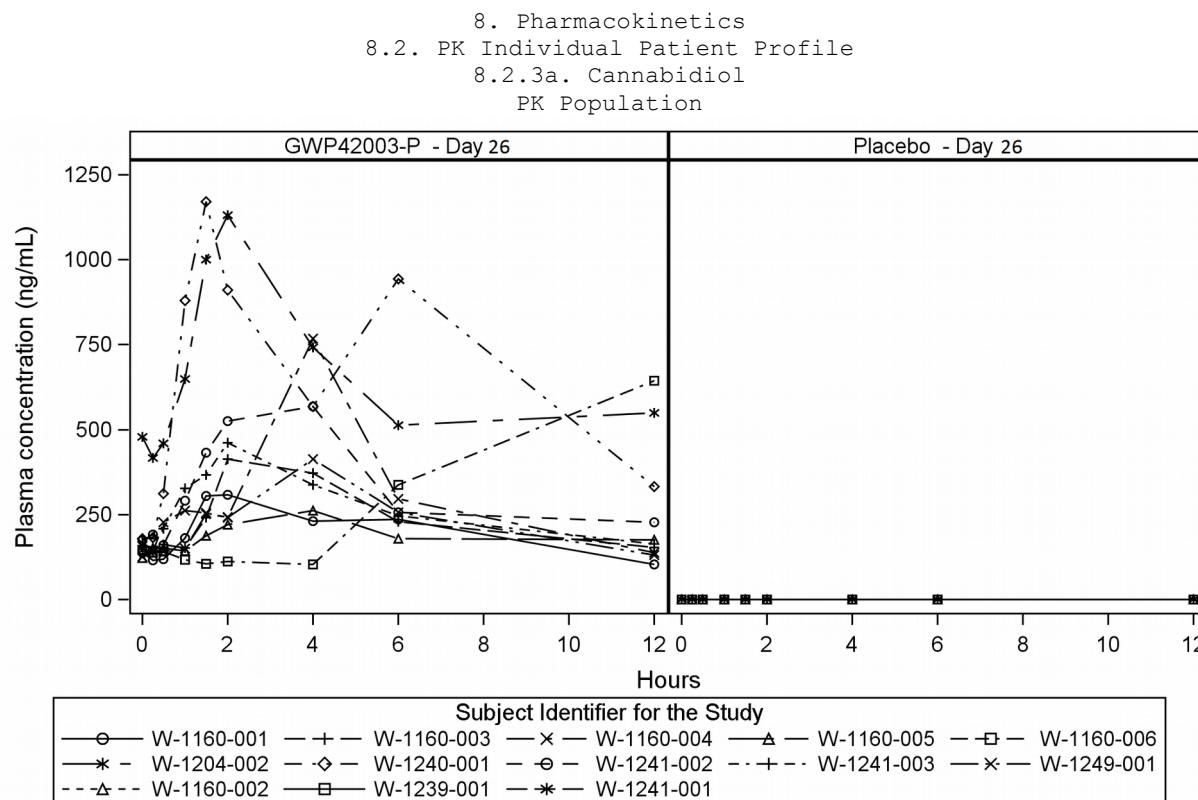
Source: Listing 8.1

Programmer's note: Only applicable for VPA arm.



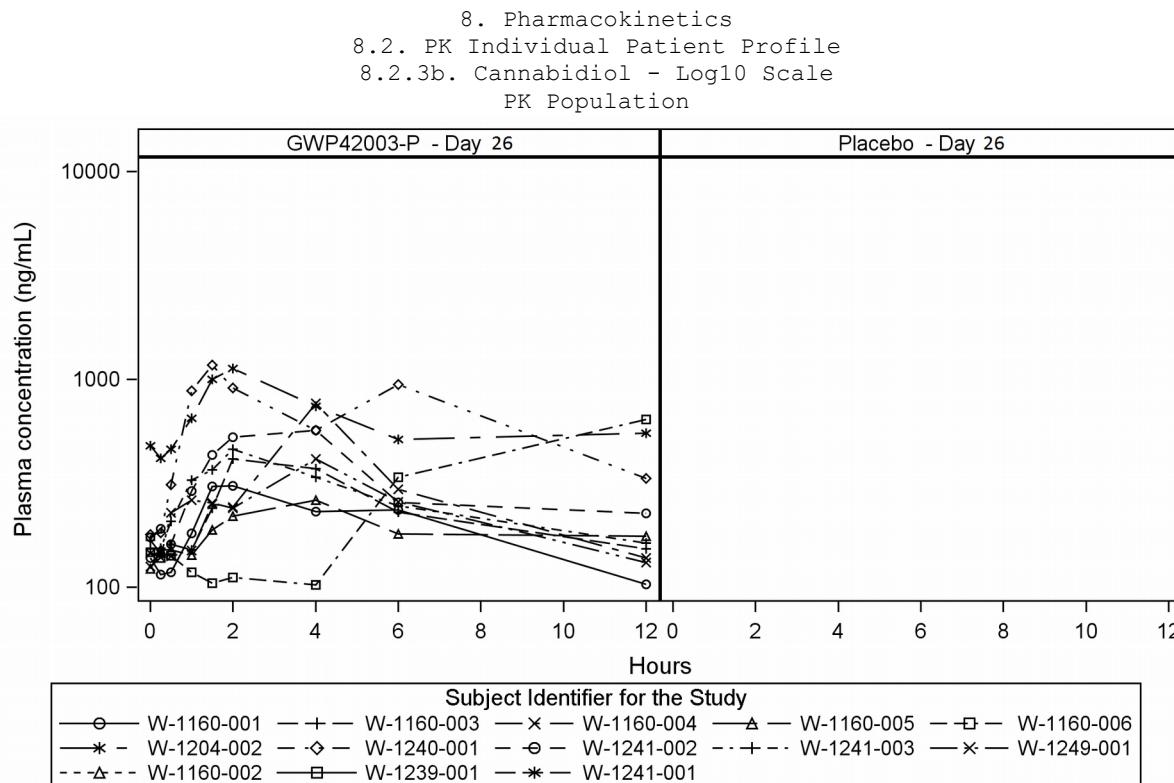
Source: Listing 8.1

Programmer's note: Only applicable for VPA arm.



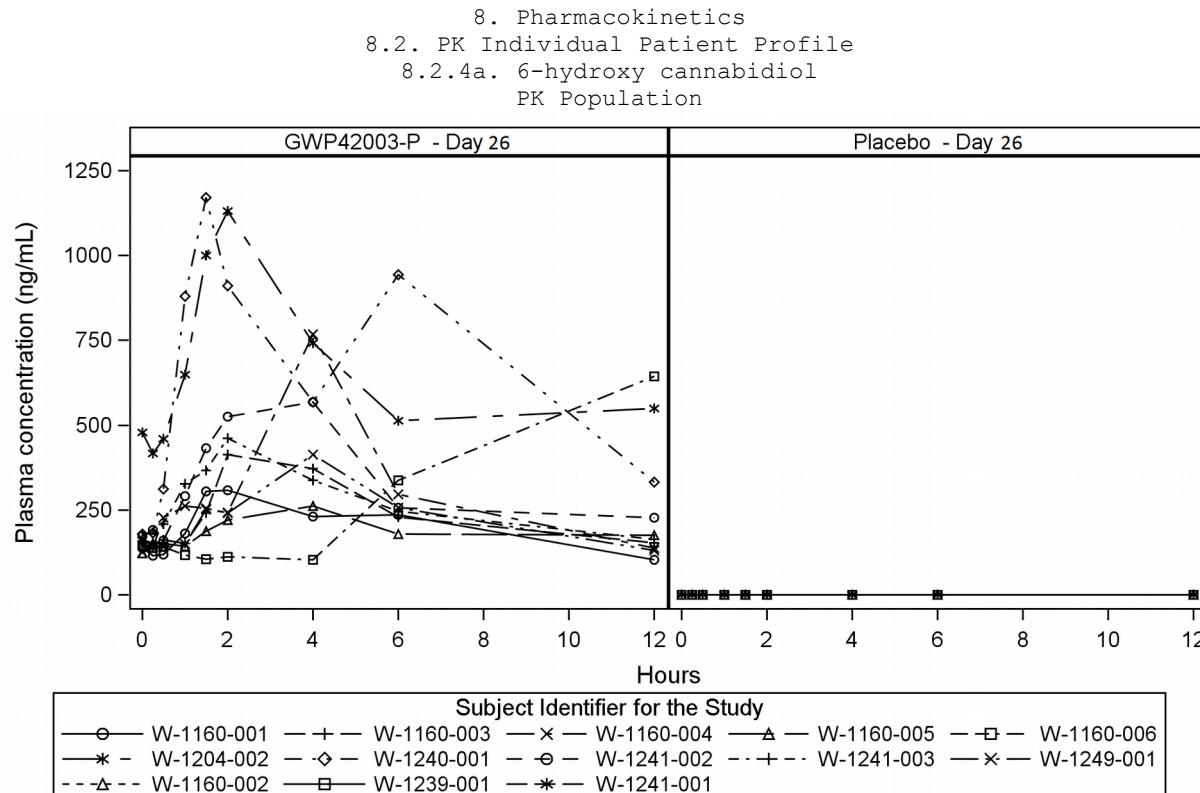
Source: Listing 8.1

Programmer's note: Only Day 26 will be plotted.



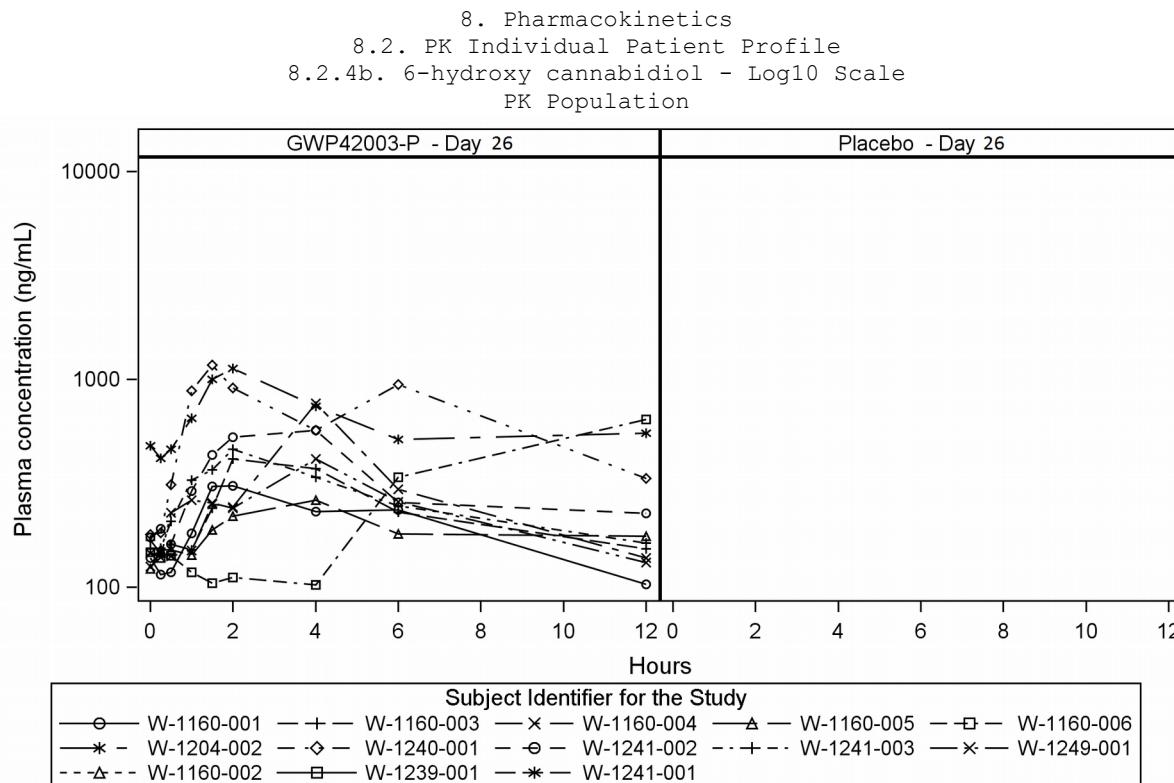
Source: Listing 8.1

Programmer's note: Only Day 26 will be plotted.



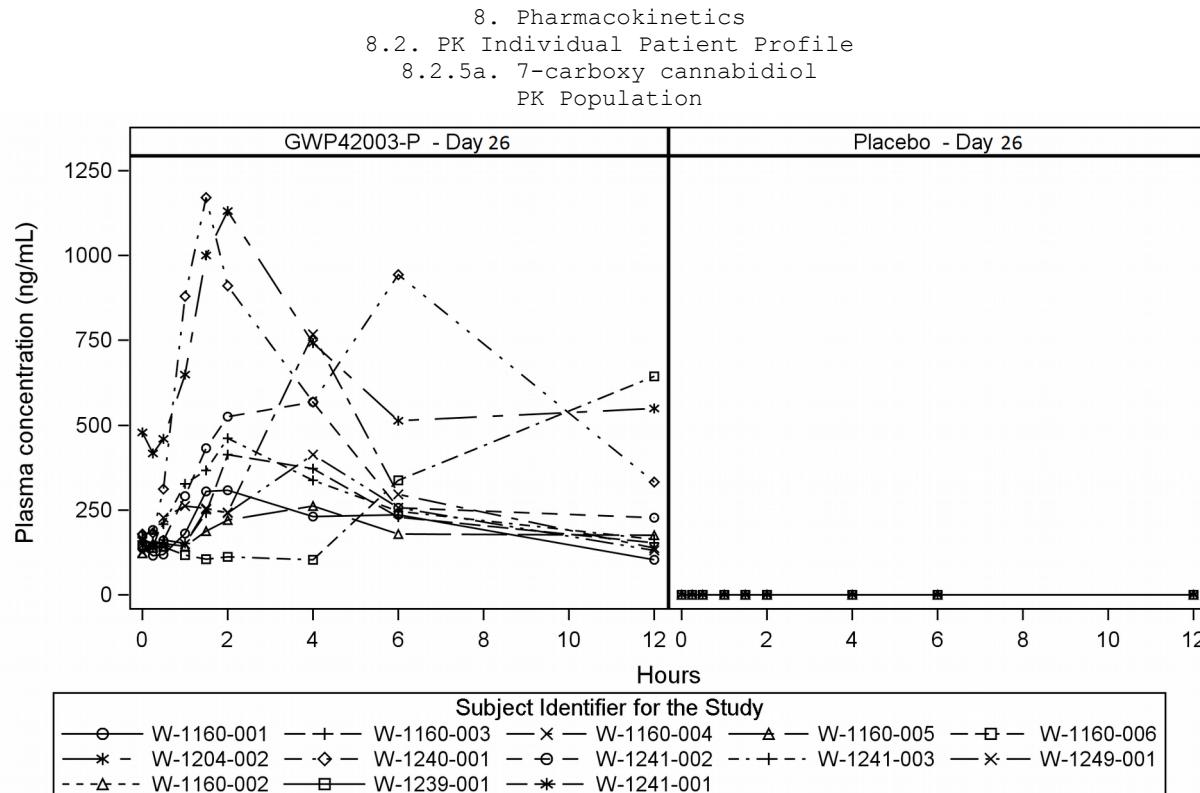
Source: Listing 8.1

Programmer's note: Only Day 26 will be plotted.



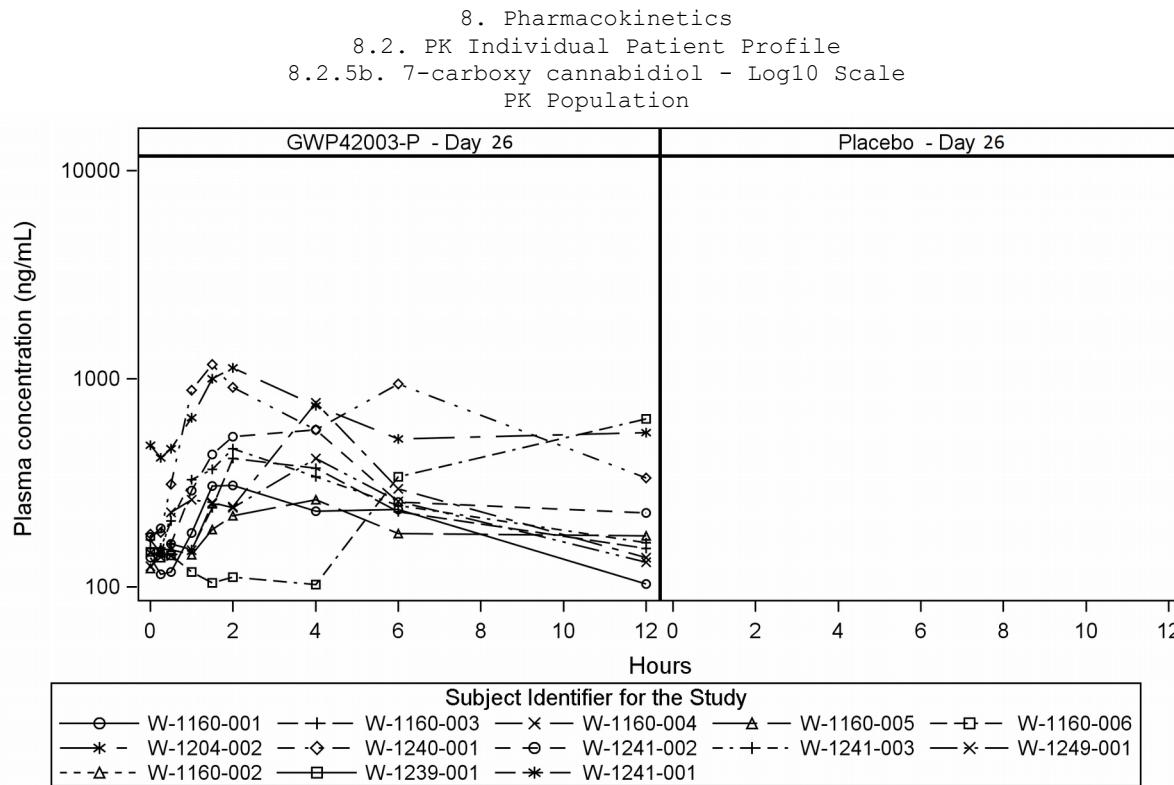
Source: Listing 8.1

Programmer's note: Only Day 26 will be plotted.



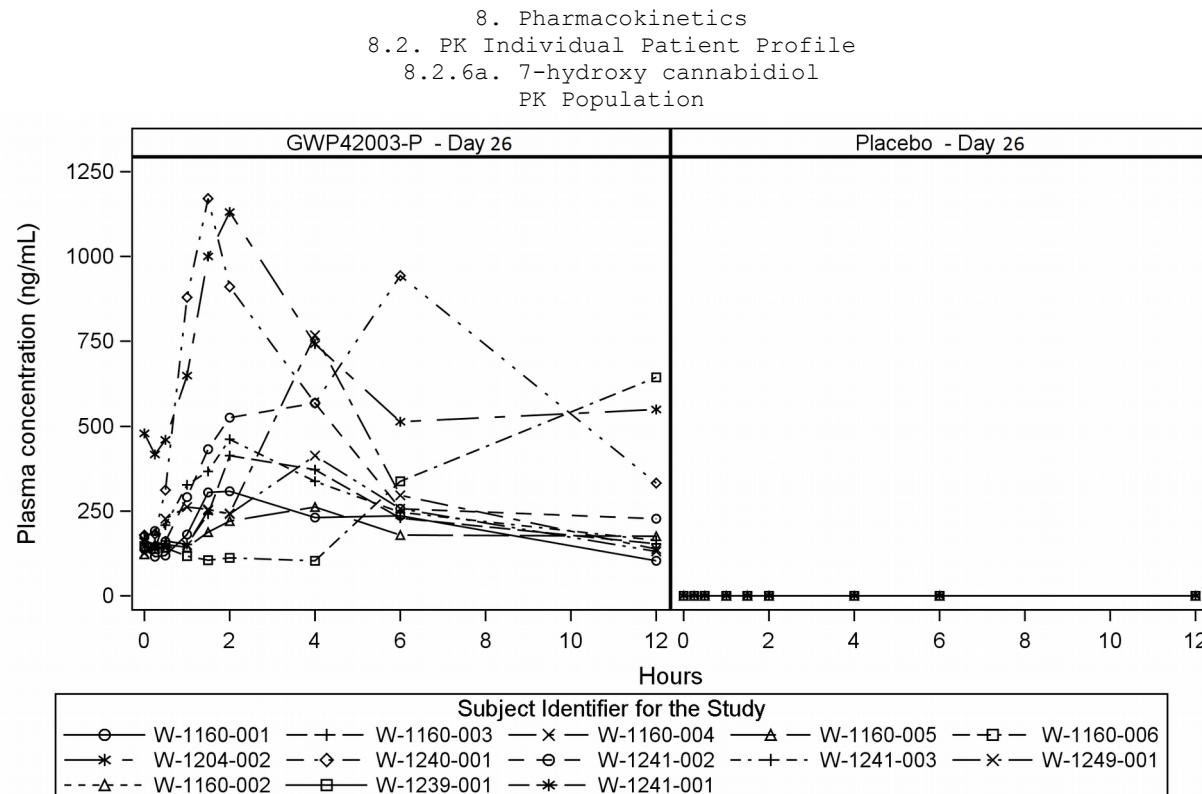
Source: Listing 8.1

Programmer's note: Only Day 26 will be plotted.



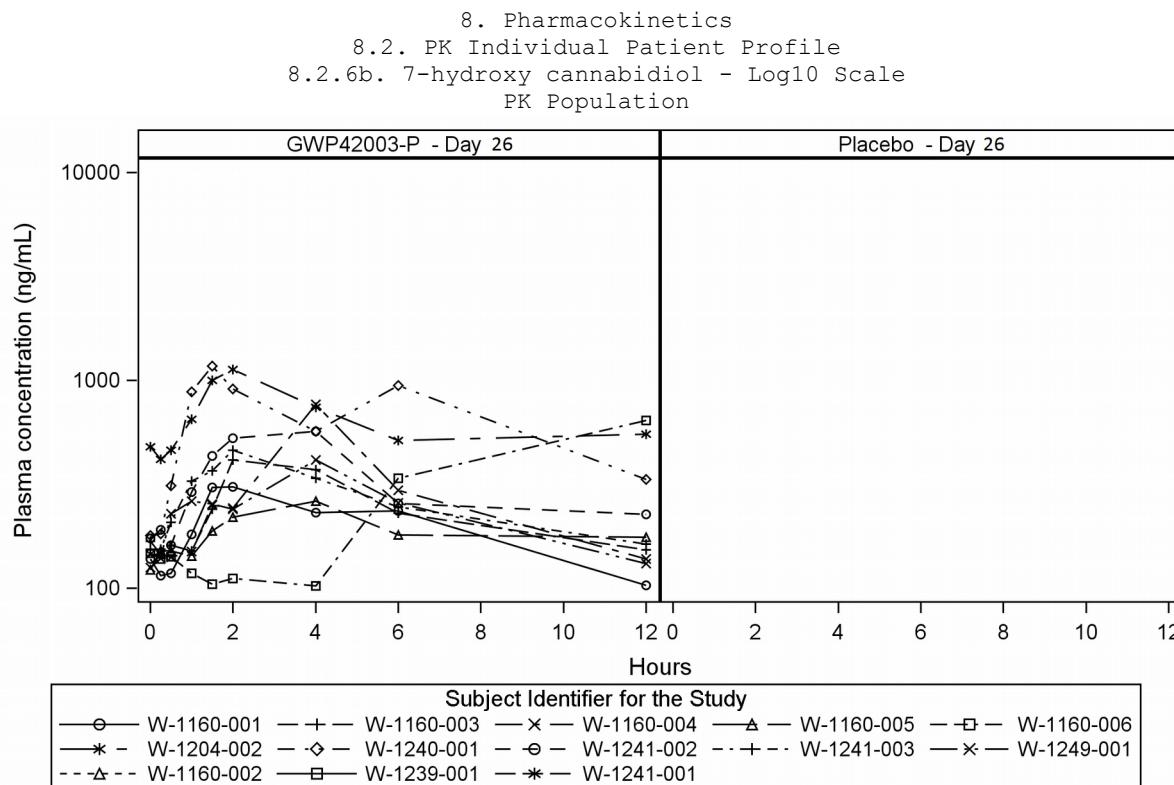
Source: Listing 8.1

Programmer's note: Only Day 26 will be plotted.



