

## List of Abbreviations and Acronyms

AWIPT	Adsorb, Wash, <i>In Vitro</i> Pyrogen Test
BET	Bacterial Endotoxin Test
BRD	Background Review Document
CBER	Center for Biologics Evaluation and Research
CCAC	Canadian Council on Animal Care
CDER	Center for Drug Evaluation and Research
CDRH	Center for Devices and Radiological Health
CEC	Commission of the European Communities
CFR	Code of Federal Regulations
CLB	Central Laboratory for the Blood Transfusion Service
Cryo	Cryopreserved
CSF	Colony Stimulating Factor
CV	Coefficient of variation
CVM	Center for Veterinary Medicine
DMSO	Dimethyl sulfoxide
DSMZ	Deutsche Sammlung von Mikroorganismen und Zellkulturen (German Collection of Microorganisms and Cell Cultures)
ECVAM	European Centre for the Validation of Alternative Methods
EDQM	European Directorate for the Quality of Medicines
EEC	European Economic Community
ELC	Endotoxin limit concentration
ELISA	Enzyme-linked immunosorbent assay
EMEA	European Medicines Agency
EP	European Pharmacopeia
EPA	U.S. Environmental Protection Agency
ESAC	ECVAM Scientific Advisory Committee
EU	European Union
EU/mL	Endotoxin units/mL
FDA	U.S. Food and Drug Administration
Fn	Fibronectin
<i>FR</i>	<i>Federal Register</i>
GLP	Good Laboratory Practice
GM-CSF	Granulocyte-Macrophage-Colony Stimulating Factor
Hb	Hemoglobin
hGH	Human growth hormone
HSA	Human serum albumin
ICCVAM	Interagency Coordinating Committee on the Validation of Alternative Methods
IFN- $\gamma$	Interferon- $\gamma$
IgG	Immunoglobulin G
IL	Interleukin
i.m.	Intramuscular
ISO	International Standards Organization
IU	International units

i.v.	Intravenous
JP	Japanese Pharmacopeia
LAL	<i>Limulus</i> Amebocyte Lysate
LPS	Lipopolysaccharide
LTA	Lipoteichoic acid
MEM	Minimum essential medium
MM6	Mono Mac 6
MVD	Maximum valid dilution
NA	Not applicable
NC	Negative control
n.c.	Not calculated
ND	Not done
n.d.	Not detectable
NF	National Formulary
NI	Not included
NICEATM	National Toxicology Program Interagency Center for the Evaluation of Alternative Toxicological Methods
NPC	Negative product control
OECD	Organisation for Economic Co-operation and Development
OD	Optical density
PBMC	Peripheral Blood Mononuclear Cell
PC	Positive control
PEI	Paul Ehrlich Institut
PFS	Pyrogen-free saline
PG	Peptidoglycan
PHA	Phytohemagglutinin
PPC	Positive product control
PWG	Pyrogenicity Working Group
QA	Quality assurance
rec	Recombinant
RPT	Rabbit Pyrogen Test
SD	Standard deviation
SOP	Standard operating procedure
TBE	Tick-borne encephalitis
THP-1	Acute monocyte leukemia cell line
TLR	Toll-like Receptor
TNF- $\alpha$	Tumor Necrosis Factor- $\alpha$
U	Units
U.K.	United Kingdom
U.S.	United States
U.S.C.	United States Code
USDA	U.S. Department of Agriculture
USP	U.S. Pharmacopeia
USPTO	United States Patent and Trademark Office
UV	Ultraviolet
WB	Whole blood

WHO	World Health Organization
x g	Times gravity