

Appendix

Glossary of Abbreviations Used in This Book

ANOVA	Analysis of variance
ARWU	Academic ranking of world universities
AUC	Area under the concentration vs. time curve
BMI	Body mass index
CDER	Center for Drug Evaluation and Research
CI	Confidence interval
C_{\max}	Maximum concentration
COPE	Committee on Publication Ethics
CRF	Case report form
CRO	Contract research organization
CTA	Clinical trial application
CTD	Common Technical Document
CV	Coefficient of variation
DBP	Diastolic blood pressure
DF	Degrees of freedom
EC	Ethics committee
ECG	Electrocardiogram
eCTD	Electronic Common Technical Document
EMA	European Medicines Agency
ESL	English-as-Second-Language
EU	European Union
FDA	Food and Drug Administration
GCP	Good Clinical Practice
GLP	Good Laboratory Practice
GMP	Good Manufacturing Practice
IB	Investigator's Brochure
ICH	International Conference on Harmonization
ICMJE	International Committee of Medical Journal Editors

IMP	Investigational Medicinal Product
IMPD	Investigational Medical Product Dossier
IMRAD	Introduction, Methods, Results, and Discussion
IND	Investigational New Drug
IRB	Institutional Review Board
MAD	Multiple ascending dose
MedDRA	Medical Dictionary for Regulatory Activities
NDA	New Drug Application
PD	Pharmacodynamic
PK	Pharmacokinetic
SAD	Single ascending dose
SBP	Systolic blood pressure
SD	Standard deviation
SE / SEM	Standard error / Standard error of the mean
SPC or SmPC	Summary of product characteristics
$T_{1/2}$	Half-life
T_{\max}	Time taken to reach C_{\max}

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