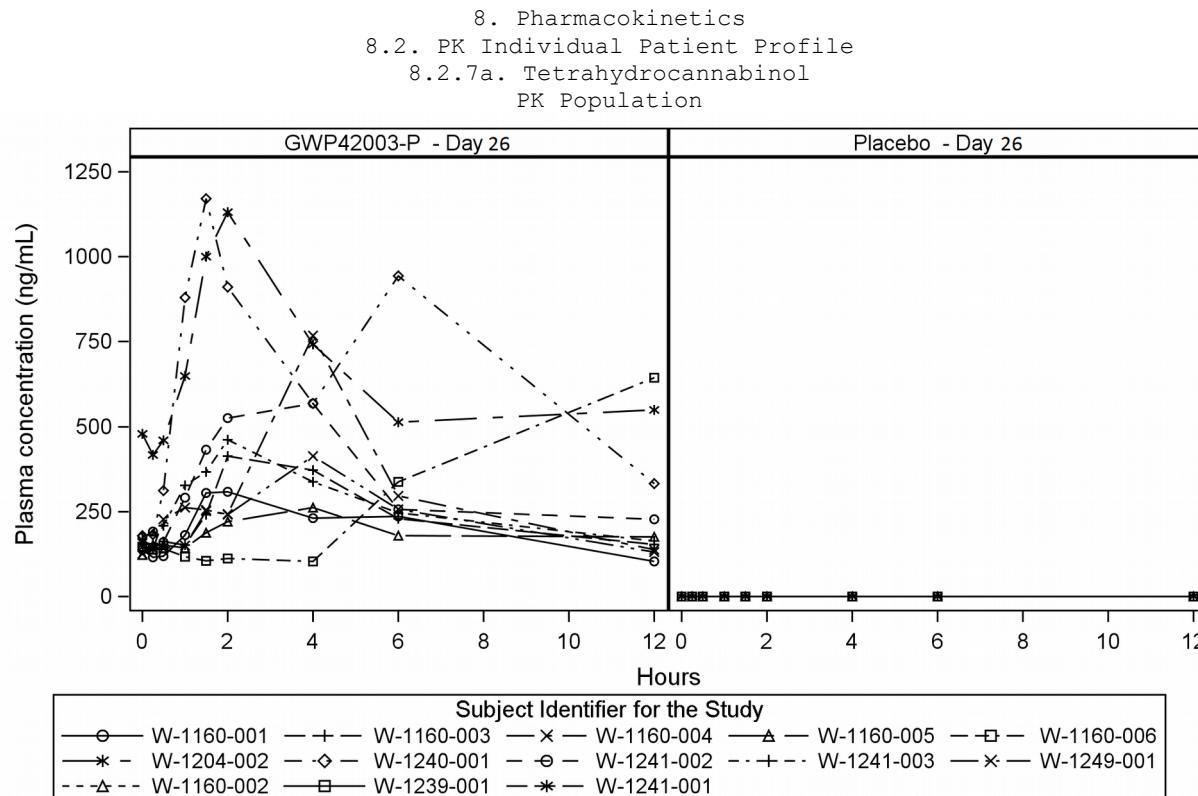
Source: Listing 8.1

Programmer's note: Only Day 26 will be plotted.



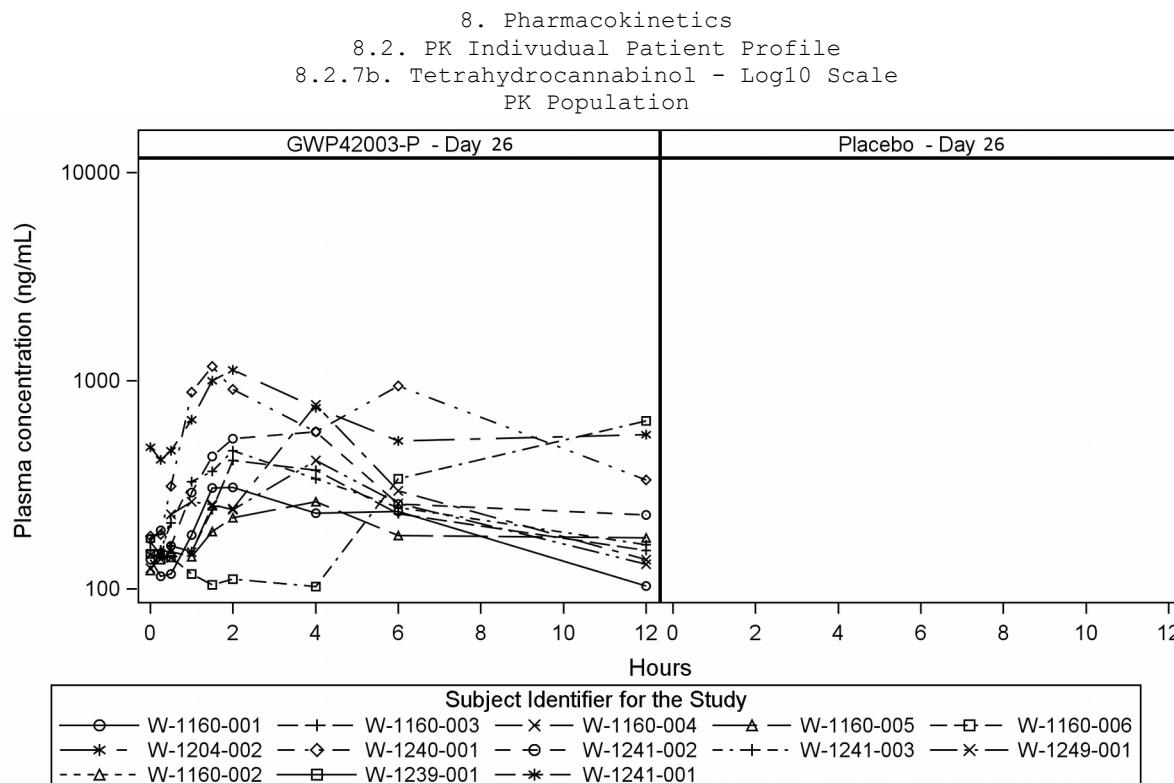
Source: Listing 8.1

Programmer's note: Only Day 26 will be plotted.



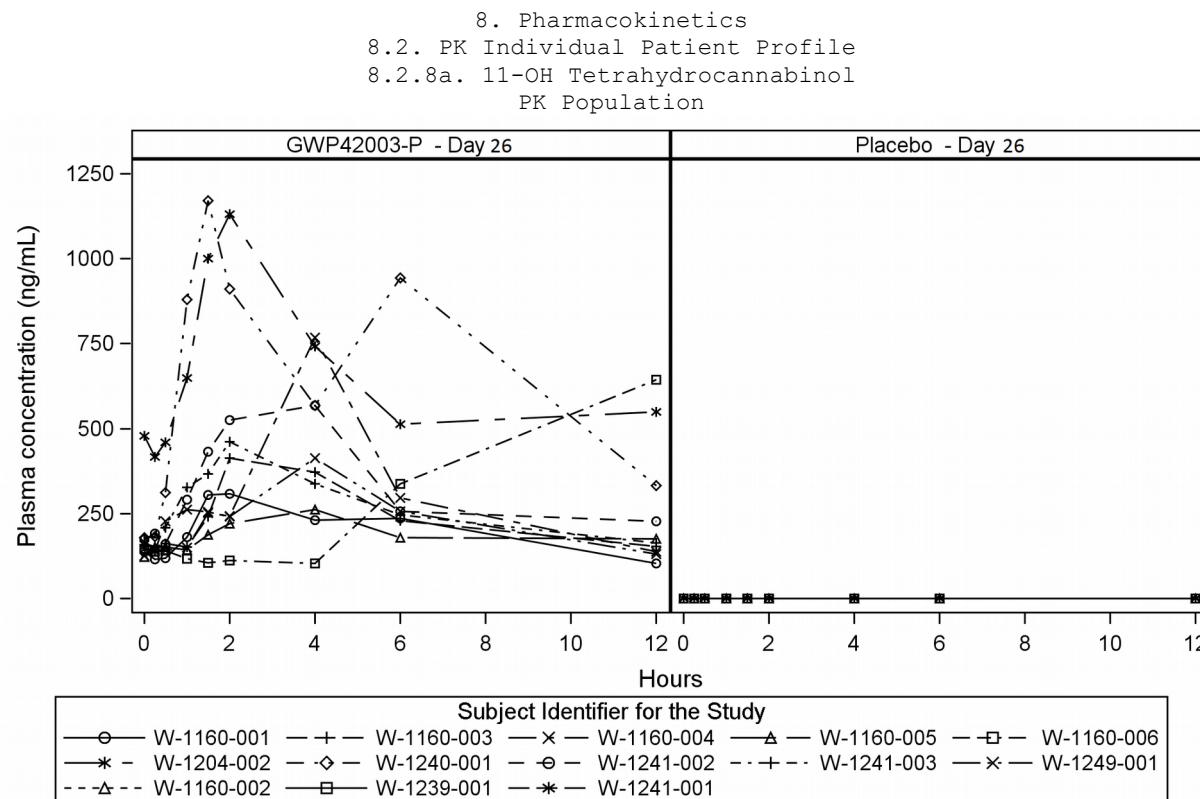
Source: Listing 8.1

Programmer's note: Only Day 26 will be plotted.



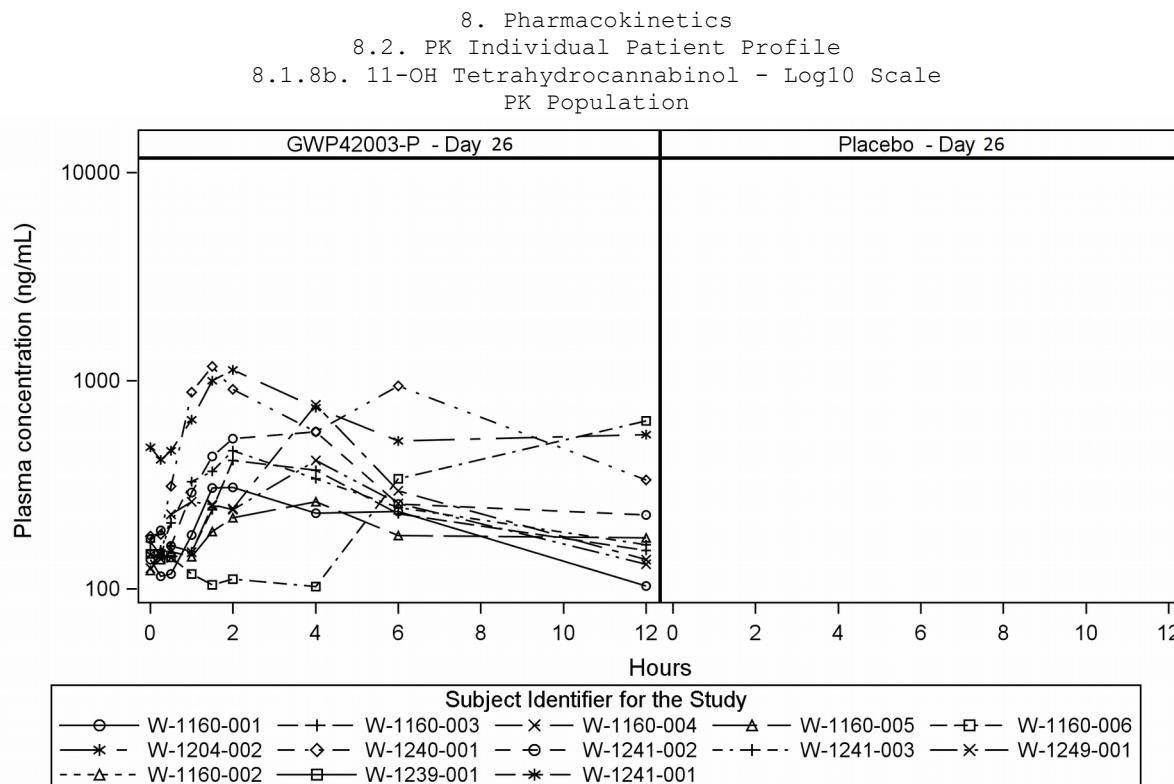
Source: Listing 8.1

Programmer's note: Only Day 26 will be plotted.



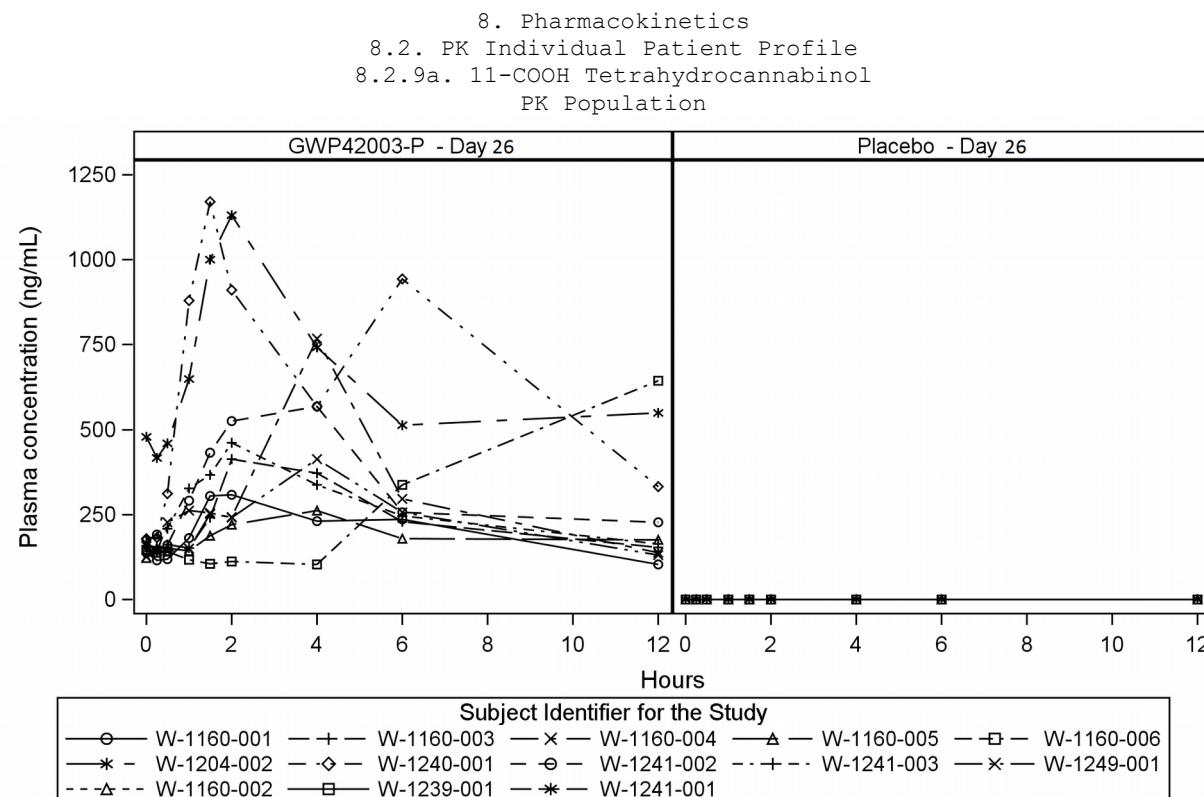
Source: Listing 8.1

Programmer's note: Only Day 26 will be plotted.



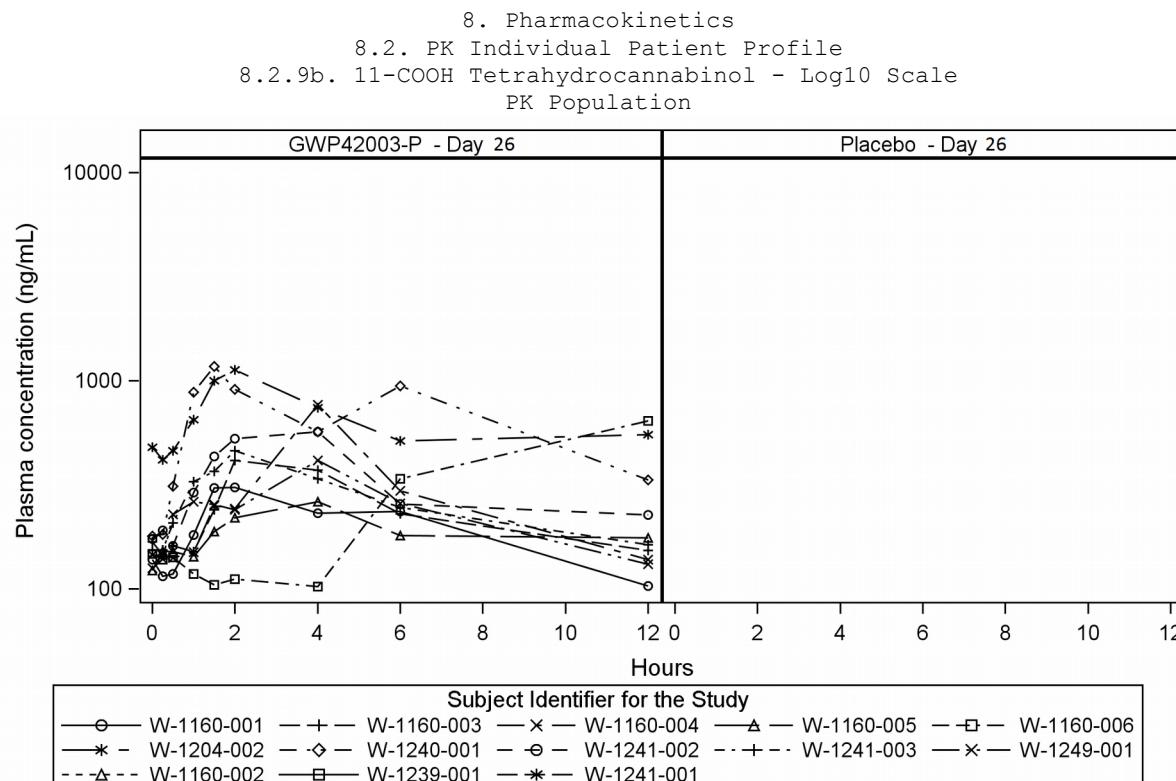
Source: Listing 8.1

Programmer's note: Only Day 26 will be plotted.



Source: Listing 8.1

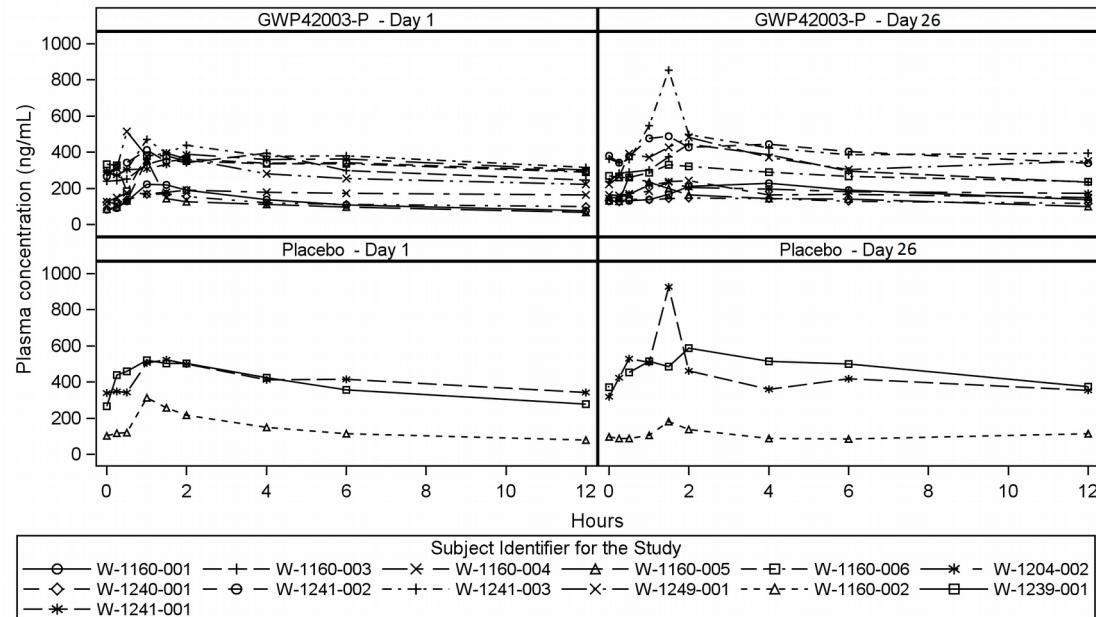
Programmer's note: Only Day 26 will be plotted.



