List of Abbreviations

Acronym	Definition
ACN	Acetonitrile
ACVA	azobis-cyan valeric acid
AFM	atomic force microscope
AIBN	2,2-azobisisobutyronitrile
AMPD	azobis methyl propionamidine dihydrochloride
ANDA	Abbreviated New Drug Application
ANVISA	Agência Nacional de Vigilância Sanitária
API	Active Pharmaceutical Ingredient
AR & D	Analytical Research & Development
ASEAN	Association of South East Asian Nations
ASTM	American Society for Testing and Materials
ATR	Attenuated total reflectance
BA	Bioavailability
BE	Bioequivalence
BLA	Biologics License Application
CAPA	Corrective and Preventive Actions
CBE	Changes Being Effected
CBE-30	Changes Being Effected – 30 Days
CBER	Center for Biologics Evaluation and Research
CDER	Center for Drug Evaluation & Research
CDRH	Center for Devices and Radiological Health
CE	Capillary Electrophoresis
CE	Conformité Européenne
CFR	Code of Federal Regulations
cGMPs	current Good Manufacturing Practices
CHMP	Committee for Medicinal Products for Human Use
CI	confidence interval
CMC	Chemistry, Manufacturing & Controls
COA	Certificate of Analysis
CQA	Critical Quality Attribute
CR	Child Resistant
CRH	Critical relative Humidity

CRO	Contract Research Organization
CRT	Controlled Room Temperature
CTD	Common Technical Document
DES	Drug eluting stent
DMF	Device Master File
DMSO	Dimethylsulfoxide
DPI	Dry powder inhaler
DRIFTS	Diffuse reflectance infrared Fourier-transform spectroscopy
DSC	Differential scanning calorimetry
ECMWF	European Centre for Medium-Range Weather Forecasts
EEC	European Economic Community
ELISA	Enzyme-linked immunosorbent assay
EMEA	European Medicines Agency
EMRO	World Health Organization (WHO) Regional Office for the Eastern Mediterranean
EP	European Pharmacopoeia
ERH	Equilibrium relative humidity
EU	European Union
FAR	Field Alert Report
FDA	Food and Drug Administration
FID	Flame Ionization Detector
FMEA	Failure Mode and Effects Analysis
FT-IR	Fourier Transform Infrared spectroscopy
GC	Gas Chromatography
GCC	Cooperation Council for the Arab States of the Gulf
GHTF	Global Harmonization Task Force
HDPE	High density polyethylene
HMG	3-hydroxy-3-methyl-glutaryl
HPLC	High performance liquid chromatography
ICH	International Conference on Harmonization
IEF	Isoelectric focusing
IFPMA	International Federation of Pharmaceutical Manufacturers & Associations
IFU	Instructions for use
IGC	Inverse gas chromatography
IND	Investigational New Drug
IP	Intellectual property
IPAC-RS	International Pharmaceutical Aerosol Consortium on Regulation and Science
IQ	Installation qualification
IRA	Interim Revision Announcement
ISO	International Organization for Standardization
ITFG	Inhalation Technology Focus Group
J-NDA	(Japan) New Drug Application
JPMA	Japan Pharmaceutical Manufacturers Association

KBr	Potassium bromide
LC/MS-MS	Liquid chromatography/Mass spectroscopy-Mass spectroscopy
LC-NMR	Liquid chromatography/Nuclear magnetic resonance
LC-PDA	Liquid chromatography/photo-diode array
LIMS	Laboratory information management system
LOD	Limit of Detection
LOD	Loss on Drying
LOQ	Limit of Quantitation
LVP	Large Volume Parenteral
MDD	Medical Devices Directive
MDI	Metered Dose Inhaler
MHLW	(Japan) Ministry of Health, Labour and Welfare
MKT	Mean Kinetic Temperature
MPD	Medicinal Products Directive
MRI	Magnetic Resonance Imaging
MS/ELSD/CAD	Mass Spectrometry/Evaporative Light Scattering Detector/Charged Aerosol Detector
MVA	Multi-variate analysis
MVTR	Moisture vapor transmission rate
NCEs	New Chemical Entities
NDA	New Drug Application
NIR	Near-infrared (IR)
NIST	National Institute of Standards and Technology
NMP	*N*-methylpyrrolidone
NMR	Nuclear Magnetic Resonance
OCP	Office of Combination Products
OINDP	Orally Inhaled and Nasal Drug Products
OOS	Out of Specification
OOT	Out-of-Trend
OQ	Operational qualification
OTC	Over-the-counter
P & ID	
PAC-ATLS	Post-Approval Changes – Analytical Testing Lab Site
PAL	(Japan) Pharmaceutical Affairs Law
PAS	Prior Approval Supplement
PAT	Process analytical technology
PCA	Principal component analysis
PDA	Photo-diode array
Ph. Eur.	European Pharmacopoeia
PLS	Partial least squares
PMDA	(Japan) Pharmaceutical and Medical Devices Agency
PMOA	Primary Mode of Action
PQ	Performance qualification
PQRI	Product Quality Research Institute
PTI	Parametric tolerance interval

PVC	Polyvinyl chloride
QA	Quality Assurance
QA/QC	Quality Assurance/Quality Control
QbD	Quality by Design
QL	Quantitation Limit
RA	Regulatory Affairs
rDNA	Recombinant DNA
RFD	Request for Designation
RH	Relative humidity
RMS	Root-mean-square
RS	Reference Standards
RSD	Relative standard deviation
SADC	Southern African Development Community
SBI	Significant Body of Information
SDS-PAGE	Sodium dodecyl sulfate polyacrylamide gel electrophoresis
SEC	Size-exclusion chromatography
SE-HPLC	Size-exclusion HPLC
SEP	Standard error of prediction
SFC	Supercritical fluid chromatography
SIM	Stability-indicating method
SOP	Standard Operating Procedure
SUPAC	Scale Up and Post-Approval Changes
TGA	Thermogravimetric analysis
TLC	Thin layer chromatography
UHPLC	Ultra High Performance Liquid Chromatography
UPLC	Ultra Performance Liquid Chromatography
USP	United States Pharmacopeia
USP/NF	United States Pharmacopeia/National Formulary
UTC	Coordinated Universal Time
UV	Ultraviolet
WFI	Water for Injection
WHO	World Health Organization
XRPD	X-ray powder diffraction
YP_D	Yearly mean partial water vapor pressure

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