Checklist for Reporting an Animal Pharmacokinetic/Pharmacodynamic Study[a]

Note for authors: Please verify all sub-items of an item are reported in the manuscript before checking the button. Save the form after completing and submit it along with the manuscript.

Item		Reported	Not reported	Reason for not reporting
	Title page/Abstract			
1	Title; Running header; Authors names, affiliations and corresponding author(s) details	○	○	
2	Abstract in the required format and including objective(s) of the study, drug(s) name, route of administration, animal species and sample size, results of the primary objective and key pharmacokinetic/pharmacodynamic parameters	○	○	
	Introduction/Background			
3	An explanation of the study rationale	○	○	
4	Pharmacokinetic/pharmacodynamic data that are known and relevant to the study	○	○	
5	Aims/objectives of the study	○	○	
	Materials and Methods			
6	Institute Review Board/Ethics Committee that approved the study and approval number	○	○	
7	Animal model(s) studied and the justification of the animal model(s) used	○	○	
8	Strain, sex, age, body weight, genotype, health, nutritional and immune status	○	○	
9	Source of animals	○	○	
10	Housing and husbandry conditions of animals	○	○	

11	Guidelines (institutional, national or international) followed for the care of the animals	○	○	
12	Study design, including randomization, method of randomization, number and sex of animals in treatment and control groups, washout period	○	○	
13	Sample size and method of sample size calculation, or justification of sample size based on published rules or guidelines	○	○	
14	Inclusion and exclusion criteria	○	○	
15	Test item(s) including formulation, dose, dosing scheme, route of administration	○	○	
16	Body fluid or tissue sampling protocol including volume/weight, sampling time points, description of blood vessels or tissues, sampling technique, number of animals per sampling time point	○	○	
17	Preparation and storage conditions of the analyte(s)	○	○	
18	Details of quantitative bioanalytical methods including instrumental characteristics, chromatography conditions, sample preparation, internal standard, calibration range, appropriate measures of accuracy and precision, method of handling samples below or above the limits of quantification	○	○	
19	List of pharmacokinetic/pharmacodynamic parameters to be reported and the formulas for their calculations	○	○	

20	Pharmacokinetic/pharmacodynamic modeling method and software used	○	○	
21	Statistical methods including the software used	○	○	
22	Protocol for reporting safety and tolerability	○	○	
	Results			
23	Analyzed parameters with appropriate measures of variability or precision (e.g. standard deviation or 95 % confidence intervals)	○	○	
24	Quantification of missing or excluded data	○	○	
	Discussion			
25	Relevance of study findings	○	○	
26	Study limitations	○	○	
	Conclusion			
27	A synopsis of the study, based on the observed results	○	○	
	Other information			
28	Source of funding, conflicts of interest, acknowledgements, if any	○	○	

[a] Adapted from Singh J, Elbarbry F, Lan K, Grabowski T. Animal Pharmacokinetic/Pharmacodynamic Studies (APPS) Reporting Guidelines. Eur J Drug Metab Pharmacokinet. 2018;43:483-494.

Authors, reviewers and editors are encouraged to provide feedback on the APPS reporting guidelines and the checklist to the authors.

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