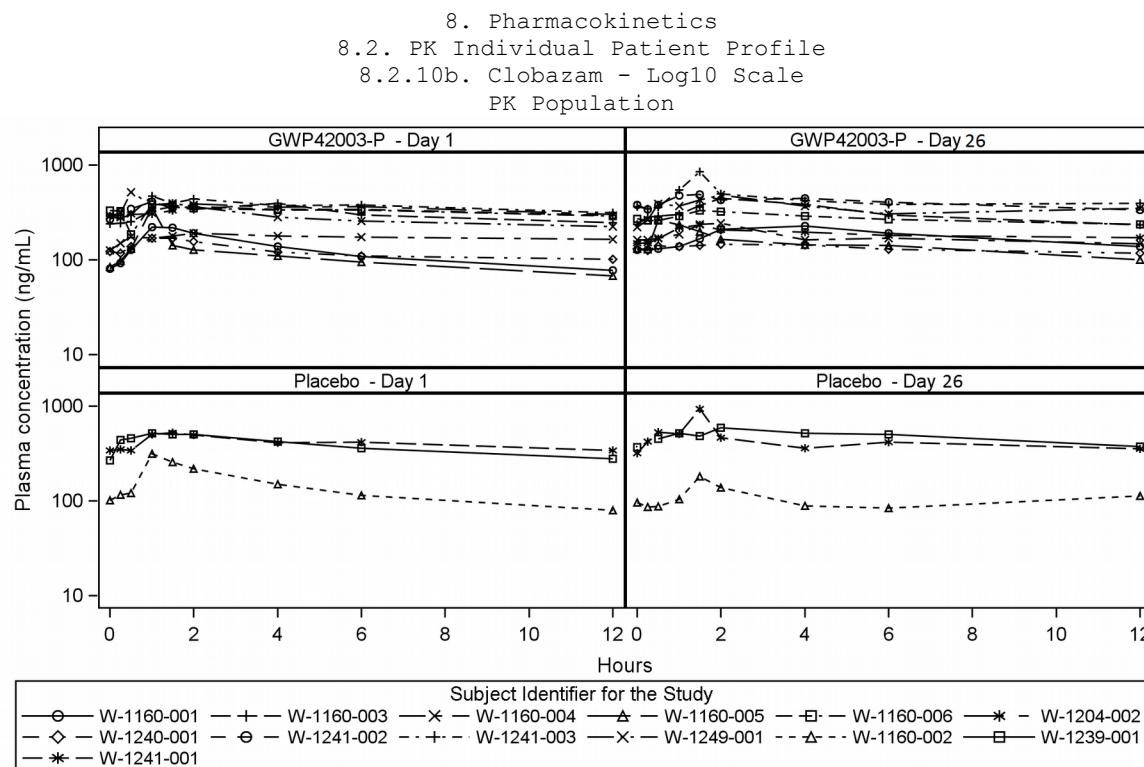
Source: Listing 8.1

Programmer's note: Only Day 26 will be plotted.

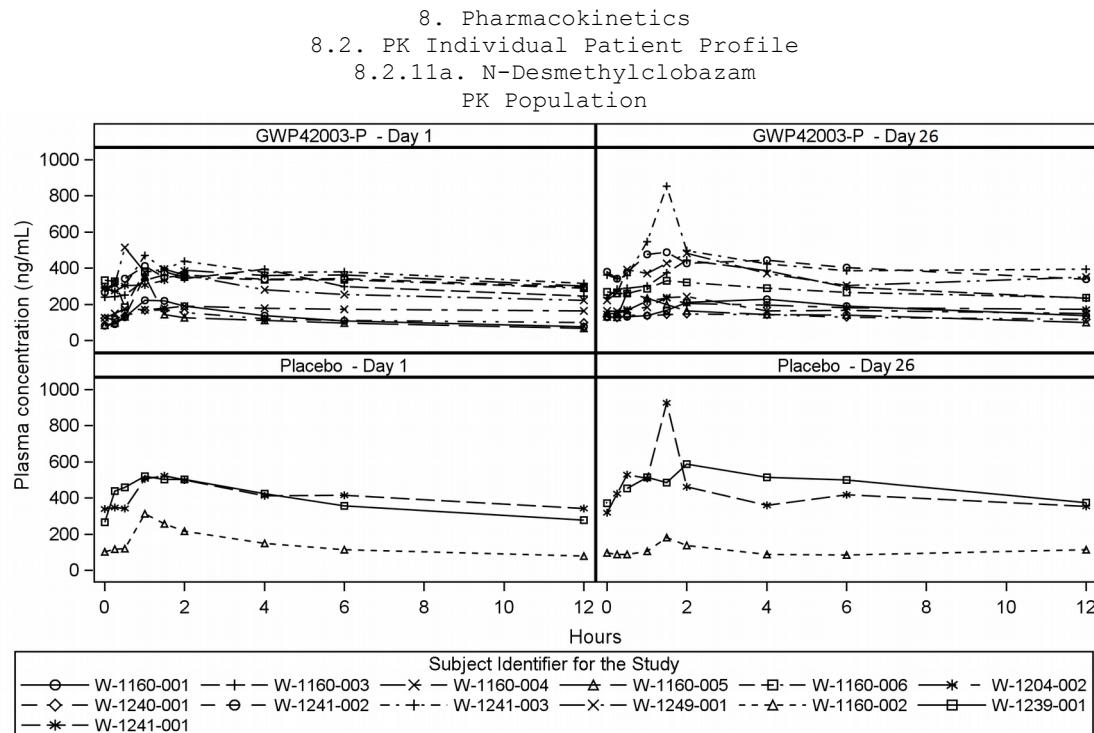
8. Pharmacokinetics
8.2. PK Individual Patient Profile
8.2.10a. Clobazam
PK Population



