

14.2.3 PK data

Table 14.2.3.1 Plasma concentrations (PK set 1)

Parameter	Time Point	Statistics	PK Set 1 Chloroprocaine 1%			Overall N=45
			30 mg N=15	40 mg N=15	50 mg N=15	
Chloroprocaine 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
Chloroprocaine 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

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			Chloroprocaine 1%			Overall
			30 mg N=15	40 mg N=15	50 mg N=15	
Chloroprocaine 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
Chloroprocaine 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
Chloroprocaine 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

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Parameter	Time Point	Statistics	PK Set 1			
			Chloroprocaine 1%			Overall
			30 mg N=15	40 mg N=15	50 mg N=15	
		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

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			Chloroprocaine 1%			Overall N=45
			30 mg N=15	40 mg N=15	50 mg N=15	
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
			Chloroprocaine 1%			
			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 Chloroprocaine = 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