



CONFIDENTIAL

# Analysis data specification

2019-01-12

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## 1 spec

**Description:** [data set description]

Column	Type	Field	Value
C	character	short-name values long-name	commented row indicator ., C commented rows
USUBJID	character	short-name long-name	USUBJID universal subject identifier
ID	numeric	short-name long-name	ID NONMEM ID number
EVID	numeric	short-name long-name comment	event ID event ID indicator per NONMEM specifications
MDV	numeric	short-name long-name comment	MDV missing DV indicator per NONMEM specifications
SEQ	numeric	short-name values long-name	SEQ 1 = concentration, 2 = response, 3 = other record type indicators
AMT	numeric	short-name unit range long-name	amount mg 0 to 1000 dose amount
II	numeric	short-name unit long-name	II hours interdose interval
CMT	numeric	short-name values long-name comment	Compartment 1, 2, 3, 4 compartment number per NONMEM specifications
TAFD	numeric	short-name unit long-name	TAFD hours time after first dose
WT	numeric	short-name unit range long-name	Weight kg 40 to 100 baseline weight
EGFR	numeric	short-name unit range	eGFR ml/min/1.73m2 10 to 300

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Column	Type	Field	Value
		long-name	estimated glomerular filtration rate
STUDY	character	short-name values  long-name	Study 100 = The first phase 1 study, 202 = The first phase 2 study conducted only at sites 1, 2, 3 when the formulation was still oral liquid only, 303 = The renal impairment study, 203 = The second phase 2 study study identifier
SEX	numeric	short-name values	SEX 0 = male, 1 = female
BQL	numeric	short-name values long-name	below limit of quantification 0 = FALSE, 1 = TRUE DV value is below the quantitation limit
DV	numeric	short-name unit long-name comment	DV ng/mL dependent variable see SEQ
DV2	numeric	short-name long-name	DV2 second dependent variable
HAIR	character	short-name values long-name	HAIR 0 = brown, 1 = blonde, 2 = black patient hair color
CLCR	numeric	short-name unit range	creatinine clearance ml/min 40 to 180
ALB	numeric	short-name unit range comment	adjusted albumin g/dL 1 to 5 in the lookup document as ALB2

## 2 DEM104101F\_PKPD

**Description:** Population PKPD analysis data set

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

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