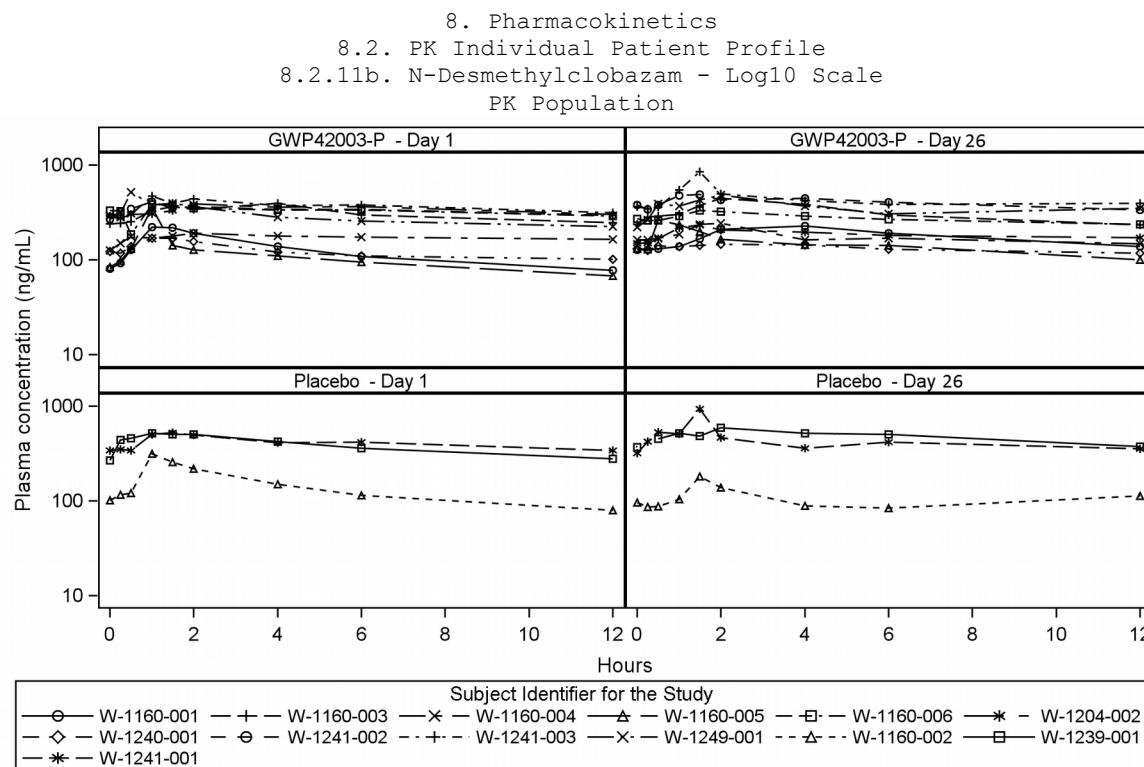
Source: Listing 8.1



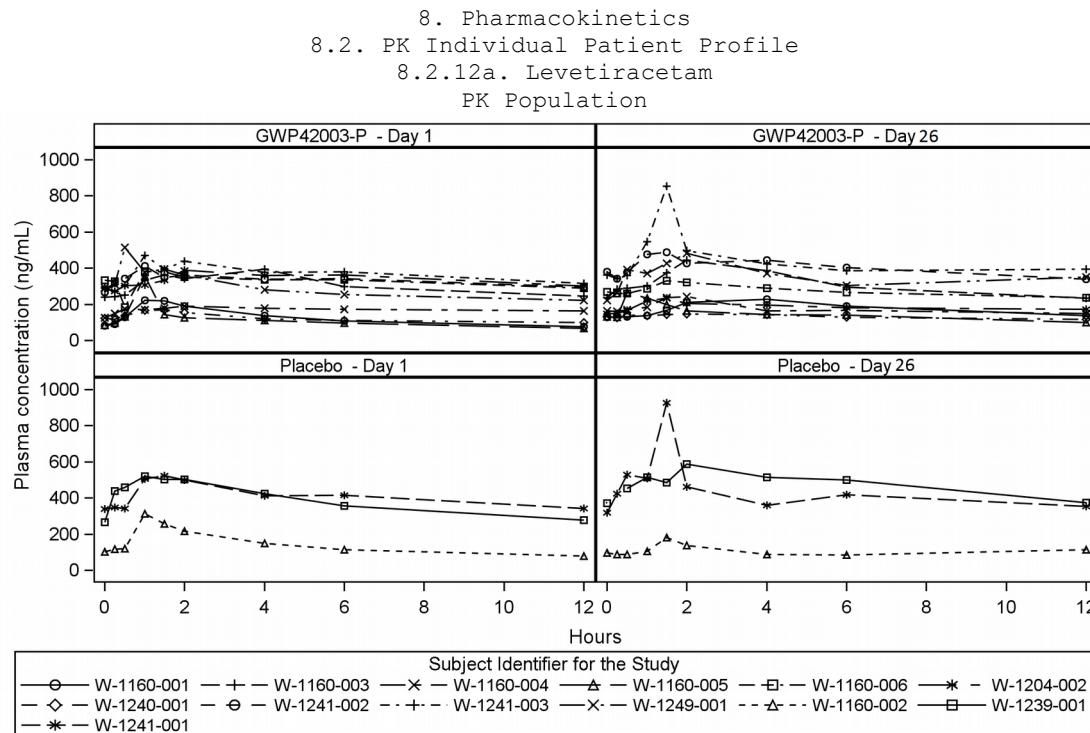
Source: Listing 8.1



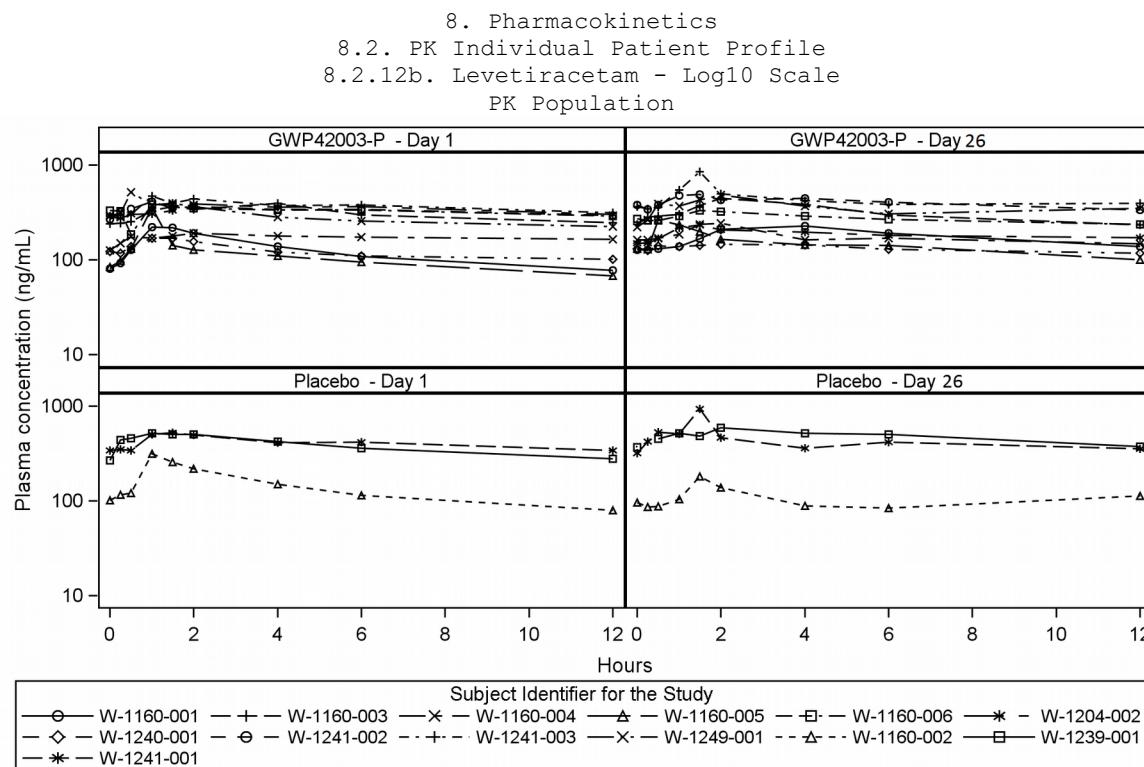
Source: Listing 8.1



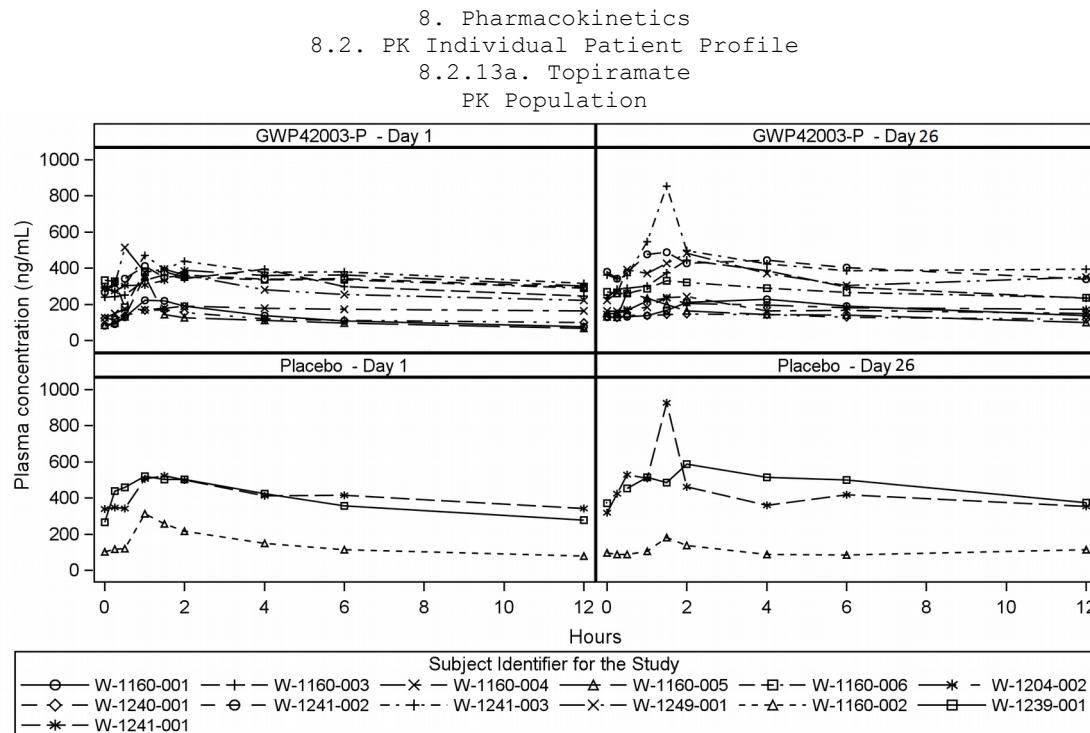
Source: Listing 8.1



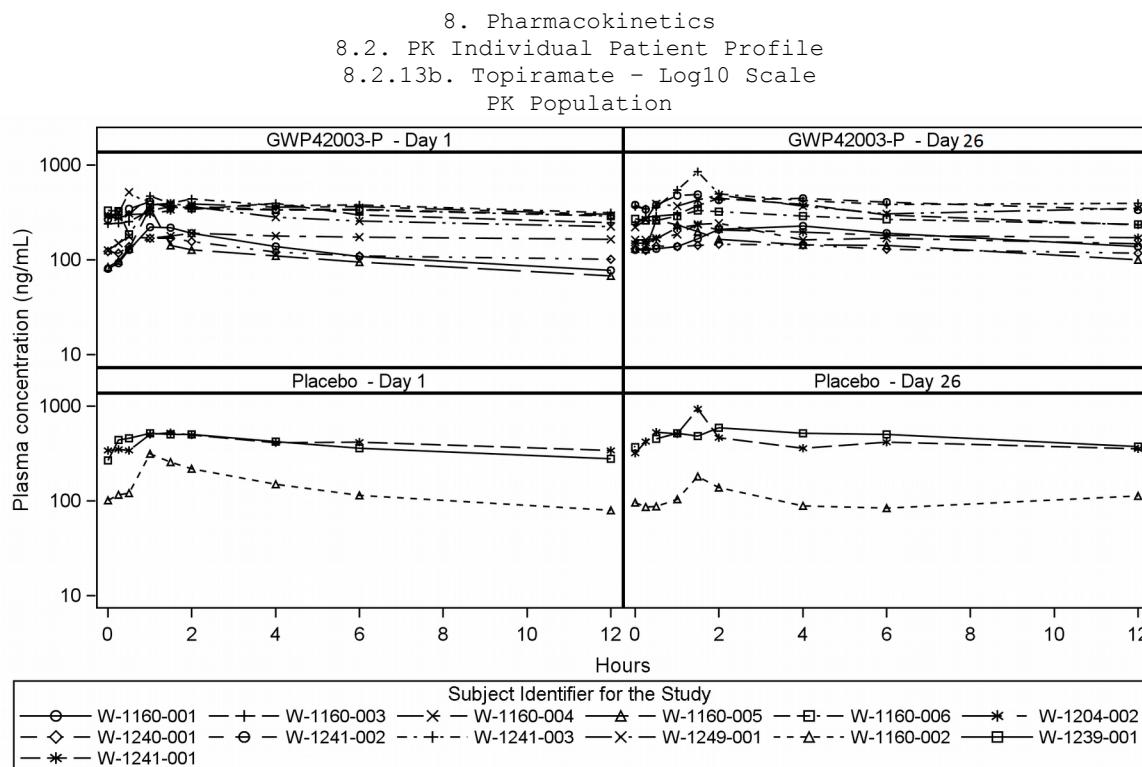
Source: Listing 8.1



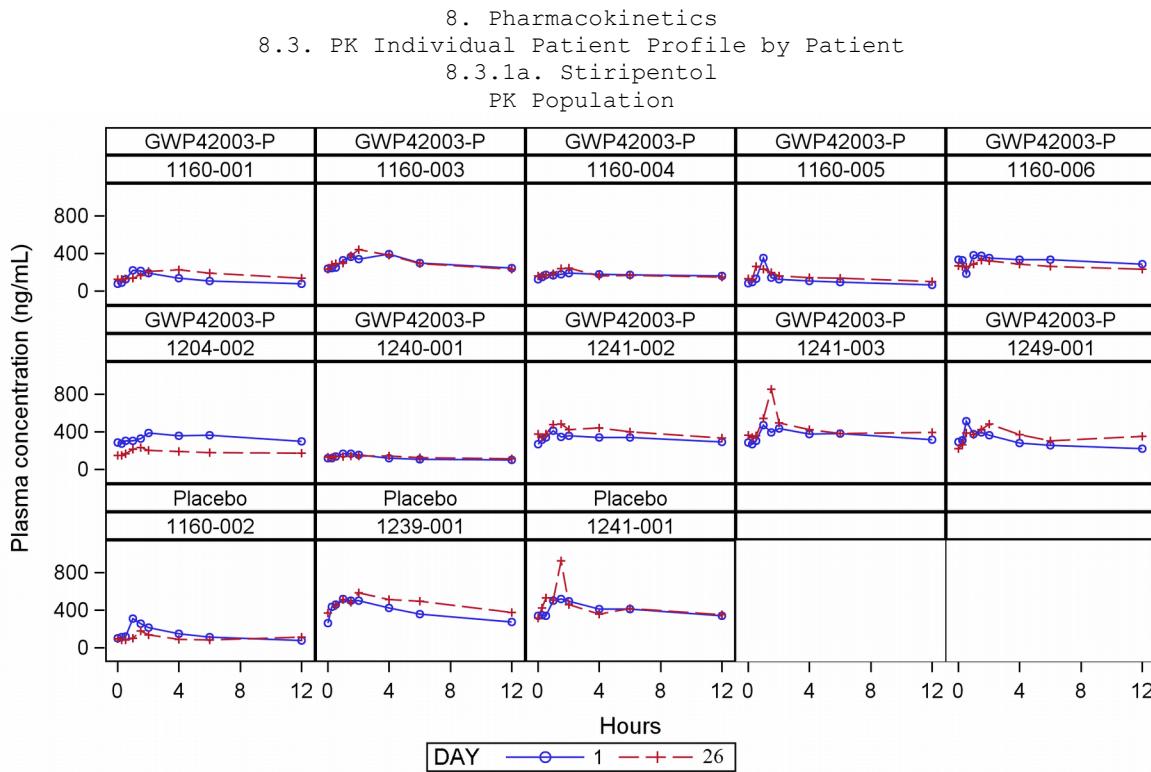
Source: Listing 8.1



Source: Listing 8.1



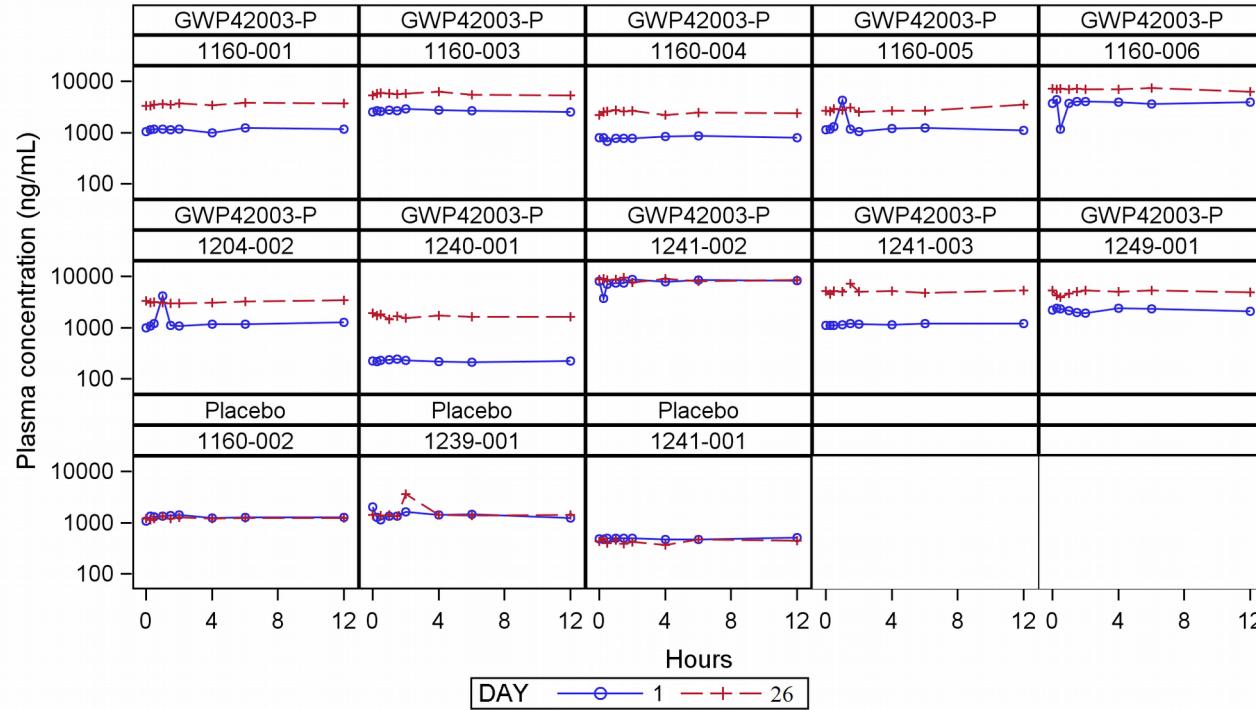
Source: Listing 8.1



Source: Listing 8.1

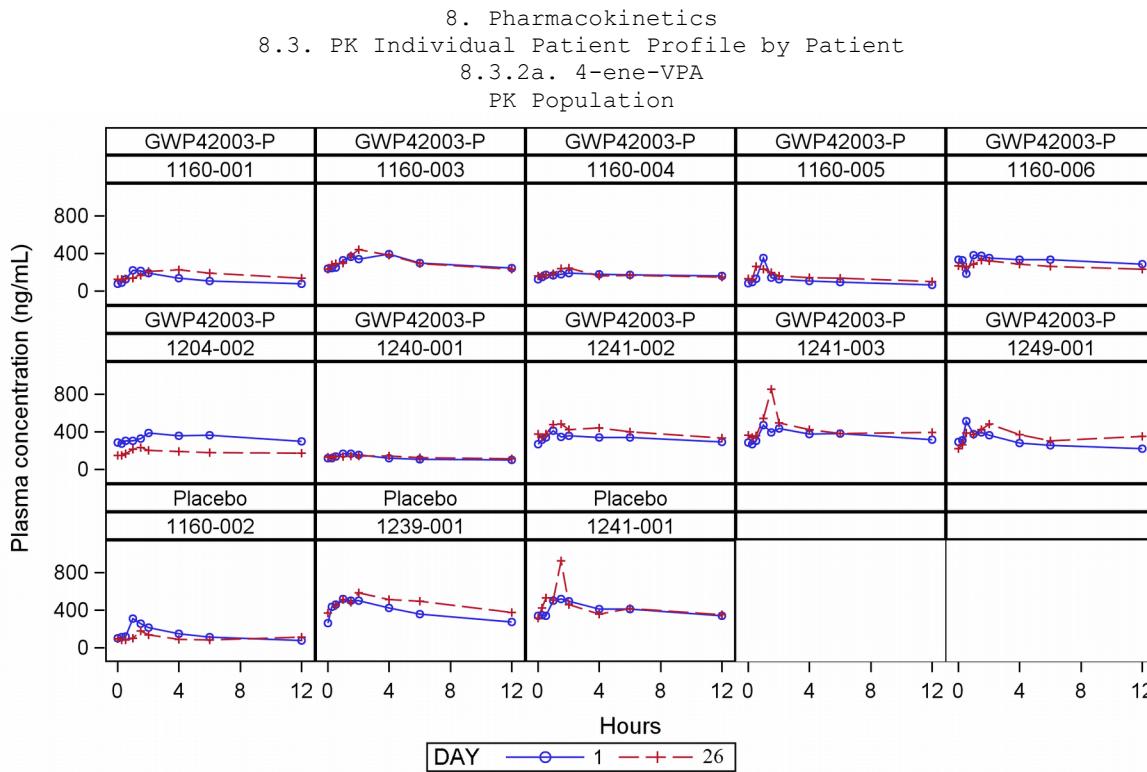
Programmer's note: This title is applicable for STP arm. For VPA arm that will be "8.3.1b. Valproic Acid".

8. Pharmacokinetics
 8.3. PK Individual Patient Profile by Patient
 8.3.1b. Stiripentol - Log10 Scale
 PK Population



Source: Listing 8.1

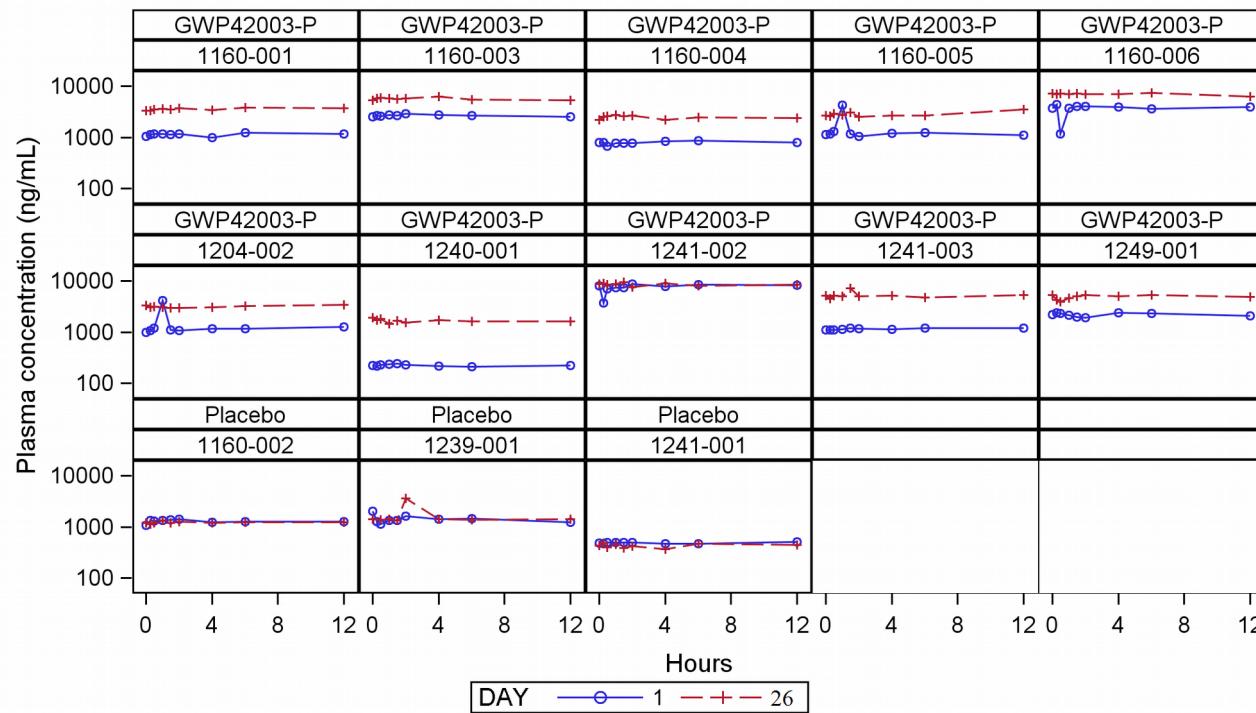
Programmer's note: This title is applicable for STP arm. For VPA arm that will be "8.3.1b. Valproic Acid - Log10 Scale".



Source: Listing 8.1

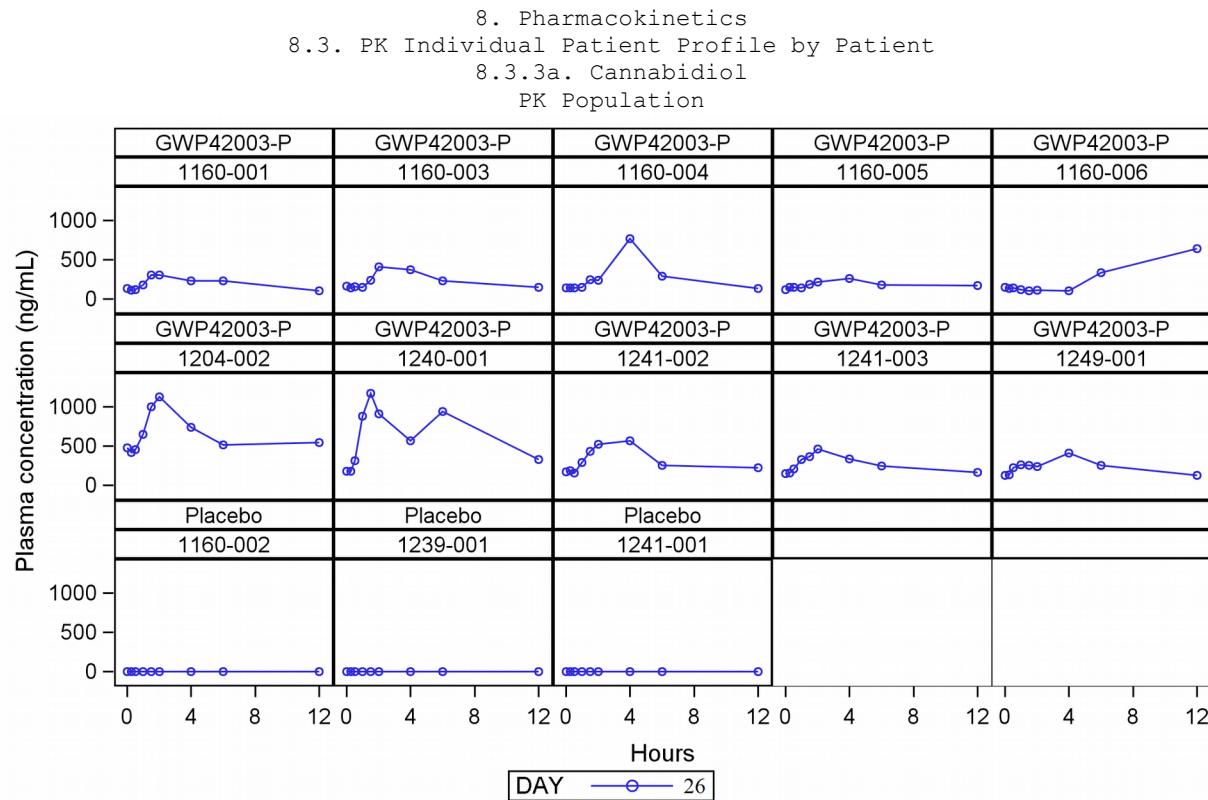
Programmer's note: Only applicable for VPA arm.

8. Pharmacokinetics
 8.3. PK Individual Patient Profile by Patient
 8.3.2b. 4-ene-VPA - Log10 Scale
 PK Population



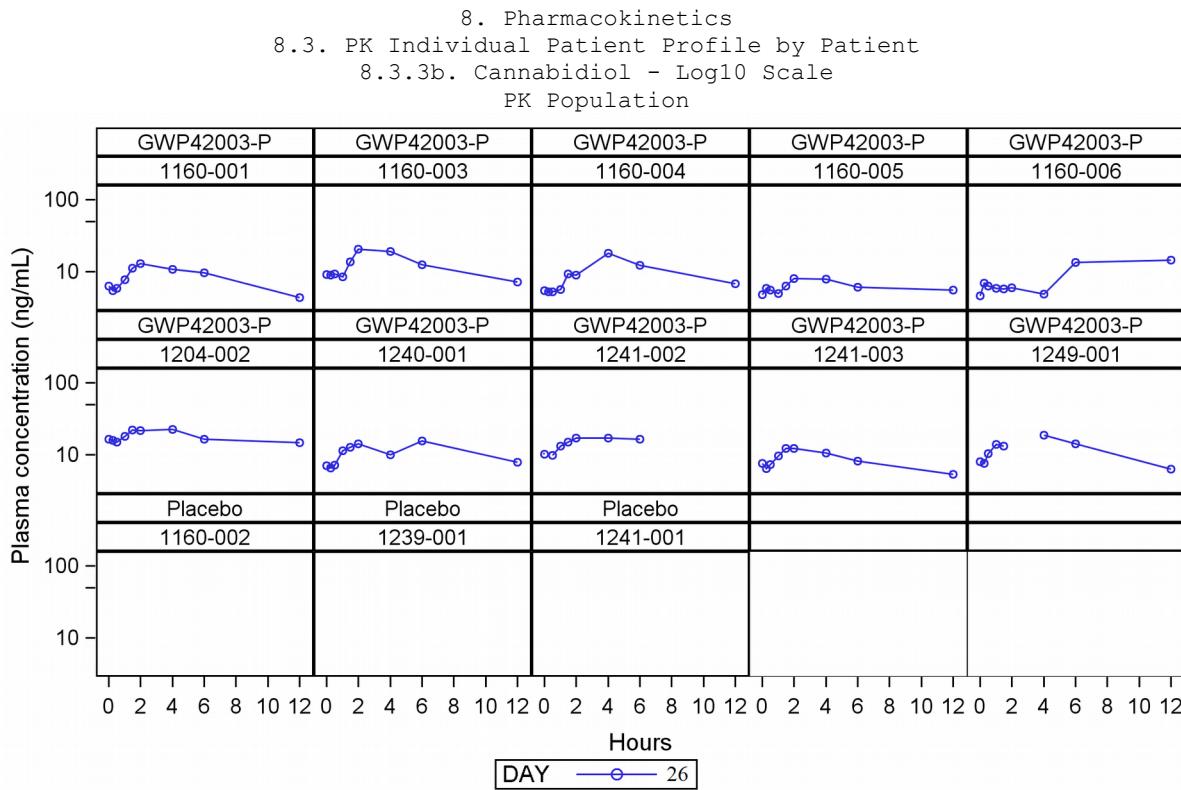
Source: Listing 8.1

Programmer's note: Only applicable for VPA arm.



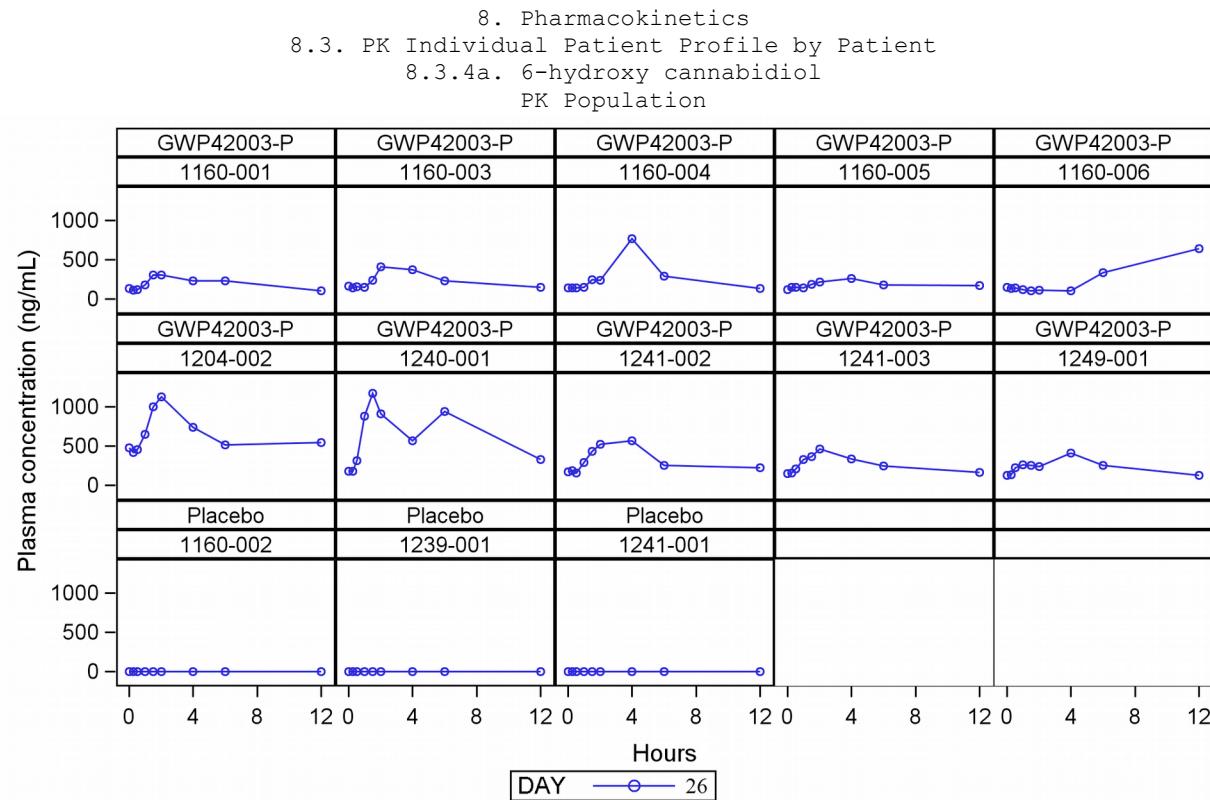
Source: Listing 8.1

Programmer's note: Only Day 26 will be plotted.



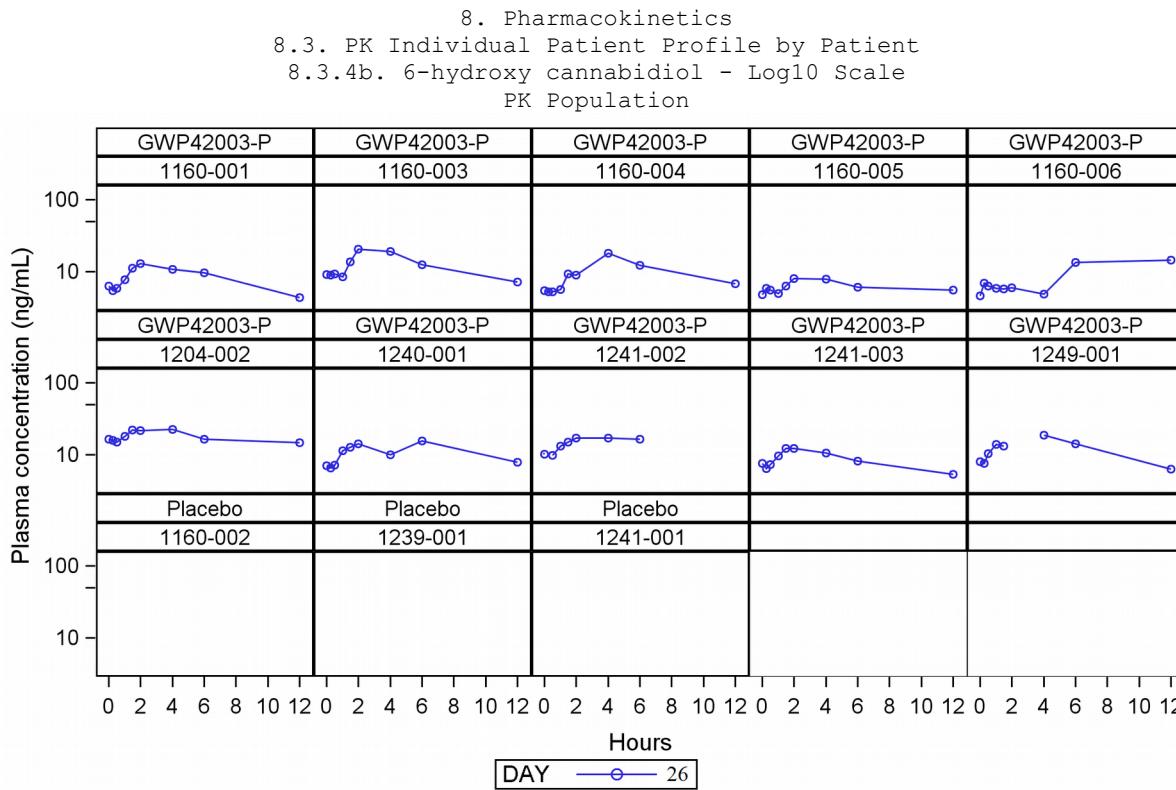
Source: Listing 8.1

Programmer's note: Only Day 26 will be plotted.



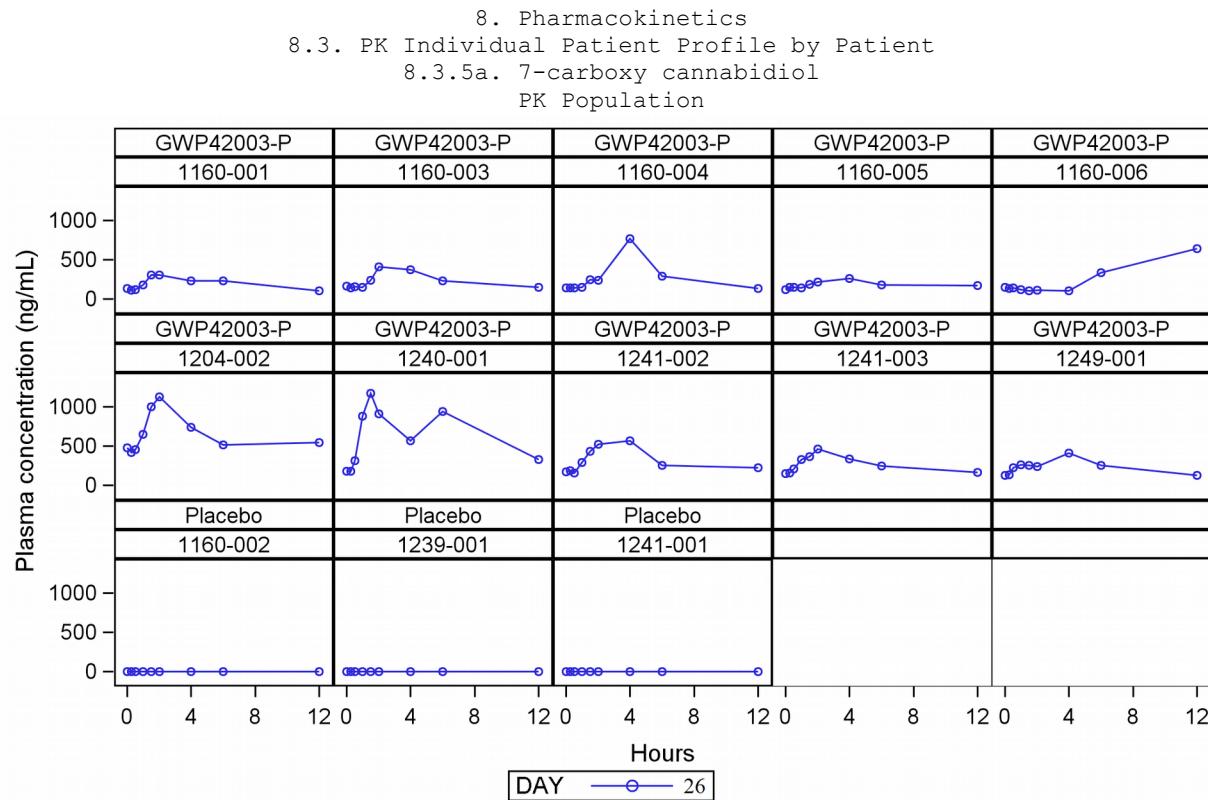
Source: Listing 8.1

Programmer's note: Only Day 26 will be plotted.



