

14.2.3 PK data

Table 14.2.3.1 Plasma concentrations (PK set 1)

Parameter	Time Point	Statistics	PK Set 1			Overall N=45
			30 mg N=15	40 mg N=15	50 mg N=15	
Chlorprocaine Plasmatic Concentration (ng/mL)	Pre-dose (0)	N	15	15	15	45
		Geo.Mean	NC	NC	NC	NC
		Mean	BLQ	BLQ	BLQ	BLQ
		SD	0.000	0.000	0.000	0.000
		CV%	NC	NC	NC	NC
		Min	BLQ	BLQ	BLQ	BLQ
		Median	BLQ	BLQ	BLQ	BLQ
		Max	BLQ	BLQ	BLQ	BLQ
Chlorprocaine Plasmatic Concentration (ng/mL)	5 min after spinal injection	N	15	15	15	45
		Geo.Mean	NC	NC	NC	NC
		Mean	BLQ	BLQ	BLQ	BLQ
		SD	0.000	0.000	0.000	0.000
		CV%	NC	NC	NC	NC
		Min	BLQ	BLQ	BLQ	BLQ
		Median	BLQ	BLQ	BLQ	BLQ
		Max	BLQ	BLQ	BLQ	BLQ

Table 14.2.3.1 Plasma concentrations (PK set 1)

Parameter	Time Point	Statistics	PK Set 1			
			Chlorprocaine 1%			
			30 mg N=15	40 mg N=15	50 mg N=15	Overall N=45
Chlorprocaine Plasmatic Concentration (ng/mL)	10 min after spinal injection	N	15	15	15	45
		Geo.Mean	NC	NC	NC	NC
		Mean	BLQ	BLQ	BLQ	BLQ
		SD	0.000	0.000	0.000	0.000
		CV%	NC	NC	NC	NC
		Min	BLQ	BLQ	BLQ	BLQ
		Median	BLQ	BLQ	BLQ	BLQ
		Max	BLQ	BLQ	BLQ	BLQ
Chlorprocaine Plasmatic Concentration (ng/mL)	30 min after spinal injection	N	15	15	15	45
		Geo.Mean	NC	NC	NC	NC
		Mean	BLQ	BLQ	BLQ	BLQ
		SD	0.000	0.000	0.000	0.000
		CV%	NC	NC	NC	NC
		Min	BLQ	BLQ	BLQ	BLQ
		Median	BLQ	BLQ	BLQ	BLQ
		Max	BLQ	BLQ	BLQ	BLQ
Chlorprocaine Plasmatic Concentration (ng/mL)	60 min after spinal injection	N	15	15	15	45
		Geo.Mean	NC	NC	NC	NC
		Mean	BLQ	BLQ	BLQ	BLQ
		SD	0.000	0.000	0.000	0.000

Table 14.2.3.1 Plasma concentrations (PK set 1)

Parameter	Time Point	Statistics	PK Set 1			
			Chlorprocaine 1%			
			30 mg N=15	40 mg N=15	50 mg N=15	Overall N=45
		CV%	NC	NC	NC	NC
		Min	BLQ	BLQ	BLQ	BLQ
		Median	BLQ	BLQ	BLQ	BLQ
		Max	BLQ	BLQ	BLQ	BLQ
CABA Plasmatic Concentration (ng/mL)	Pre-dose (0)	N	15	15	15	45
		Geo.Mean	NC	NC	NC	NC
		Mean	BLQ	BLQ	BLQ	BLQ
		SD	0.000	0.000	0.000	0.000
		CV%	NC	NC	NC	NC
		Min	BLQ	BLQ	BLQ	BLQ
		Median	BLQ	BLQ	BLQ	BLQ
		Max	BLQ	BLQ	BLQ	BLQ
CABA Plasmatic Concentration (ng/mL)	5 min after spinal injection	N	15	15	15	45
		Geo.Mean	NC	NC	NC	NC
		Mean	16.127	20.411	24.887	20.475
		SD	20.108	23.037	20.340	21.030
		CV%	124.690	112.865	81.732	102.709
		Min	BLQ	BLQ	BLQ	BLQ
		Median	10.400	10.900	21.300	15.100
		Max	59.50	75.00	72.10	75.00

Table 14.2.3.1 Plasma concentrations (PK set 1)

Parameter	Time Point	Statistics	PK Set 1			
			30 mg N=15	40 mg N=15	50 mg N=15	Overall N=45
CABA Plasmatic Concentration (ng/mL)	10 min after spinal injection	N	15	15	15	45
		Geo.Mean	NC	28.075	50.700	NC
		Mean	41.440	38.851	75.833	52.041
		SD	31.778	25.492	67.635	47.689
		CV%	76.684	65.616	89.190	91.637
		Min	BLQ	4.24	8.79	BLQ
		Median	32.900	39.500	54.000	39.500
		Max	96.90	76.70	236.00	236.00
CABA Plasmatic Concentration (ng/mL)	30 min after spinal injection	N	15	15	15	45
		Geo.Mean	41.779	55.404	79.371	56.849
		Mean	57.459	67.180	97.647	74.095
		SD	43.773	36.899	61.704	50.538
		CV%	76.182	54.926	63.191	68.207
		Min	5.68	12.70	17.70	5.68
		Median	50.900	75.800	69.900	67.900
		Max	169.00	137.00	221.00	221.00
CABA Plasmatic Concentration (ng/mL)	60 min after spinal injection	N	15	15	15	45
		Geo.Mean	34.474	NC	64.724	NC

Table 14.2.3.1 Plasma concentrations (PK set 1)

Parameter	Time Point	Statistics	PK Set 1			Overall N=45
			30 mg N=15	40 mg N=15	50 mg N=15	
		Mean	47.020	53.093	78.380	59.498
		SD	41.381	31.803	48.403	42.435
		CV%	88.008	59.901	61.755	71.323
		Min	12.30	BLQ	20.20	BLQ
		Median	36.200	51.700	71.400	51.700
		Max	156.00	117.00	202.00	202.00

Note: Subjects are summarised according to the dose level of the product they actually received

NC = Not Calculated, BLQ = Below Lower Quantification Limit

Lower Quantification Limit of Chlorprocaine = 4.0 ng/mL, Lower Quantification Limit of 2-chloro-4-aminobenzoic acid (CABA) = 4.0 ng/mL

Source: [Listing 16.2.5.3](#) - PK blood samples collection and plasma concentrations

Program: Tables\c122-pc-tbl.sas