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Pharmacokinetics PK
PK

PK PK

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PK PK
PK - -

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PK PK / PK
PK -

PK PK
PK PK

PK

PK
Pharmacologically Active Dose PAD /
Anticipated Therapeutic Dose ATD PK

PK

PK
/
/
/

PD

PK
-
-

PK

PK PD

MTD
/

Maximum Tolerated Dose, MTD

/ /

PK
-

???????

PK
PK

PK 3

/ /

PK PD
-

PD

PK
/

???????

PK $C_{min,ss}$ $C_{max,ss}$ $C_{av,ss}$ AUC_{0-t}
DF PK Tmax PK

?????-??-??????

-PK PK Power
Model PK -
PD -

????????????????

PK

?????

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PK
PK/PD PK
PK/PD

PK /

PK -

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[1] . 2005.

[2] . 2021.

[3] European Medicines Agency. Guideline on strategies to identify and mitigate risks for first-in-human and early clinical trials with investigational medicinal products, EMA/CHMP/SWP/28367/07

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[4] European Medicines Agency. Guideline on the use of pharmacogenetic methodologies in the pharmacokinetic evaluation of medicinal products EMA/ CHMP/37646/2009 Committee for Medicinal Products for Human Use (CHMP) 12 December 2011.

[5] . 9012 .2020.

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