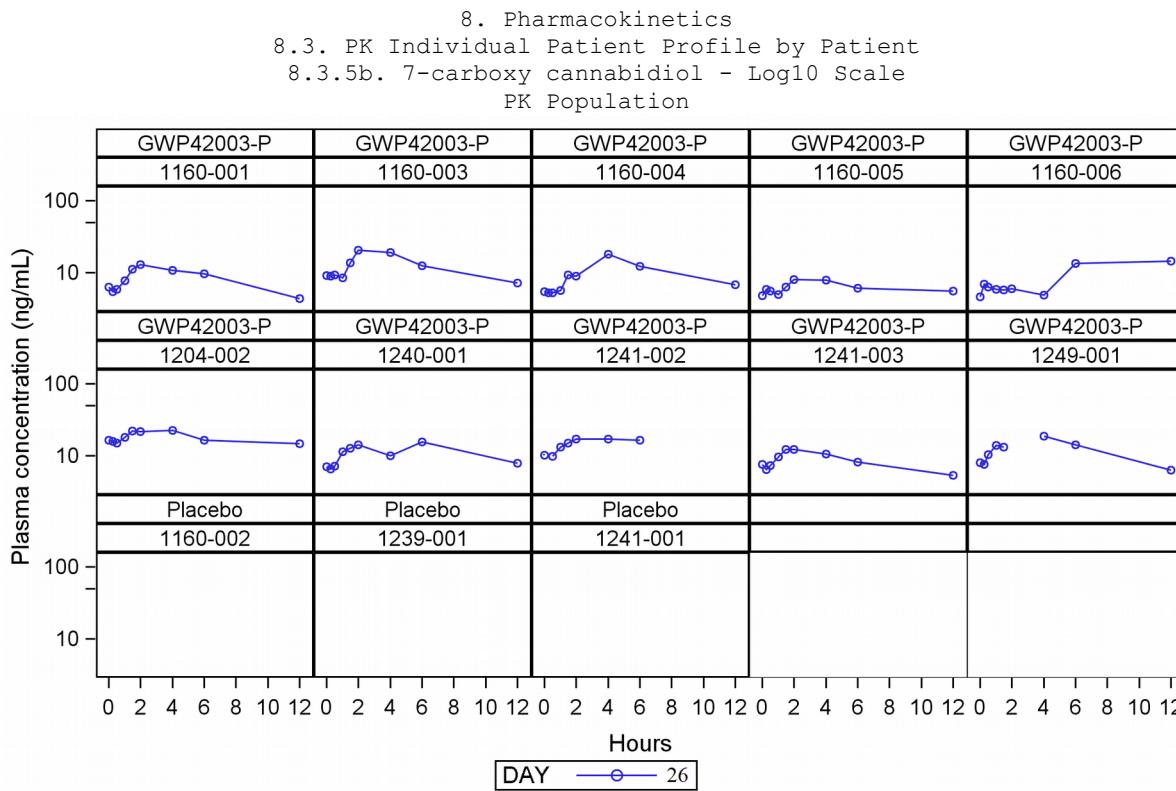
Source: Listing 8.1

Programmer's note: Only Day 26 will be plotted.



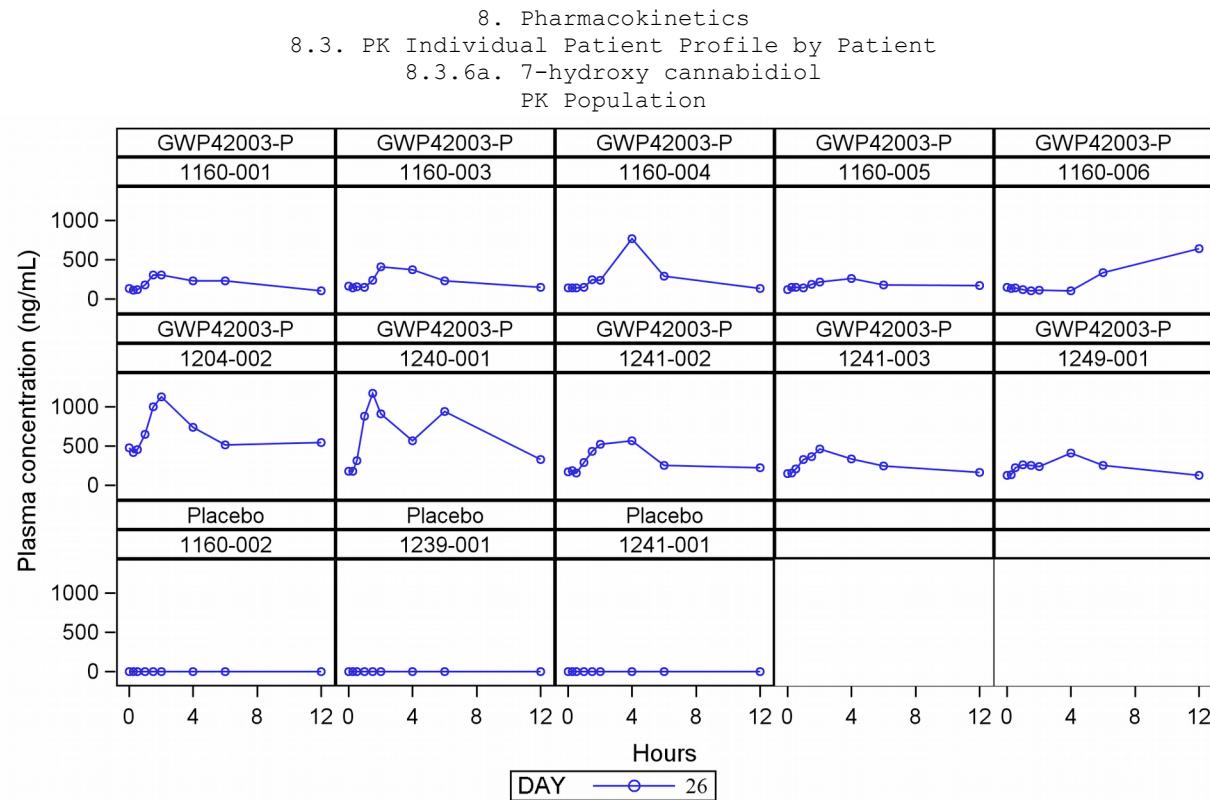
Source: Listing 8.1

Programmer's note: Only Day 26 will be plotted.



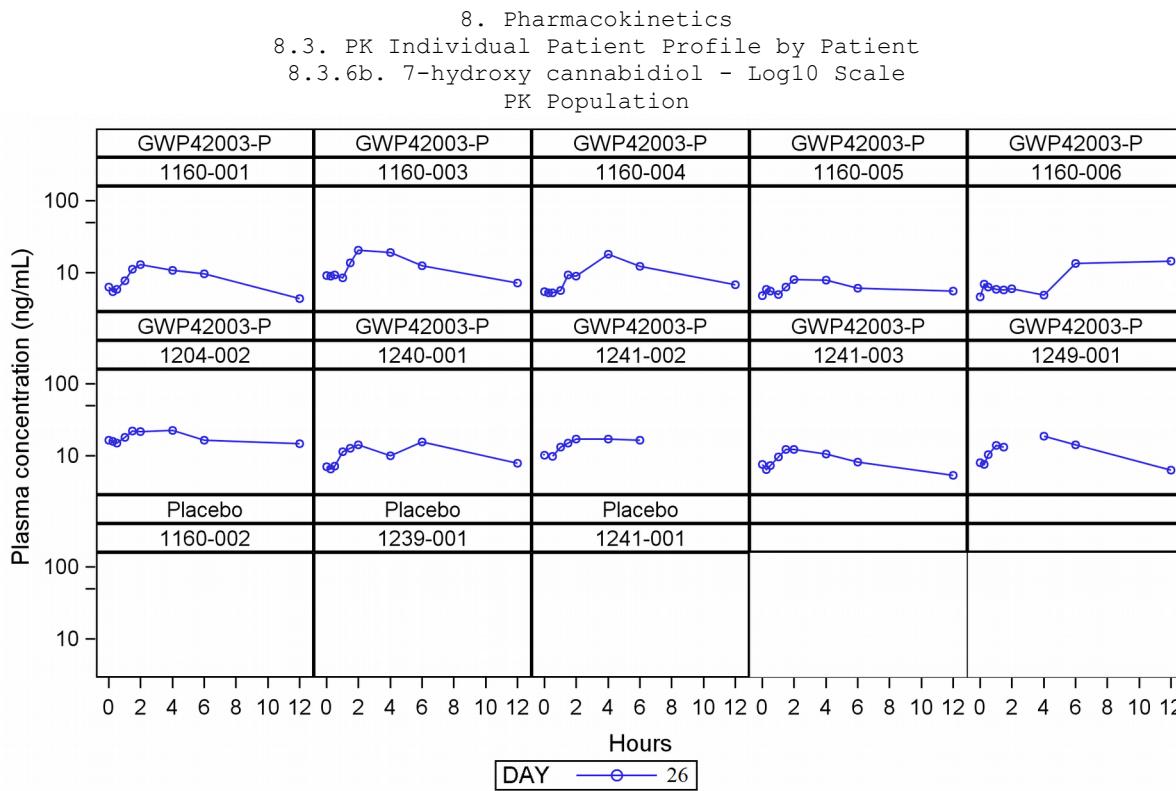
Source: Listing 8.1

Programmer's note: Only Day 26 will be plotted.



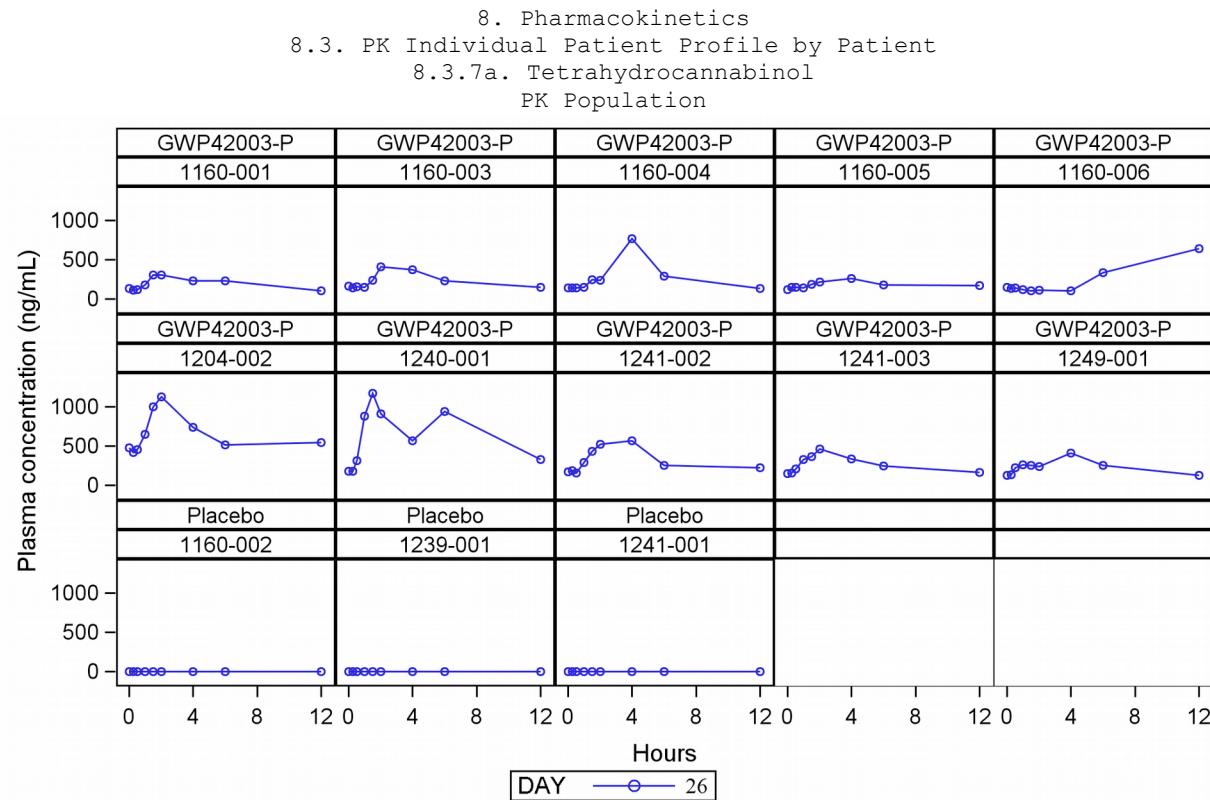
Source: Listing 8.1

Programmer's note: Only Day 26 will be plotted.



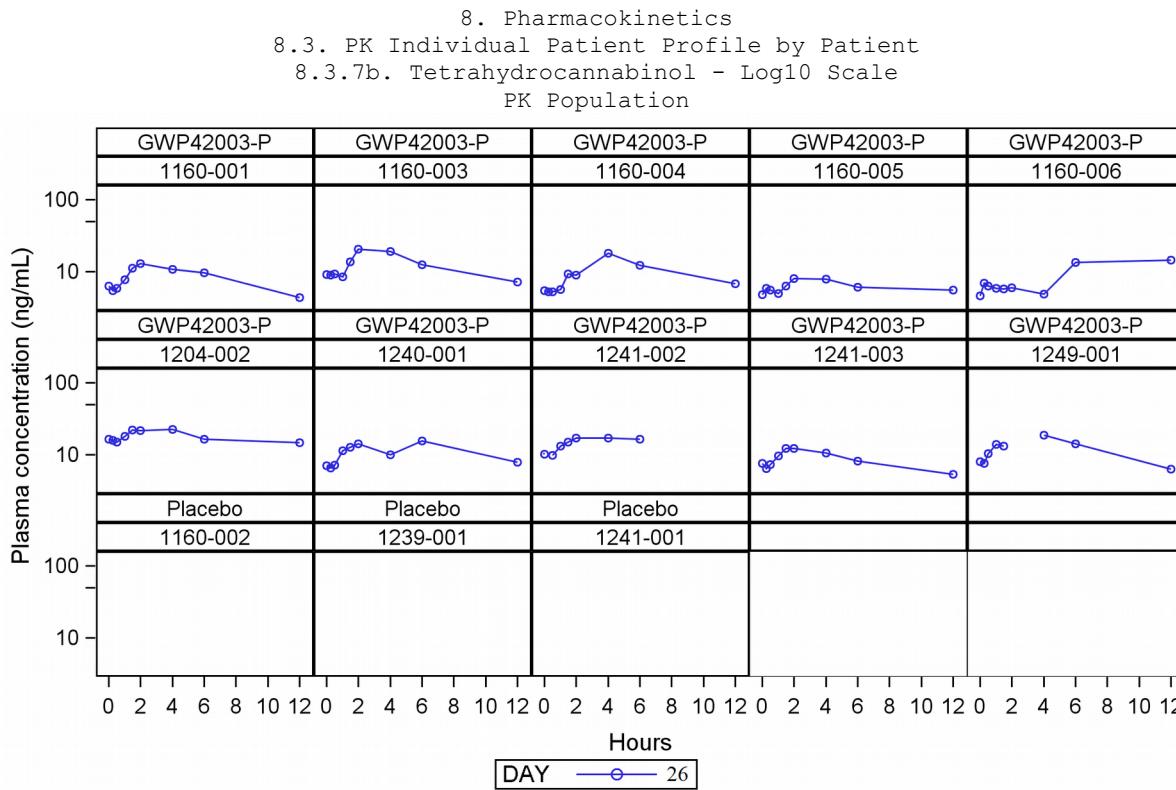
Source: Listing 8.1

Programmer's note: Only Day 26 will be plotted.



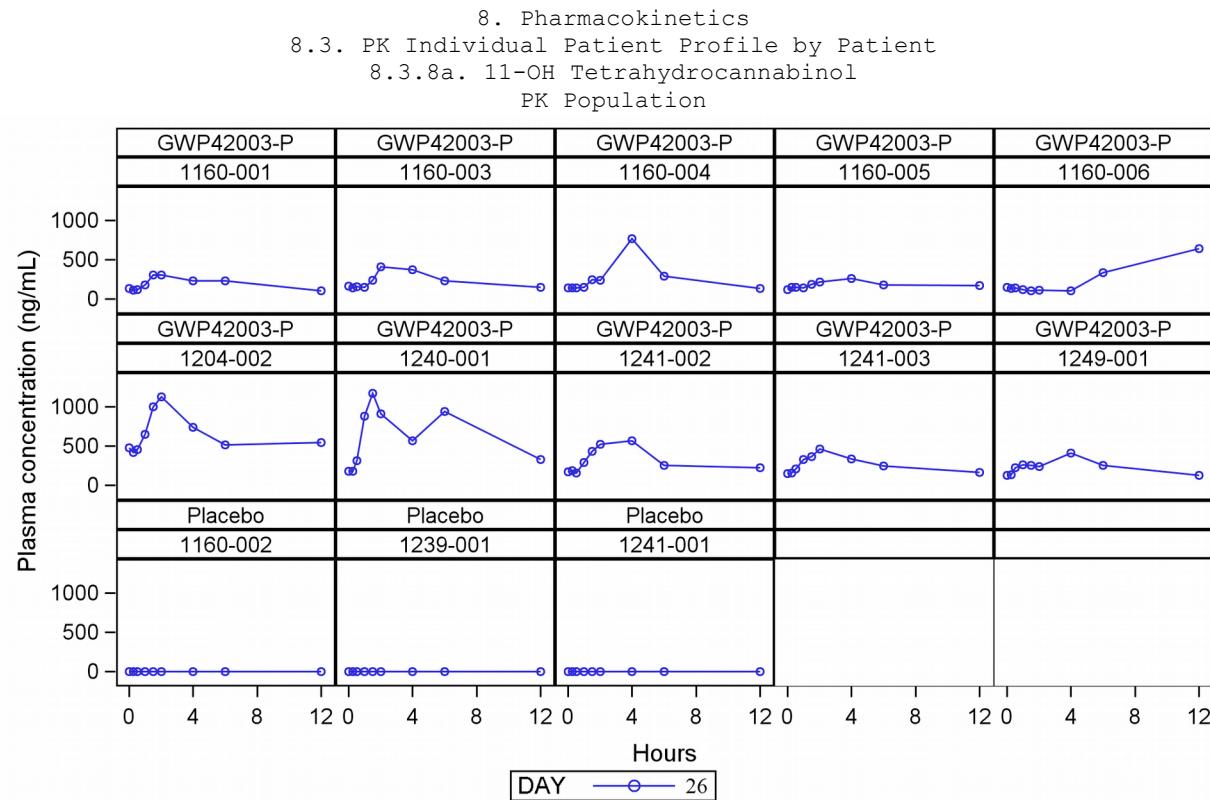
Source: Listing 8.1

Programmer's note: Only Day 26 will be plotted.



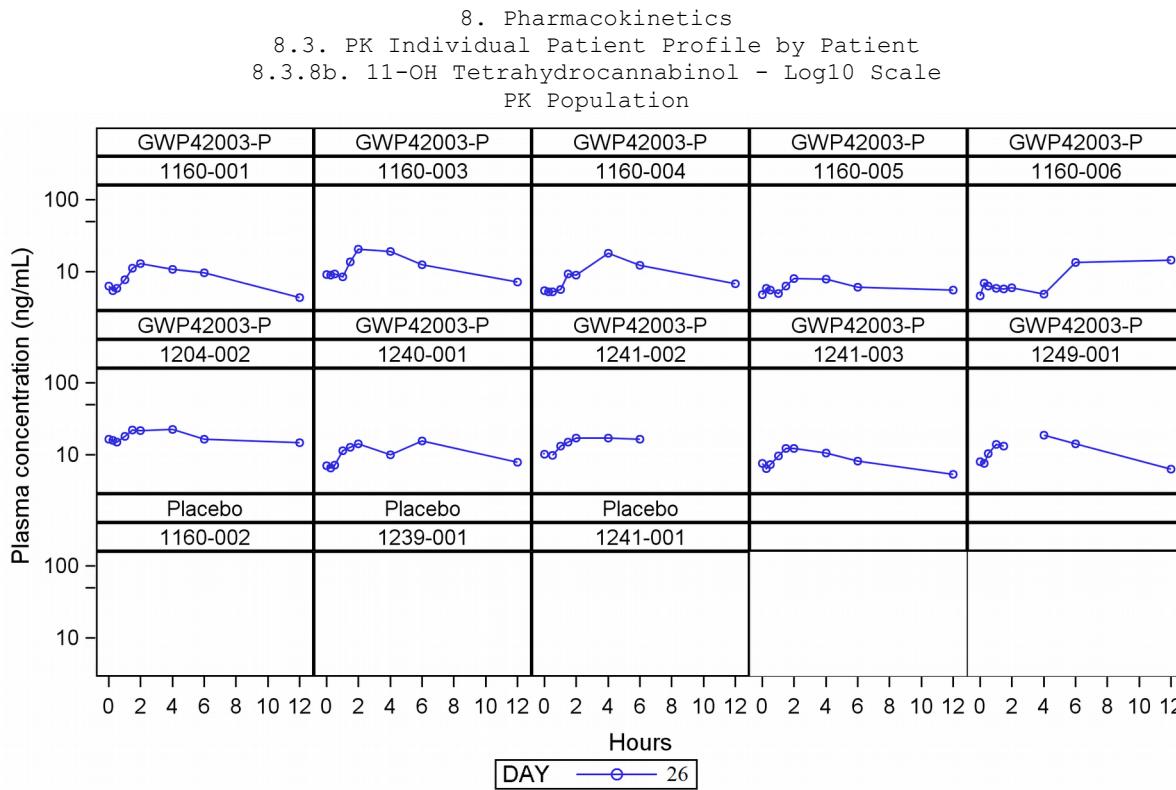
Source: Listing 8.1

Programmer's note: Only Day 26 will be plotted.



