DEM104101 PK/PD Analysis Data Sets

MetrumRG

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Contents

1 DEM104101F_PK

Description: Population PK analysis data set

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

2 DEM104101F_PKPD

Description: Population PK/PD analysis data set

Column	Type	Field	Value
C	character	unit	
		short-name	C
		long-name	commented rows
		values	., C

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

3 DEM104101F_AE

Description: AE analysis data set

Column	Type	Field	Value
C	character	unit	
		short-name	C
		long-name	commented rows
		values	., C
MDV	numeric	unit	
		short-name	MDV
		long-name	missing DV indicator
		comment	per NONMEM specifications

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