DEM104101 PK/PD Analysis Data Sets

MetrumRG

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1 DEM104101F_PK

Description: Population PK analysis data set

Column	Туре	Field	Value
С	character	short-name	С
		values	. = not a comment, C = comment
		long-name	commented rows
USUBJID	character	short-name	USUBJID
		long-name	universal subject identifier
ID	character	short-name	ID
		long-name	NONMEM ID number
EVID	numeric	short-name	EVID
		long-name	event ID indicator
		comment	per NONMEM specifications
WT	numeric	short-name	WT
		range	2 to 4

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Description: Population PK/PD analysis data set

Column	Type	Field	Value
С	character	short-name	С
		values	., C
		long-name	commented rows
MDV	numeric	short-name	MDV
		long-name	missing DV indicator
		comment	per NONMEM specifications
SEQ	numeric	short-name	SEQ
		values	1 = concentration, $2 = $ response, $3 = $ other
		long-name	record type indicators

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Column	Туре	Field	Value
AMT	numeric	short-name	AMT
		unit	mg
		range	0 to 1000
		long-name	dose amount
II	numeric	short-name	II
		unit	hours
		long-name	interdose interval
CMT	numeric	short-name	Compartment
		values	1, 2, 3, 4
		long-name	compartment number
		comment	per NONMEM specifications
TAFD	numeric	short-name	TAFD
		unit	hours
		long-name	time after first dose
WT	numeric	short-name	Weight
		unit	kg
		range	40 to 100
		long-name	baseline weight
EGFR	numeric	short-name	eGFR
		unit	ml/min/1.73 m2
		range	10 to 300
		long-name	estimated glomerular filtration rate
SEX	numeric	short-name	SEX
		values	0 = male, 1 = female

3 DEM104101F_AE

Description: AE analysis data set

Column	Type	Field	Value
С	character	short-name	С
		values	., C
		long-name	commented rows
MDV	numeric	short-name	MDV
		long-name	missing DV indicator
		comment	per NONMEM specifications
SEQ	numeric	short-name	SEQ
		values	1 = concentration, $2 = $ response, $3 = $ other
		long-name	record type indicators
AMT	numeric	short-name	AMT
		unit	mg
		range	0 to 1000
		long-name	dose amount
II	numeric	short-name	II
		unit	hours
		long-name	interdose interval
CMT	numeric	short-name	Compartment
		values	1, 2, 3, 4

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Column	Туре	Field	Value
		long-name	compartment number
		comment	per NONMEM specifications
TAFD	numeric	short-name	TAFD
		unit	hours
		long-name	time after first dose
WT	numeric	short-name	Weight
		unit	kg
		range	40 to 100
		long-name	baseline weight
EGFR	numeric	short-name	eGFR
		unit	ml/min/1.73 m2
		range	10 to 300
		long-name	estimated glomerular filtration rate