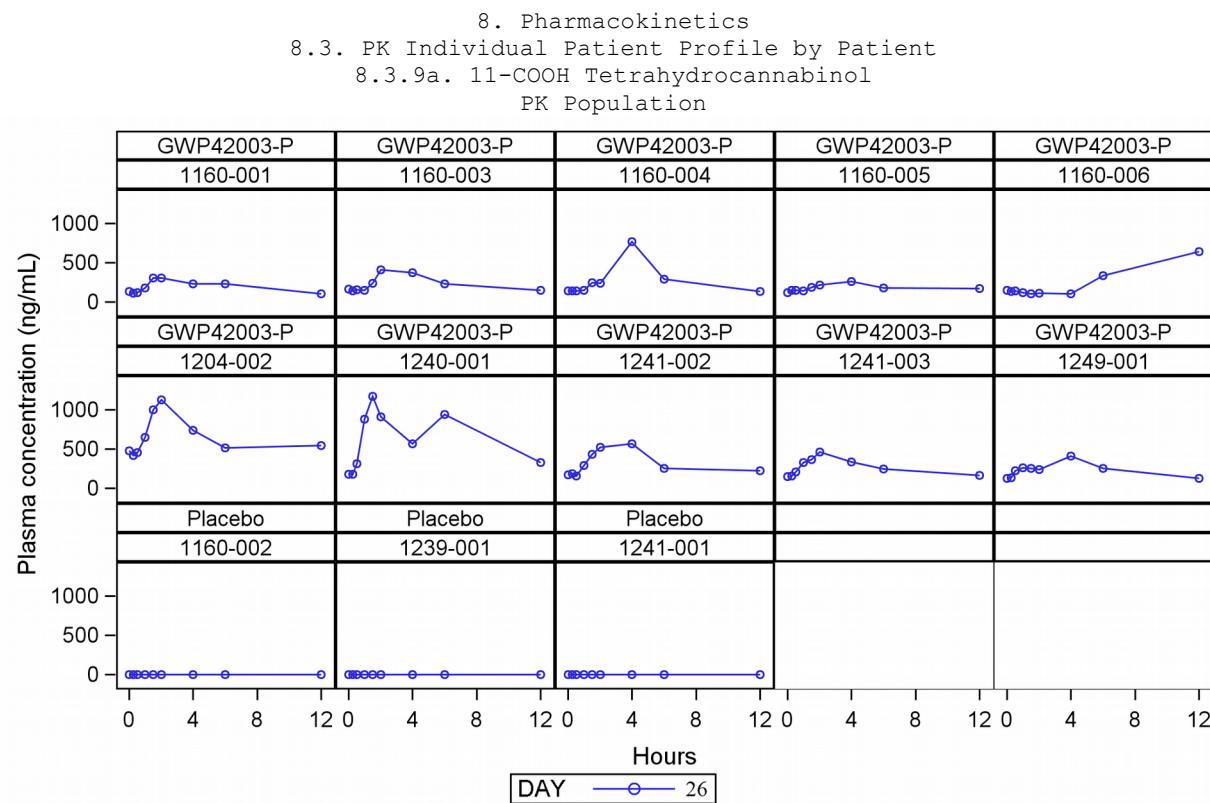
Source: Listing 8.1

Programmer's note: Only Day 26 will be plotted.



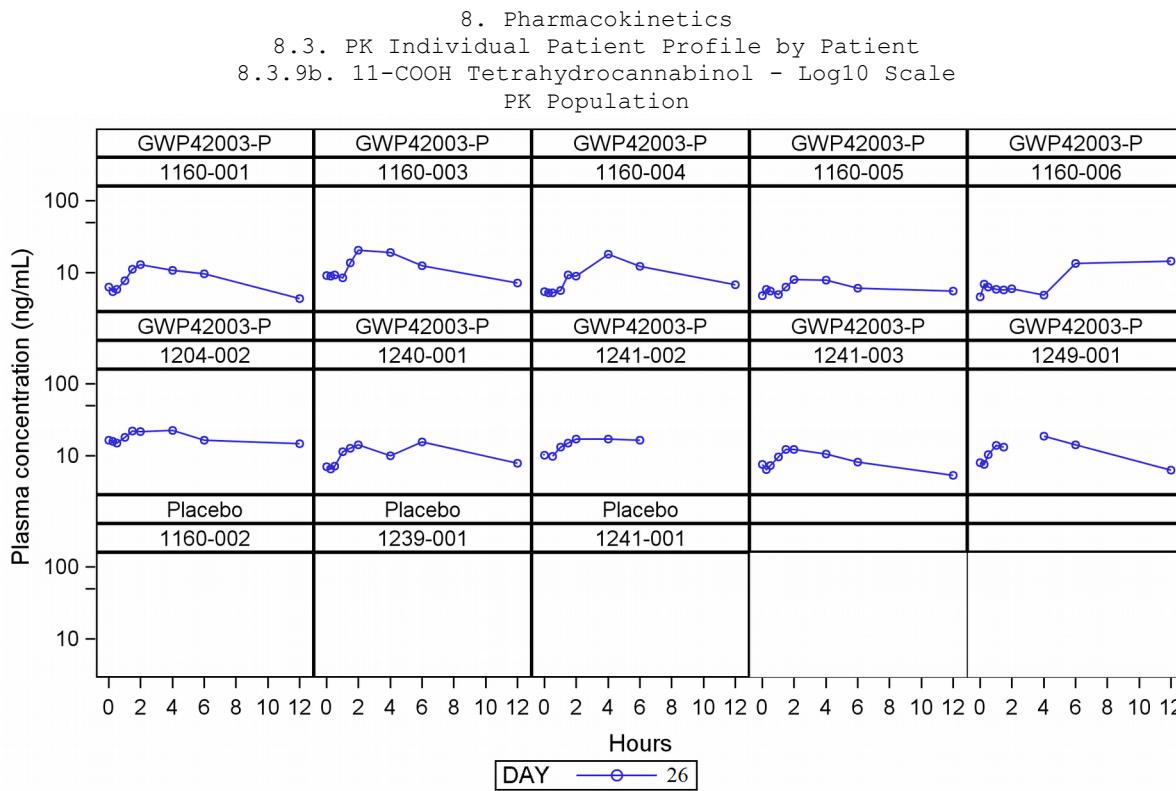
Source: Listing 8.1

Programmer's note: Only Day 26 will be plotted.



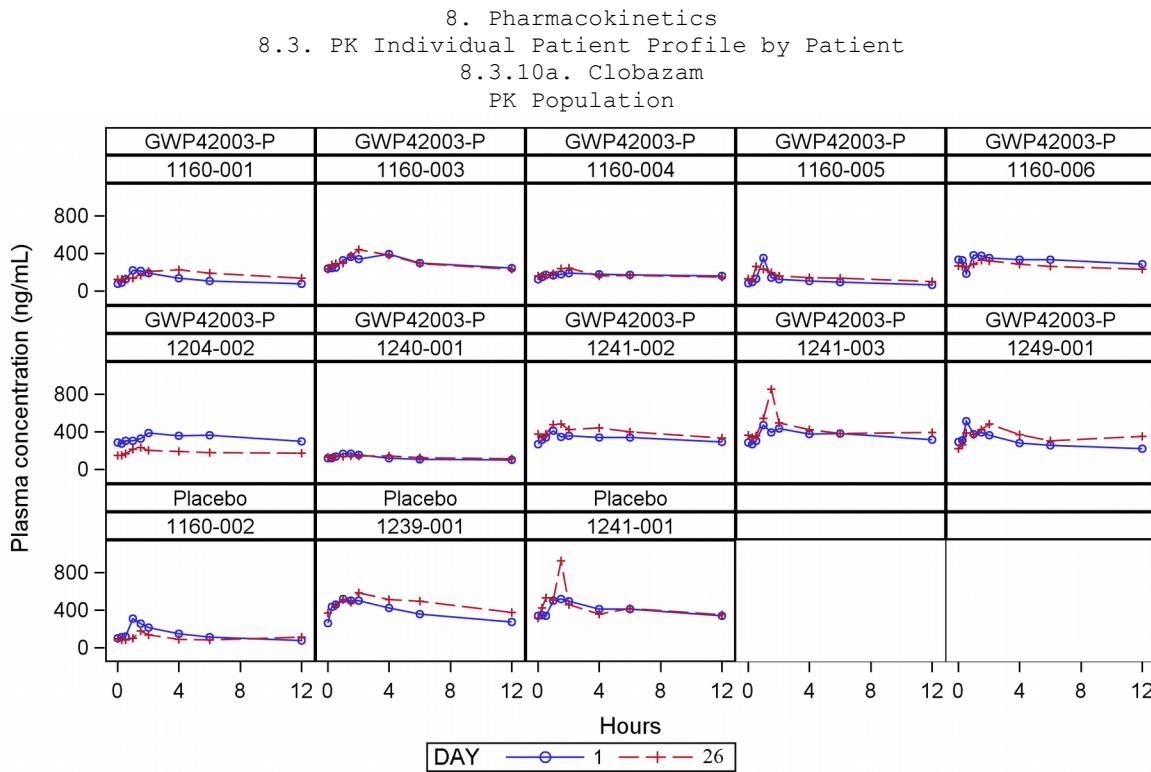
Source: Listing 8.1

Programmer's note: Only Day 26 will be plotted.



Source: Listing 8.1

Programmer's note: Only Day 26 will be plotted.



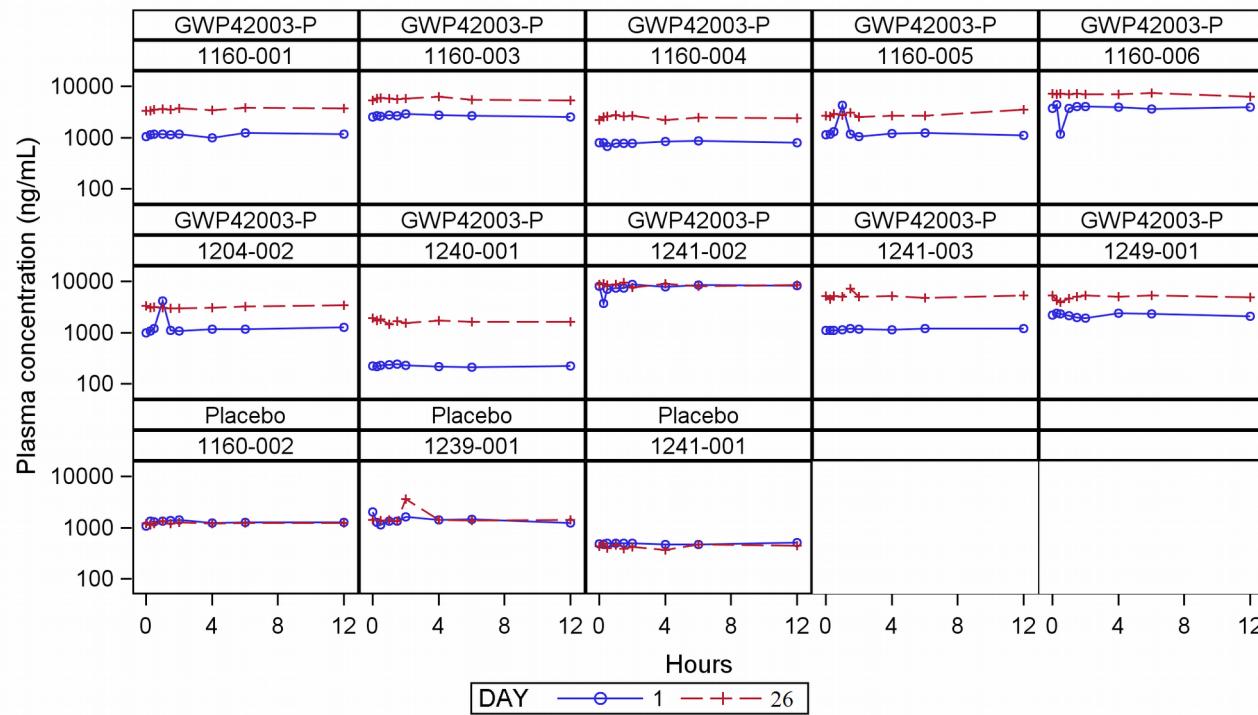
Source: Listing 8.1

8. Pharmacokinetics

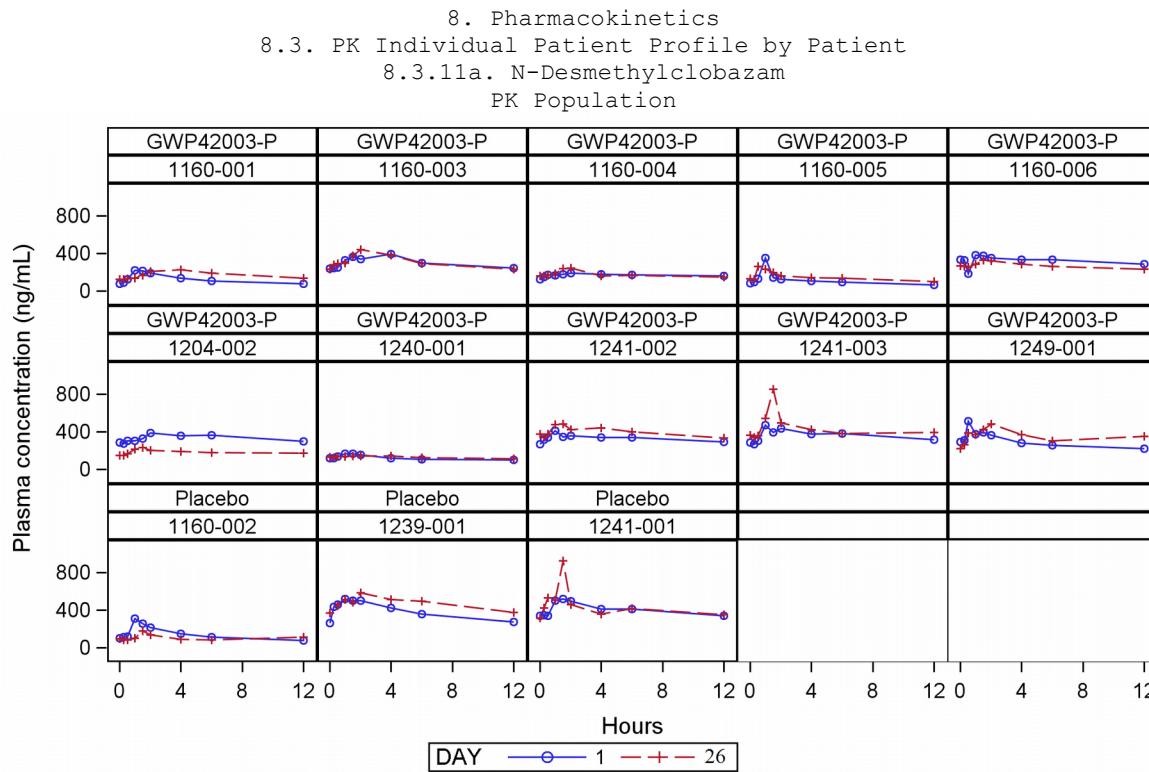
8.3. PK Individual Patient Profile by Patient

8.3.10b. Clobazam - Log10 Scale

PK Population



Source: Listing 8.1

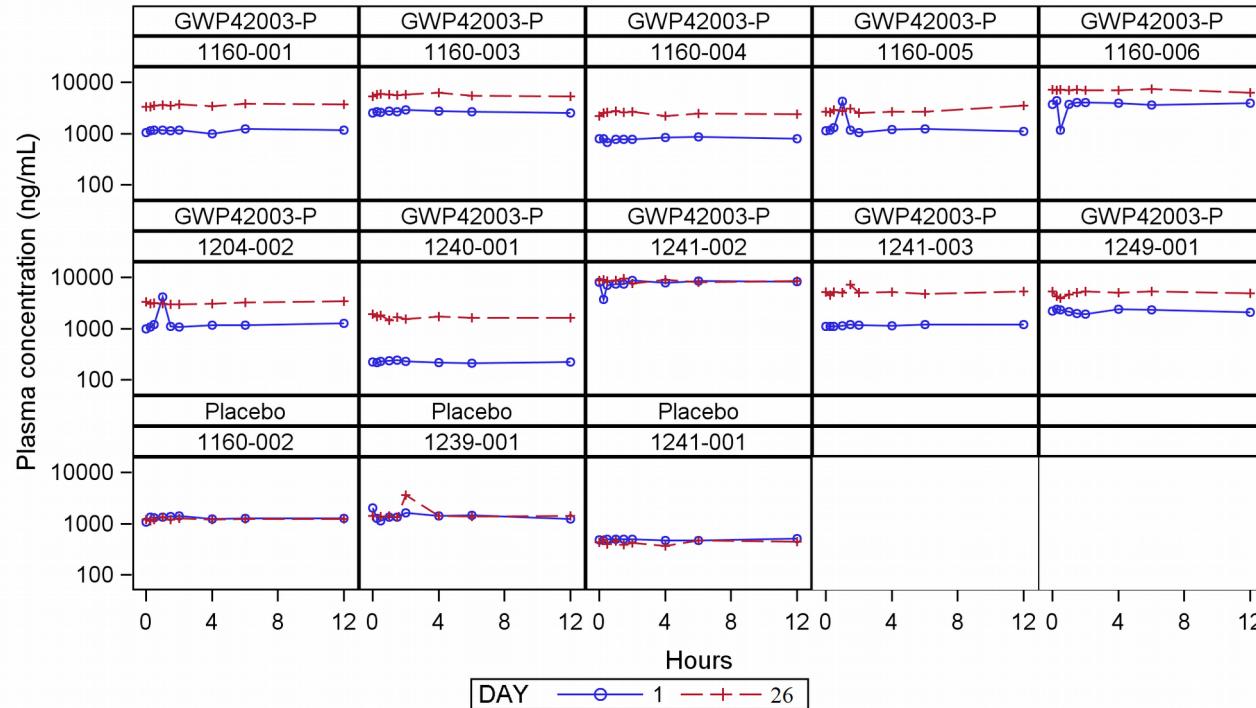


Source: Listing 8.1

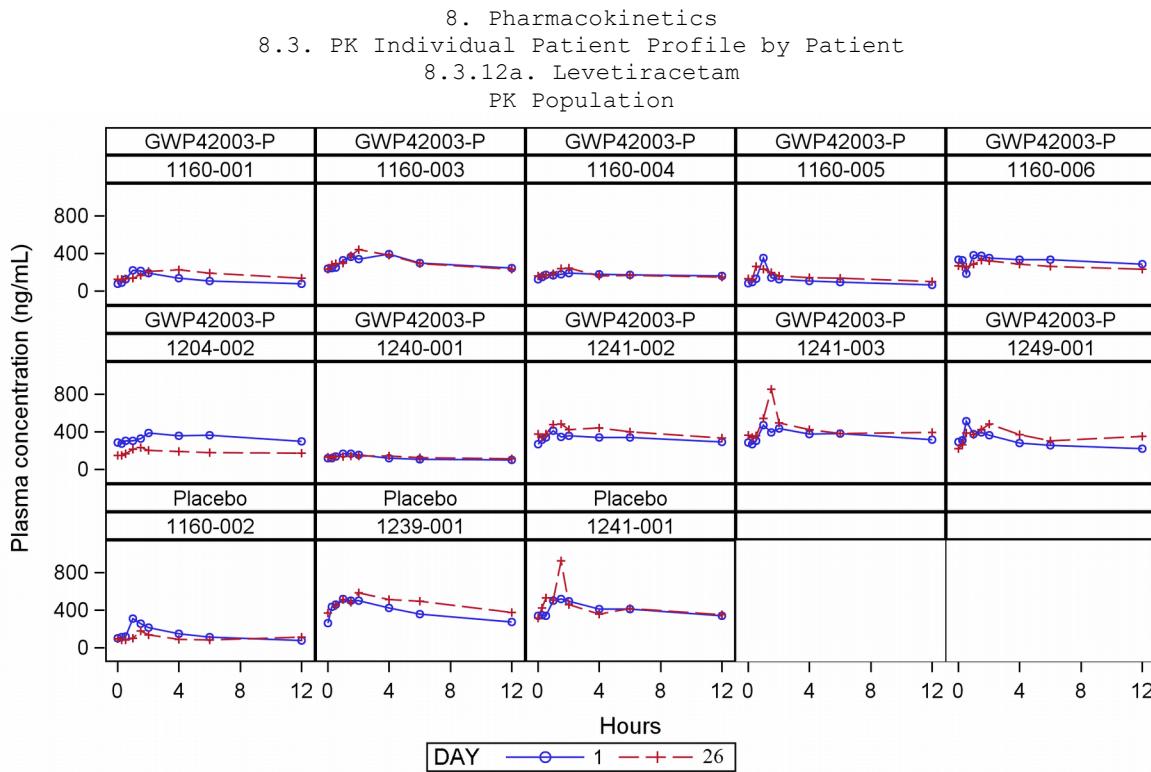
8. Pharmacokinetics

8.3. PK Individual Patient Profile by Patient

8.3.11b. N-Desmethylclobazam - Log10 Scale
PK Population



Source: Listing 8.1



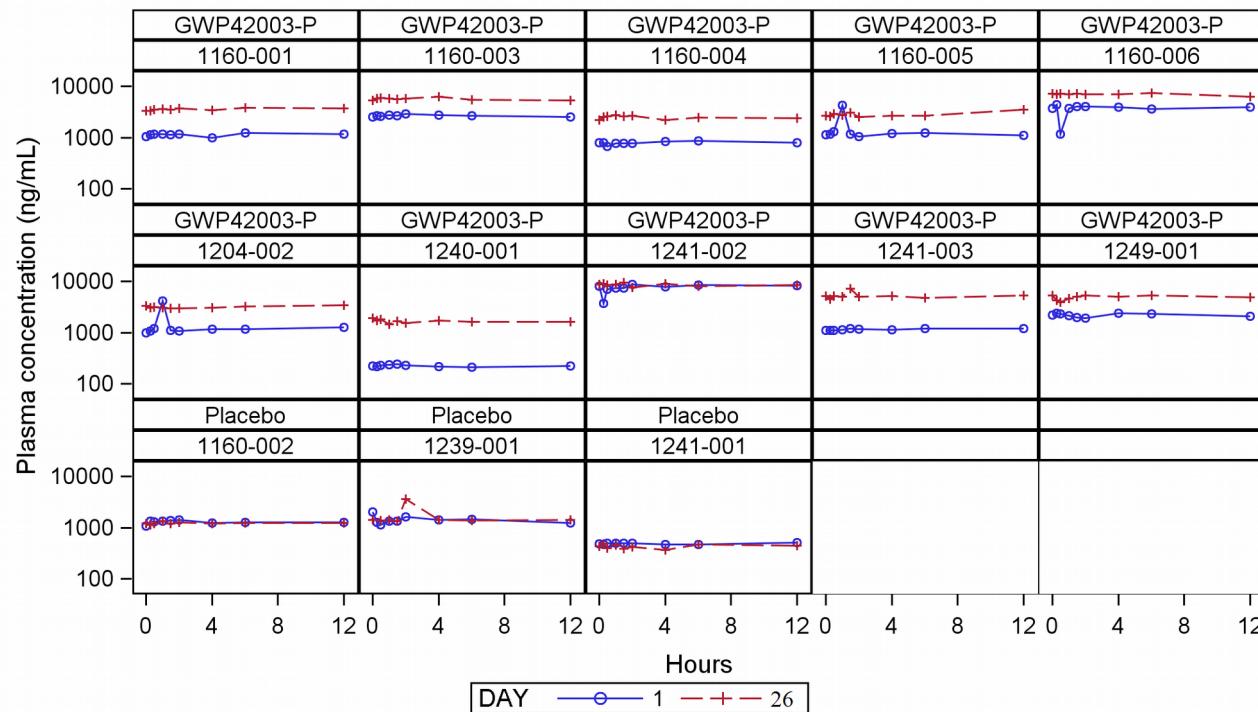
Source: Listing 8.1

8. Pharmacokinetics

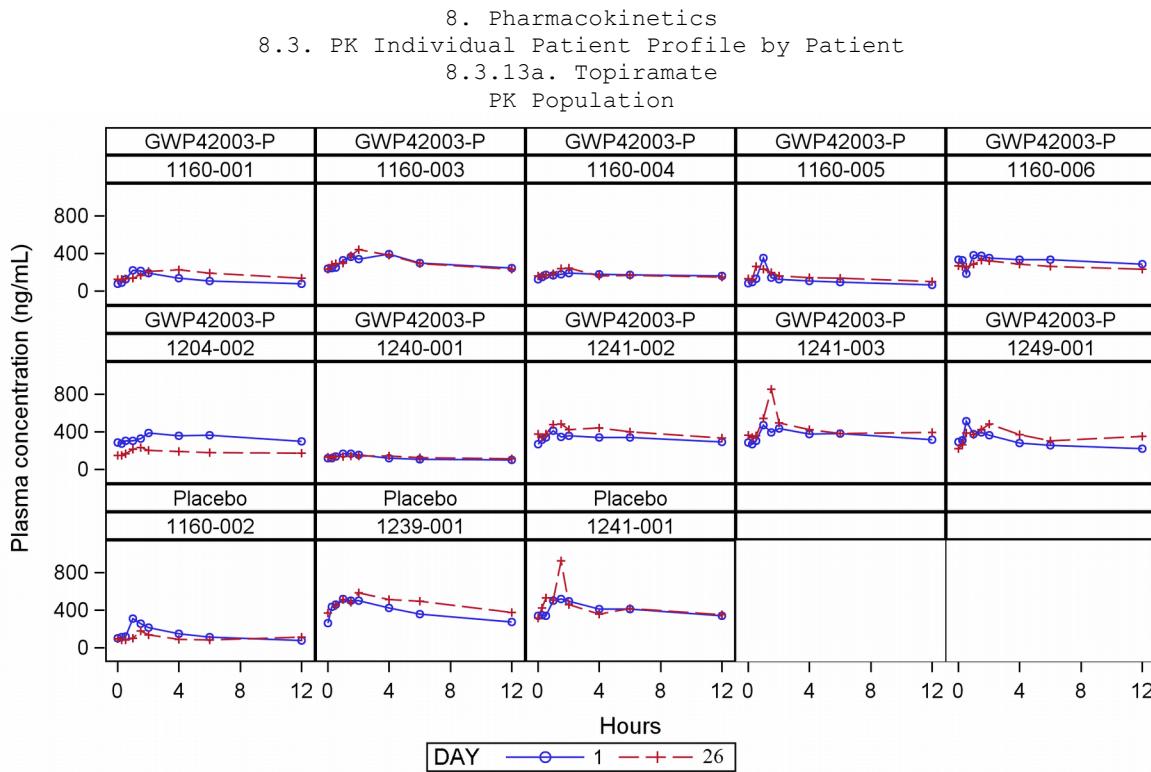
8.3. PK Individual Patient Profile by Patient

8.3.12b. Levetiracetam - Log10 Scale

PK Population



Source: Listing 8.1



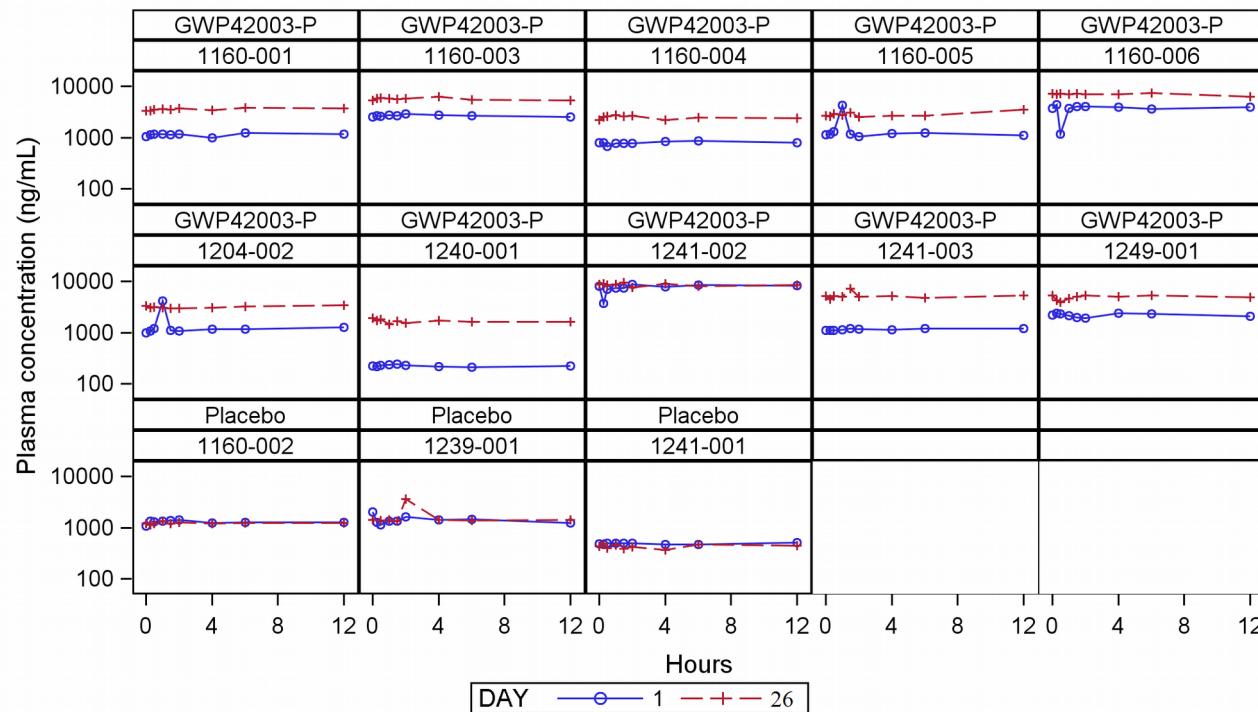
Source: Listing 8.1

8. Pharmacokinetics

8.3. PK Individual Patient Profile by Patient

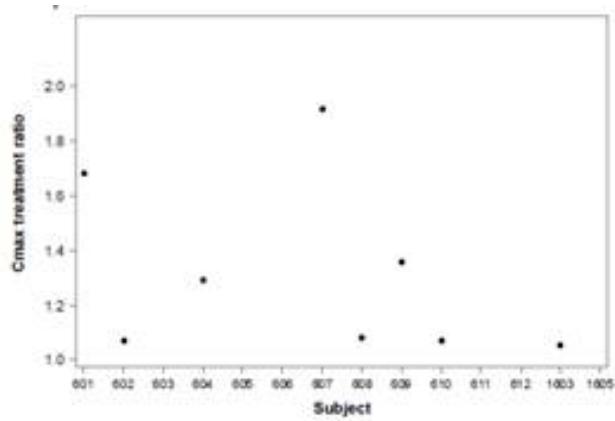
8.3.13b. Topiramate - Log10 Scale

PK Population



Source: Listing 8.1

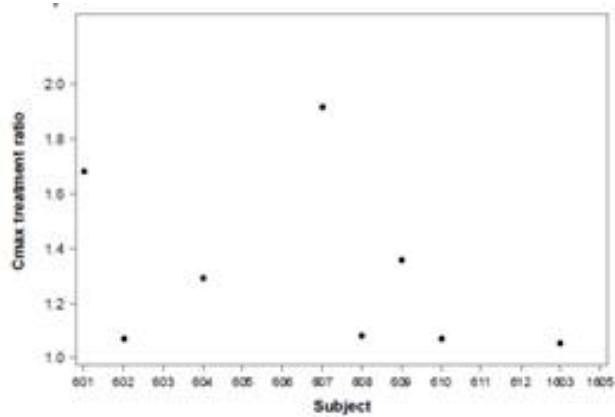
8. Pharmacokinetics
8.4. PK Parameters Individual Ratios
8.4.1a. Stiripentol - Cmax
PK Population



Source: Listing 8.2

Programmer's note: This title is applicable for STP arm. For VPA arm that will be "8.4.1a. Valproic Acid - Cmax". Ratio refers to actual value at Day 26 divided by actual value at Day 1.

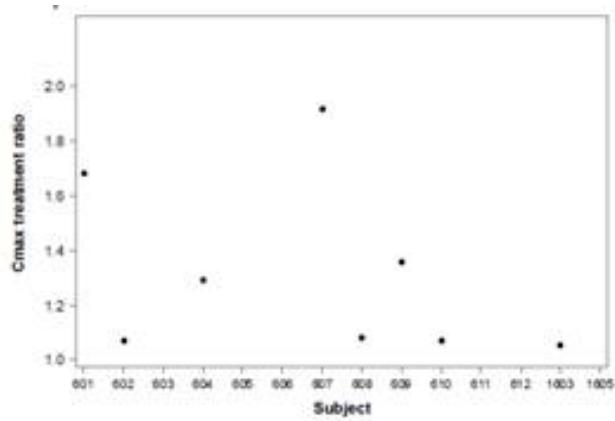
8. Pharmacokinetics
8.4. PK Parameters Individual Ratios
8.4.1b. Stiripentol - AU_{Ctau}
PK Population



Source: Listing 8.2

Programmer's note: This title is applicable for STP arm. For VPA arm that will be "8.4.1b. Valproic Acid - AU_{Ctau}". Ratio refers to actual value at Day 26 divided by actual value at Day 1.

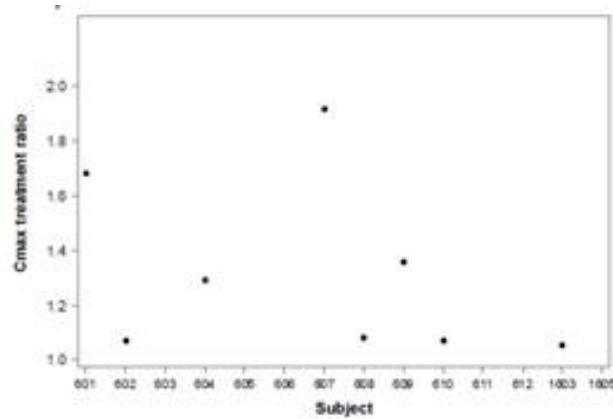
8. Pharmacokinetics
8.4. PK Parameters Individual Ratios
8.4.2a. 2-ene-VPA - Cmax
PK Population



Source: Listing 8.2

Programmer's note: Only applicable for VPA arm.
Ratio refers to actual value at Day 26 divided by actual value at Day 1.

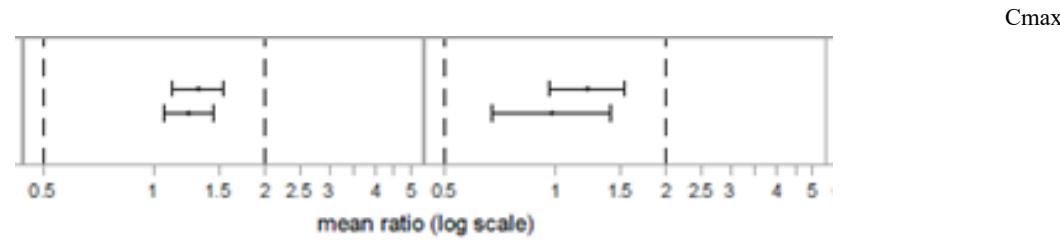
8. Pharmacokinetics
8.4. PK Parameters Individual Ratios
8.4.2b. 2-ene-VPA - AU τ
PK Population



Source: Listing 8.2

Programmer's note: Only applicable for VPA arm.
Ratio refers to actual value at Day 26 divided by actual value at Day 1.

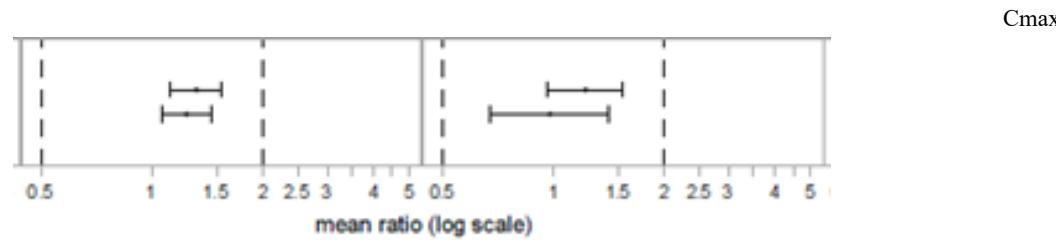
8. Pharmacokinetics
8.5. PK Parameters Mean Ratios
8.5.1a. Stiripentol
PK Population



Source: Table 8.3.1

Programmer's note: This title is applicable for STP arm. For VPA arm that will be "8.5.1a. Valproic Acid". Ratio and 90%CI refer to Day 26 to Day 1 ratio from tables 8.3 Drug Drug Interaction.

8. Pharmacokinetics
8.5. PK Parameters Mean Ratios
8.5.1b. Stiripentol - Dose Normalized
PK Population

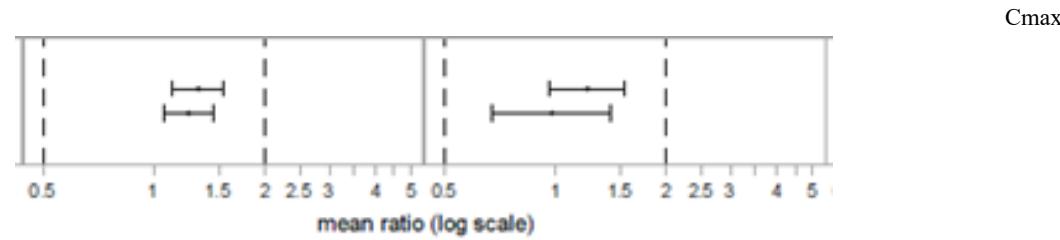


Source: Table 8.3.2

Programmer's note: This title is applicable for STP arm. For VPA arm that will be "8.5.1a. Valproic Acid - Dose Normalized".

Ratio and 90%CI refer to Day 26 to Day 1 ratio from tables 8.3 Drug Drug Interaction.

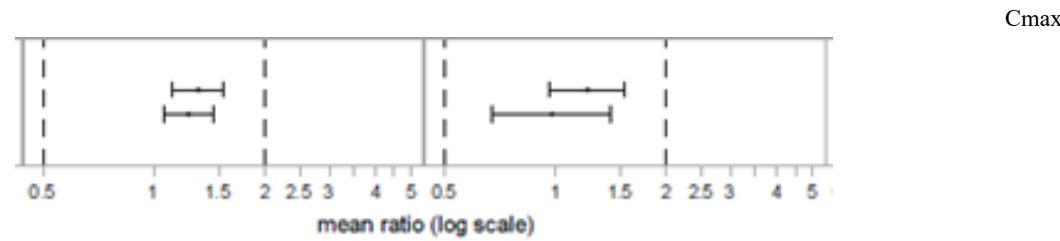
8. Pharmacokinetics
8.5. PK Parameters Mean Ratios
8.5.2a. 2-ene-VPA
PK Population



Source: Table 8.3.3

Programmer's note: Only applicable for VPA arm.
Ratio and 90%CI refer to Day 26 to Day 1 ratio from tables 8.3 Drug Drug Interaction.

8. Pharmacokinetics
8.5. PK Parameters Mean Ratios
8.5.2b. 2-ene-VPA - Dose Normalized
PK Population



Source: Table 8.3.4

Programmer's note: Only applicable for VPA arm.
Ratio and 90%CI refer to Day 26 to Day 1 ratio from tables 8.3 Drug Drug Interaction.

Appendix 2

Section A2.1 Demographic Data and Subject Characteristics

1. Subject Disposition, Visit Attendance, Protocol Violations

1.1. Patient Disposition

Screened Population

Actual Treatment for DB Phase	Country/ Site	Unique Subject Identifier	Screened	Failure: Reason	Date of Randomized	Date of First Exposure	End of Treatment Status	Reason for Discontinuation Specify
Not randomized	xxxx /	GWEP1428-W-xxxx-xxx	Y	Y: xxx	N			
GWP42003-P	xxxx / 1160	GWEP1428-W-1160-xxx	Y	N	Y	yyyyymmdd	yyyyymmdd	Completed
		GWEP1428-W-1160-xxx	Y	N	Y	yyyyymmdd	yyyyymmdd	Discontinued Other xxxx
				...				
Placebo	xxxx / xxxx	GWEP1428-W-xxxx-xxx	Y	N	Y	yyyyymmdd	yyyyymmdd	Completed
		GWEP1428-W-xxxx-xxx	Y	N	Y	yyyyymmdd	yyyyymmdd	Completed
				...				

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1. Subject Disposition, Visit Attendance, Protocol Violations
1.2. Inclusion/Exclusion Criteria not Met
Screened Population

Actual Treatment for DB Phase	Unique Subject Identifier	Visit Name	Criteria	Evaluation
GWP42003-P	GWEP1428-W-xxxx-xxx	PERIOD V1 (D- 14)	EXC19	Unknown
GWP42003-P	GWEP1428-W-xxxx-xxx	PERIOD V1 (D- 14)	INC6	No
...				

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1. Subject Disposition, Visit Attendance, Protocol Violations

1.3. Visit Dates, Including IC Dates

Screened Population

Actual Treatment for DB Phase	Unique Subject Identifier	Informed Consent	Genetic Testing							
			Informed Consent	V1 (Day -14 to -7)	V2 (Day 1)	V2 (Day 2)	V3 (Day 12)	V4 (Day 33)	V4 (Day 34)	
Not randomized	GWEP1428-W-xxxx-xxx	yyyyymmdd	---	yyyyymmdd						
GWP42003-P	GWEP1428-W-xxxx-xxx	yyyyymmdd	yyyyymmdd	yyyyymmdd	yyyyymmdd	yyyyymmdd	yyyyymmdd	yyyyymmdd	yyyyymmdd	yyyyymmdd
	GWEP1428-W-xxxx-xxx	yyyyymmdd	yyyyymmdd	yyyyymmdd	yyyyymmdd	yyyyymmdd	yyyyymmdd	yyyyymmdd	yyyyymmdd	yyyyymmdd
	...									
Placebo	GWEP1428-W-xxxx-xxx	yyyyymmdd	yyyyymmdd	yyyyymmdd	yyyyymmdd	yyyyymmdd	yyyyymmdd	yyyyymmdd	yyyyymmdd	yyyyymmdd
	GWEP1428-W-xxxx-xxx	yyyyymmdd	yyyyymmdd	yyyyymmdd	yyyyymmdd	yyyyymmdd	yyyyymmdd	yyyyymmdd	yyyyymmdd	yyyyymmdd
	...									

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1. Subject Disposition, Visit Attendance, Protocol Violations
1.4. Protocol Deviations
Safety Population

Actual Treatment for DB Phase	Unique Subject Identifier*	Domain	Visit	Type of Deviation**Description	Importance
GW42003-P	GWEP1428-W-xxxx-xxx*	DB Period	Visit 1	4 xxxxx	Not Important
		DB Period	Visit 2	6 xxxxx	Not Important
		DB Period	Visit 4	5/6 xxxxx	Important
...					

* Excluded from PK population.

** 2: Inclusion/Exclusion criteria; 3: Visit date; 4: Patient assessments; 5: Study drug; 6: Labs.

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2. Analysis Sets
Screened Population

Actual		Treatment for Unique Subject Identifier		Screen		Safety	PK
DB Phase		Screened	Failure	Screen Failure Reason	Population	Population PK	Exclusion Reason
Not randomized	GWEP1428-W-xxxx-xxx	Y	Y	xxxxxx	N	N	
GWP42003-P	GWEP1428-W-xxxx-xxx	Y	N		Y	Y	
	GWEP1428-W-xxxx-xxx	Y	N		Y	N	xxxxxx
	...						
Placebo	GWEP1428-W-xxxx-xxx	Y	N		Y	Y	
	GWEP1428-W-xxxx-xxx	Y	N		Y	N	xxxxxx
	...						

PK: Pharmacokinetic.

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3. Demographics
Safety Population

Actual Treatment for DB Phase	Unique Subject Identifier	Date of Birth	Age (years)	Sex	Race	Height (cm)	Weight (kg)	BMI (kg/m2)
GWP42003-P	GWEP1428-W-xxxx-xxx	yyyymmdd	37.6	Male	White/Caucasian	188.0	79.8	22.6
	GWEP1428-W-xxxx-xxx	yyyymmdd	43.2	Female	Asian	179.0	79.0	24.7
	...							
Placebo	GWEP1428-W-xxxx-xxx	yyyymmdd	46.5	Female	White/Caucasian	161.0	69.0	26.6
	GWEP1428-W-xxxx-xxx	yyyymmdd	45.6	Male	White/Caucasian	180.0	110.0	34.0
	...							

BMI: Body Mass Index.

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4. Baseline Disease Characteristics
4.1. History of Seizures no Longer Occurring
Safety Population

Actual Treatment for DB Phase	Unique Subject Identifier	Seizure Type	Patients Age when This Seizure Type Last Occurred
GWP42003-P	GWEP1428-W-xxxx-xxx	C	39 years 00 months
	GWEP1428-W-xxxx-xxx	C	18 years 00 months
	...		
Placebo	GWEP1428-W-xxxx-xxx	C	25 years 06 months
	GWEP1428-W-xxxx-xxx	D	36 years 00 months
	...		

A: Hemiclonic ; B: Complex Partial Seizure (Focal Dyscognitive); C: Secondarily Generalized Tonic Clonic (Evolving to bilateral convulsive Seizure from partial (focal) Seizure); D: Generalized Tonic Clonic Convulsion; E: Absence (any type); F: Myoclonic; G: Tonic; H: Atonic; I: Clonic; J: Tonic/Atonic (cannot differentiate); K: Non Convulsive Status (greater than 30 min); L: Convulsive Status (greater than 30 min); M: Epileptic spasms; N: Other.

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4. Baseline Disease Characteristics

4.2. History of Current Seizures

Safety Population

Actual Treatment for DB Phase	Unique Subject Identifier	Seizure Type	Detailed Description of Seizure	Age at Onset of Seizure	Seizure Frequency	Seizure Duration	Triggers
GWP42003-P	GWEP1428-W-xxxx-xxx	B	Complex Partial Seizures With Disconnection, oral Automatism	09 y 00 m	5 per month	2-10 mins	Seizure With No Triggers
		C	Secondarily Generalized Seizures With Disconnection. Axial Stiffness Tonic With Convulsive Seizure.	09 y 00 m	2 per month	2-10 mins	Seizure With No Triggers
	GWEP1428-W-xxxx-xxx	N	Simple Partial Seizure With Autonomic Systems Or Signs (Epigastric Sensation).)	39 y	4 per month	< 2 mins	None
Placebo	GWEP1428-W-xxxx-xxx						
...							
A: Hemiclonic ; B: Complex Partial Seizure (Focal Dyscognitive); C: Secondarily Generalized Tonic Clonic (Evolving to bilateral convulsive Seizure from partial (focal) Seizure); D: Generalized Tonic Clonic Convulsion; E: Absence or Atypical absence; F: Myoclonic; G: Tonic; H: Atonic; I: Clonic; J: Tonic/Atonic (cannot differentiate); K: Non Convulsive Status (greater than 30 min); L: Convulsive Status (greater than 30 min); M: Epileptic spasms; N: Other.							

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4. Baseline Disease Characteristics
 4.3. Electroencephalography History
 Safety Population

Actual Treatment for DB Phase	Unique Subject Identifier	Has the Subject Ever Had an	Abnormal EEG	Abnormality 1*	Abnormality 2*	Abnormality 3*	Other, Specify	Seizure Type 1**	Seizure Type 2**	Specify** *	Generalized
GWP42003-P	GWEP1428-W-xxxx-xxx	Yes	1					1			
	GWEP1428-W-xxxx-xxx	No									
...		Yes	6					1			
Placebo	GWEP1428-W-xxxx-xxx	Yes	1					1			
		...									

* 1: Focal spikes; 2: Generalized spike wave discharges; 3: Hypsarrhythmia; 4: Electrographic Seizures; 5: Background slowing and/or disorganization; 6: Focal slowing; 7: Other.

** 1: Partial (focal) Seizures; 2: Generalized Seizures; 3: Other.

*** 1: Generalized spike & wave; 2: Generalized paroxysmal fast activity; 3: Generalized electrodecrement at onset.

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4. Baseline Disease Characteristics

4.4. Neuroimaging History
Safety Population

Actual DB Phase	Treatment for Unique Subject Identifier	Has the Patient Had any Neuroimaging Tests Performed in the Past?			Method of Test	Other, Imaging	Abnormality Specify Result	Abnormality Type	Specify
		Number	Date of Test	Test					
GWP42003-P	GWEP1428-W-xxxx-xxx	Yes	1	20120222	MRI		Abnormal	Partial	Cortical Dysplasia
			2	20151009	MRI		Normal		
<hr/>									
	GWEP1428-W-xxxx-xxx	Yes	1	20120618	MRI		Abnormal	Partial	Mild Right Cerebral Hemiatrophy And Right Mesial Temporal Sclerosis
<hr/>									
Placebo	GWEP1428-W-xxxx-xxx	Yes	1	20150411	Other	Brain Pet Fdg	Normal		
<hr/>									

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4. Baseline Disease Characteristics

4.5. Genetic Testing History

Safety Population

Actual Treatment for DB Phase	Unique Subject Identifier	Has the Patient Had Genetic Testing Performed in the Past?	Test Name	Found?	? ?	If Tested Off-site, Has the Report from the Genetic Testing Was a GenomeWide SNP Epilepsy Gene Panel	Was a Whole Exome Sequencing Spec	Performed? Spec	Performed? Spec
GWP42003-P	GWEP1428-W-xxxx-xxx	No				NA			
	GWEP1428-W-xxxx-xxx	Yes	xxxxx	No	Unknown	Unknown NA	No	No	No
		...							
Placebo	GWEP1428-W-xxxx-xxx	No				NA			
		...							

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4. Baseline Disease Characteristics

4.6. Previous Use of Cannabis
Safety Population

Actual Treatment for DB Phase	Unique Subject Identifier	Has the Patient Previously Used Cannabis?	Date of Last Use	Time Since Last Use (Months)	If Yes, how Often Did the Patient Use Cannabis?
GWP42003-P	GWEP1428-W-xxxx-xxx	No			
	GWEP1428-W-xxxx-xxx	Yes	yyyymmdd	5	
	...				
Placebo	GWEP1428-W-xxxx-xxx	No			
	...				

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5. Non-Epilepsy Medical History
Safety Population

Actual Treatment for DB Phase	Unique Subject Identifier	Any Medical History?System Organ Class	Preferred Term	Condition	Start Date	Status at Stop DateScreening
GWP42003-P GWEP1428-W-xxxx-xxx No						
GWEP1428-W-xxxx-xxx Yes		Respiratory, Thoracic Asthma And Mediastinal Disorders		Chronic Asthmatic Bronchitis	1974	Ongoing
...						
Placebo GWEP1428-W-xxxx-xxx No						
GWEP1428-W-xxxx-xxx Yes		Psychiatric Disorders Depression		Mild Depression	20150807	Ongoing
...						
Page 1 of x						

6. Medications

6.1. History of Antiepileptic Medications and Therapies
 Safety Population

Actual Treatment for DB Phase	Unique Subject Identifier	ATC2 Term	Generic Name	Start Date	End Date	Reason Discontinuation*	Specify	Comments
GW42003-P	GWEP1428-W-xxxx-xxx	All Other Therapeutic Products	External Trigeminal Nerve Stimulation	yyyy-mm-dd	yyyy-mm-dd	1		
		Antiepileptics	Clobazam	yyyy-mm-dd	yyyy-mm-dd	5	Change Of Dose	
			xxxxxxxx	yyyy-mm-dd	yyyy-mm-dd	2		
			xxxxxxxx	yyyy-mm-dd	yyyy-mm-dd	2		
...								
Placebo	GWEP1428-W-xxxx-xxx	Antiepileptics	Carbamazepine	yyyy-mm-dd	yyyy-mm-dd	5	Adequate Control	

* 1: Inadequate control; 2: Adverse Events; 3: Epilepsy worsened; 4: Treatment no longer available; 5: Other; 6: Unknown.

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6. Medications
6.2. Concomitant AEDs and Dosing
Safety Population

Actual Treatment for DB Phase	Unique Subject Identifier	AED Name	Time of AM Dose	Time of PM Dose
GWP42003-P	GWEP1428-W-xxxx-xxx	CLOBAZAM	hhmm hhmm	hhmm
		LEVETIRACETAM	hhmm	hhmm
	...			
Placebo	GWEP1428-W-xxxx-xxx	CLOBAZAM	hhmm hhmm hhmm hhmm	hhmm
...				
x			Page 1 of	

6. Medications
 6.3. Other Prior and Concomitant Medications
 Safety Population

Actual Treatment for DB Phase	Unique Subject Identifier	CM Period*Category	ATC2 Term	Preferred Term	Start/End Date	Dose/Route	Reason Discontinuation	Specify	Indication
GWP42003-P	GWEP1428-W-xxxx-xxx	1	HAEM	All Other Therapeutic Products	Other Therapeutic Products	yyyymmdd/ yyyymmdd	xx MG/PO	Inadequate control	
			Antiepileptics	Clobazam	yyyymmdd/ yyyymmdd	/	Other		
		2	CAEM	Antiepileptics	Carbamazepine	yyyymmdd/ Ong	400 MG TID /PO		
									...
Placebo	GWEP1428-W-xxxx-xxx	1	HAEM	Antiepileptics	Carbamazepine	yyyy/ yyyymmdd	/	Inadequate control	
									...

CM: Concomitant Medication; CAEM: Concomitant anti epileptic Medication; HAEM: History of anti epileptic medications and therapies.
 * 1: Pre-treatment; 2: Baseline ongoing; 3: DB period emergent.

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7. Compliance
Safety Population

Actual Treatment for DB Phase	Unique Subject Identifier	Compliance	Visit Name	Visit Date	Dosing Schedule?	Did the Patient Comply with the Dosing Schedule?	Does the Actual IMP Usage Reflect the Expected Amount	Were There some Signals of Abuse Used as per the Potential Dosing Since Last Visit?
GWP42003-P	GWEP1428-W-xxxx-xxx	Yes		PERIOD V3 (D12)	yyyymmdd	Yes		
				PERIOD V4 (D26)	yyyymmdd	Yes	Yes	No
	GWEP1428-W-xxxx-xxx	No		PERIOD V3 (D12)	yyyymmdd	Yes		
				PERIOD V4 (D26)	yyyymmdd	Yes	No	No
...								
Placebo	GWEP1428-W-xxxx-xxx	No		PERIOD V3 (D12)	yyyymmdd	Yes		
				PERIOD V4 (D26)	yyyymmdd	No	No	No
...								
x							Page 1 of	

A.2.2 Efficacy

A.2.2.1 Pharmacokinetics Data

8. Pharmacokinetics

8.1. PK Values

PK Population

Actual Treatment	Unique Subject Identifier	Parameter (Unit)	Visit	Assessment Date	Time	Analysis	Value
GWP42003-P	GWEP1428-W-xxxx-xxx	Clobazam (ng/mL)	Visit 2 Day 1	yyyyymmdd	Pre-dose	81.0	
					15 min	92.1	
					30 min	128	
					1h	222	
					1.5h	218	
					2h	190	
					4h	139	
					6h	108	
					12h	77.3	
			Visit 2 Day 2	yyyyymmdd	24h	86.5	
			Visit 4 Day 26	yyyyymmdd	Pre-dose	128	
					15 min	128	
					30 min	131	
					1h	139	
					1.5h	167	
					2h	210	
					4h	228	
					6h	191	
					12h	139	
...							

24 hour kinetic data points excluded from PK analysis and plasma concentration-time profiles (12 hour dosing interval).

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8. Pharmacokinetics

8.2. PK Parameters

PK Population

Actual Treatment	Unique Identifier	Subject Population	Assessment	Parameter (Unit)	Analysis Value	Comment
		Flag	Parameter Category	Visit Date		
GWP42003-P	GWEP1428-W-xxxx-xxx	N/N/N/N	Clobazam 20 mg/day	Day 1 yyyymmdd	TMAX (h) x	xxxxxxxx
					CMAX (ng/mL) xxx	
					AUC _{TAU} (h*ng/mL) xxxx.xx	
					...	
				Day 26 yyyymmdd	TMAX (h) x.xxx	
					CMAX (ng/mL) xxx	
					...	
			N-Desmethylclobazam 20 mg/day	Day 1 yyyymmdd	TMAX (h) x	
					CMAX (ng/mL) xxx	
					AUC _{TAU} (h*ng/mL) xxxx.xx	
					...	

TMAX=Time to the maximum measured plasma concentration; CMAX=Maximum measured plasma concentration; AUC_{TAU}=AUC over a dosing interval; AUC_{IIFO}=AUC from zero to infinity obs; AUC_{IFPE}=AUC from zero to infinity with extrapolation of the terminal phase; LAMZHL=Half-life Lambda z; MPAUCR=Metabolite/Parent AUC ratio; MPCMAXR=Metabolite/Parent Cmax ratio.

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A.2.3 Safety

A.2.3.1 Exposure to Study Medication

10. Exposure
10.1. Study Medication
Safety Population

Actual Treatment for DB Phase	Unique Subject Identifier	Treatment Duration (Days)	Visit Name	Dose	Date of Administration	Time of IMP Dispense	Actual IMP Usage	Reflect Signals
					(am / pm d: Administran on Site?: if Administran on Site?: if no, tion if no,	Returned	Expected number : number	of Potential Amount: if no, Applicable) of Packs
GWP42003-P	GWEP1428-W-xxxx-xxx	xx	PERIOD V2 (D2)	yyyyymmdd	hhmm	hhmm	Yes: xx	
			PERIOD V4 (D26)	yyyyymmdd	No : xxxx	hhmm/hhmm	Yes: x	Yes No
			PERIOD V4 (D27)	yyyyymmdd	hhmm	xx		
...								
Placebo	GWEP1428-W-xxxx-xxx	xx	PERIOD V2 (D2)	yyyyymmdd	hhmm	hhmm	Yes: xx	
...								
...								
...								

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10. Exposure
10.2. Study Medication Use and Behavior Survey
Safety Population

Actual Treatment for DB Phase	Unique Subject Identifier	Visit Name	Subcategory	Question	Question Result	Question comment
GWP42003-P	GWEP1428-W-xxxx-xxx	V2 (D2)	Desired Use	Addicted to the IMP	Never	xxx
Drug dosage						xxxx
...						
Page 1 of x						

10. Exposure
10.3. Study Medication Dose Adjustment
Safety Population

Actual Treatment for DB Phase	Unique Subject Identifier	Date of adjustment	Dose Adjusted	Reason for Dose Adjustment	Adverse Event
GWP42003-P	GWEP1428-W-xxxx-xxx	yyyymmdd	xx MG/KG/DAY	Adverse Event	Diarrhoea
	GWEP1428-W-xxxx-xxx	yyyymmdd	10 MG/KG/DAY	Adverse Event	xxxx
...					

1

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10. Exposure
10.4. Site Classification Form
Safety Population

Actual Treatment for DB Phase	Unique Subject Identifier	Date of assessment	Categories	Level of Certainty	Relationship to Study Medication
GWP42003-P	GWEP1428-W-xxxx-xxx	yyyymmdd	Misuse	Definite	No
	GWEP1428-W-xxxx-xxx	yyyymmdd	Therapeutic error	Definite	Unknown/NA
	...				
Placebo	GWEP1428-W-xxxx-xxx	yyyymmdd	None of the above	Definite	Yes
	...				

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10. Exposure
10.5. Supplemental Drug Accountability
Safety Population

Actual Treatment for DB Phase	Unique Subject Identifier	Date of Assessment	Reason	Return of All Drugs: if No, Specify	Returned Less Than Expected: if Yes, Specify Reason	Injection Evidence/ Specify	Behavioral Changes/ Specify Nasal Use	Suicide Potential	Additional Information
GWP42003-P	GWEP1428-W-xxxx-xxx	yyyymmdd	No: xxxx	Yes: Other xxxxx	No / No	No apparent changes / No	No		
	GWEP1428-W-xxxx-xxx	yyyymmdd	Yes	No	No / No	xxxxx / xx	No		
	...								
Placebo	GWEP1428-W-xxxx-xxx	yyyymmdd	No: Other xxxx	No	No / No	xxxxx / xx	No		
	...								

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A.2.3.2 Adverse Events

11. Adverse Events

11.1. AEs

Safety Population

Actual Treatment for DB Phase	Unique Subject Identifier	Period	SOC / PT / Reported Term*	Start Date (Day) / End Date (Day) / Duration	Severity / Serious Event	Causality / Outcome	Action Taken with Study Treatment
GWP42003-P	GWEP1428-W-xxxx-xxx	DB Period	SOC / PT / RT *	yyyy-mm-dd (xx) / yyyy-mm-dd (xx) / xx	N	Severe/ Related / Recovered	Study medication stopped
<hr/>							
<hr/>							
Placebo	GWEP1428-W-xxxx-xxx	DB Period	SOC / PT / RT *	yyyy-mm-dd (xx) / yyyy-mm-dd (xx) / xx	N	Mild/ Not Related / Recovered	None
<hr/>							
<hr/>							

* Treatment-emergent AE.

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11. Adverse Events

11.2. Supplemental AE form
Safety Population

Actual DB Phase	Treatment for	Unique Identifier	Assessment Date	Trigger AE	Change in Usage/Other Route of Administration	Medication Consistencies	Frequency/Desire to Re-create Event	Intent/Injection Evidence/Nasal Use	Liking/Disliking/Event	Behavioral Changes/Suicide	Additional Information
GWP42003-P	GWEP1428-W-	xxxx-xxx	yyyymmdd	xxxx	xxxx/xxxx	xxxx/xx	xx/xx	x/x/x	xx/x/x	xx/x/x	xxx

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A.2.3.3 Laboratory Data

13. Laboratory Evaluations
 13.1. Values Overtime
 Safety Population

Actual Treatment for DB Phase	Unique Subject Identifier	Category/ Parameter	Analysis Visit	Date and Time (Day Assessment)	Analysis Value	Change/ % Change from Baseline	Toxicity Indicator (RR)	Toxicity Grade
GWP42003-P	GWEP1428-W-xxxx-xxx	Biochemistry/ Alanine aminotransferase (U/L)	VISIT 1	yyyymmdd:hh:mm (-x)	xx	N [xx-xx]		
			VISIT 2	yyyymmdd:hh:mm (-x)	xx	N [xx-xx]		
			VISIT 3	yyyymmdd:hh:mm (xx)	xx	xx/xx.xx	N [xx-xx]	
			VISIT 4	yyyymmdd:hh:mm (xx)	xx	xx/xx.xx	H [xx-xx]	Tox increased
		Biochemistry/ Albumin (g/L)	VISIT 1	yyyymmdd:hh:mm (-x)	xx	N [xx-xx]		
			...					
...								

RR: Reference Range; N: Normal; H: High; L: Low.

* Baseline value.

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13. Laboratory Evaluations
 13.3. Clinical Laboratory Blood and Urine Sampling
 Safety Population

Actual Treatment Phase for DB	Unique Subject Identifier	Visit Name	Urine Sample Sent for Central Laboratory/ Result		Child	Sample Collected for					
			Central Laborat ory	Blood	Medical Condition/ Urine Sample	Repeat Blood	Repeat Urine	Potential: Serum	Alcohol		
			Sample	Urine Sample	Collected for	Sample: Sample:	Pregnancy	Testing:	Genetic	Result	Testing
			Taken	Taken: Reason	THC	Date	Date	Result	Result	Testing	Testing
GWP42003-P	GWEP1428-W-xxxx-xxx	PERIOD V1 (D-14)	Yes	Yes	Yes/No/Yes	No	No	NA	Yes: Neg		
		PERIOD V2 (D1)	Yes	Yes	xx/xx/xx	No	No		Yes: Neg	Yes	
		PERIOD V3 (D12)	Yes	No: xxxx	xx/xx/xx	No	No				
		PERIOD V4 (D26)	Yes	Yes	xx/xx/xx	No	No		Yes: Neg		
...											

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13. Laboratory Evaluations
13.4. Genetic Testing Data
Safety Population

Actual Treatment for DB Phase	Unique Subject Identifier	Date and Time of Visit	Analysis Assessment	CYP2C19 Result	CYP2C19 Sequence	CYP3A4 Result	CYP3A4 Sequence	Test Level Comment
GW42003-P	GWEP1428-W-xxxx-xxx	VISIT x	yyyyymmdd hh:mm	CYP2C19 *1/*1+*17; CYP2C19*1/*1+*17	Ultrarapid metabolizer	CYP3A4 *1/*1;	Extensive metabolizer	CYP3A4*1/*1 xxxxxxxxxxxx
	GWEP1428-W-xxxx-xxx	VISIT x	yyyyymmdd hh:mm	CYP2C19 *1/*1	CYP2C19*1/*1	CYP3A4 *1/*1;	Extensive metabolizer	CYP3A4*1/*1 xxxxxxxxxxxx
...								
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A.2.3.4 Vital Signs, Other Physical Findings and Other Safety Data

14. Vital signs, Other Physical Findings and Other Observations Related to Safety

14.1. Physical Examination and Vital Signs Safety Population

Actual Treatment	Unique Subject Identifier	Parameter	Analysis Visit	Date (Day) of Assessment	Analysis Value	Change from Baseline	Percent Change from Baseline	Arm Used
GWP42003-P	GWEP1428-W-xxxx-xxx	Height (cm)	PERIOD V1 (D-14)	yyyymmdd (xx)	xxx*			
		Pulse Rate (Beats/min)	PERIOD V1 (D-14)	yyyymmdd (xx)	xx			
			PERIOD V2 (D1)	yyyymmdd (xx)	xx			
			PERIOD V2 (D2)	yyyymmdd (xx)	xx*			
			PERIOD V3 (D12)	yyyymmdd (xx)	xx	xx	xx.xx	
			PERIOD V4 (D26)	yyyymmdd (xx)	xx	xx	xx.xx	
			PERIOD V4 (D27)	yyyymmdd (xx)	xx	xx	xx.xx	
Placebo	GWEP1428-W-xxxx-xxx	Sitting Diastolic Blood Pressure (mmHg)	PERIOD V1 (D-14)	yyyymmdd (xx)	xx			Right
			PERIOD V2 (D1)	yyyymmdd (xx)	xx			Right
			PERIOD V2 (D2)	yyyymmdd (xx)	xx*			Right
			PERIOD V3 (D12)	yyyymmdd (xx)	xx	xx	xx.xx	Right
			PERIOD V4 (D26)	yyyymmdd (xx)	xx	xx	xx.xx	Left
			PERIOD V4 (D27)	yyyymmdd (xx)	xx	xx	xx.xx	Right
...								

* Baseline value.

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14. Vital signs, Other Physical Findings and Other Observations Related to Safety

14.2. ECG

Safety Population

Actual Treatment	Unique Subject Identifier	Parameter	Analysis Visit	Date (Day) of Analysis	Assessment	Value	CFB / % CFB	Rhythm: comment	comment	ST or T-wave changes:	Infarct pattern/R-wave	progression
GWP42003-P GWEP1428-W-xxxx-xxx		PR Interval (msec)	PERIOD V1 (D-14) PERIOD V2 (D1) PERIOD V3 (D12) PERIOD V4 (D26)	yyyyymmdd (xx)	xx	xx	xx/xx.xx	Normal	No	No	No	No
				yyyyymmdd (xx)	xx*	xx	xx/xx.xx	Normal	No	No	No	No
				yyyyymmdd (xx)	xx	xx	xx/xx.xx	Normal	No	No	No	No
				yyyyymmdd (xx)	xx	xx	xx/xx.xx	Normal	No	No	No	No

...

* Baseline value.

CFB: Change from Baseline.

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14. Vital signs, Other Physical Findings and Other Observations Related to Safety
14.3. Physical Examination, Vital Signs or ECG results indicative of Medical Condition or AE
Safety Population

Actual Treatment	Unique Subject Identifier	Analysis Visit	Physical Examination Results Indicative of a Medical Condition?		Vital Signs or Blood Pressure Results Indicative of an Adverse Event?		ECG Results Indicative of a Medical Condition?	
			a Medical Condition?	an Adverse Event?	a Medical Condition?	an Adverse Event?	a Medical Condition?	an Adverse Event?
GWP42003-P	GWEP1428-W-xxxx-xxx	PERIOD V1 (D-14)	No		No		No	
		PERIOD V2 (D1)		No		No		No
		PERIOD V2 (D2)		No		No		No
		PERIOD V3 (D12)		No		No		No
		PERIOD V4 (D26)		No		No		No
		PERIOD V4 (D27)		No		No		No
...								

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14. Vital signs, Other Physical Findings and Other Observations Related to Safety

14.4. C-SSRS

Safety Population

Actual Treatment	Unique Subject Identifier	Parameter	Date (Day) of Analysis Visit	Assessment	Result
GWP42003-P	GWEP1428-W-xxxx-xxx	Wish to be dead	PERIOD V1 (D-14) PERIOD V2 (D1) PERIOD V3 (D12) PERIOD V4 (D26)	yyyyymmdd (xx) yyyyymmdd (xx) yyyyymmdd (xx) yyyyymmdd (xx)	No No No No
		Non-Specific Active Suicidal Thoughts	PERIOD V1 (D-14) PERIOD V2 (D1) PERIOD V3 (D12) PERIOD V4 (D33)	yyyyymmdd (xx) yyyyymmdd (xx) yyyyymmdd (xx) yyyyymmdd (xx)	No No No No
...					
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14. Vital signs, Other Physical Findings and Other Observations Related to Safety

14.5. Seizure Data From Patient Diary

Safety Population

Actual Treatment for DB Phase	Unique Subject Identifier	Visit Name	Date	Nb of Tonic/ Clonic/ Tonic- Clonic/ Atonic/ Myoclonic/			Other Absence Seizures	Nb of Countable Partial Seizure	Episodes of Status Partial	AEDs/ Epilep	Study Rescue Taken
				No Seizures	Today/	Drug					
GWP42003-P	GWEP1428-W-xxxx-xxx	PERIOD V1 (D-14)	yyyymmdd		1		Yes/No	Yes/No			
			yyyymmdd				Yes/No	Yes/No			
			yyyymmdd				Yes/No	Yes/No			
			yyyymmdd				/No	Yes/No	AM/PM		
			yyyymmdd				/No	Yes/No	AM/PM		
			yyyymmdd				/No	Yes/No	AM/PM		
			yyyymmdd				/No	Yes/No			
...											

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