ABBREVIATIONS

ABPI	Association of British pharmaceutical industry
ADE	Adverse drug event
ADHD	Attention deficit hyperactivity disorder
ADR	Adverse drug reaction
ADRAC	Adverse drug reaction advisory committee
AE	Adverse event
AEFI	Adverse event following immunization
AHFS	American hospital formulary service
AIDS	Acquired immune deficiency syndrome
AIIMS	All India institute of medical science
ALT	Alanine transaminase
AMC	Adverse drug reaction monitoring centre
AML	Acute Myeloid Leukemia
ANC	Absolute neutrophil count
ANDA	Abbreviated new drug application
AR	Adverse reaction
ASR	Annual safety report
AST	Aspartate transaminase
BID	Bis in die
BLA	Biologics license application
BNF	British national formulary
BP	Blood pressure
BR	Benefit risk

CBC	Complete blood count
CCDS	Company core data sheet
CCSI	Company core safety information
CCTV	Closed- circuit television
CDC	Centre for disease control and prevention
CDSCO	Central drugs standard control organization
CFR	Code of federal regulations
CHM	Commission on human medicines
CIOMS	Council of international organization for medical sciences
CMS	Centres for Medicare and Medicaid services
CNS	Central nervous system
CPS	Compendium of pharmaceuticals and specialties
CPWD	Central public work department
CRO	Contract research organization
CSI	Core safety information
CT	Computerized tomography
CTD	Common technical document
CTP	Core training panel
DEG	Diethylene glycol
DGHS	Directorate general of health services
DILI	Drug induced liver injury
DM	Diabetes mellitus
DSEB	Drug safety and evaluation branch
DSUR	Development safety update report
E2B	Electronic transmission of individual case safety reports

EEA	European economic area
EMEA/EMA	European medicines agency
EU	European union
FDA	Food and drug administration
FEI	Food establishment identifier
GI	Gastro – intestinal
GoI	Government of India
GSR	General statutory rules
HCPs	Health care professionals
HCTER	Human cells and tissue establishment registration
HCV	Hepatitis C Virus
HIV	Human immunodeficiency virus
HR	Human resource
HT	Hypertension
IB	Investigator's brochure
IBD	International birth date
ICH	International Council of Harmonization
ICH-GCP	International Conference on Harmonization – Good Clinical Practice
ICMR	Indian council of medical research
ICSR	Individual Case safety reports
ICU	Intensive care units
ID	Identification
IND	Investigational new drug
INR	International normalized ratio
IP	Indian pharmacopoeia

IPC	Indian pharmacopoeia Commission
ISO	International organization for Standardization
IV	Intravenous
kg	Kilogram
lb	Pound
LKM – 2	Liver kidney microsomal antibody type 2
MAH	Marketing authorization holder
MAUDE	Manufacturer and user facility device experience database
MCHC	Mean corpuscular haemoglobin concentration
MCV	Mean corpuscular volume
MDR	Medical device reporting
MedDRA	Medical dictionary for regulatory activities
Mfr	Manufacturer
MHPD	Marketed products health directorate
MHRA	Medicines and health related products regulatory agency
MIMS	Monthly index of medical specialties
MIS	Management information system
MoHFW	Ministry of health and family welfare
mmHg	Millimetre of mercury
MSSO	MedDRA maintenance and support service organization
MvPI	Meteriovigilance program of India
NA	Not applicable
NACP	National AIDS control programme
NCVIA	National childhood vaccine injury act
NDA	New drug application

NDC	National drug code
NFI	National formulary of India
NHP	National health programmes
NPAC	National Pharmacovigilance advisory committee
NPC	National Pharmacovigilance centre
NPP	National Pharmacovigilance programme
NPPI	National Pharmacovigilance program of India
NVBDCP	National vector borne disease control programme
NYHA	New York heart association
OD	Once daily
OEM	Original equipment manufacturer
OMSM	Office of medicines safety monitoring
OTC	Over the counter
PC	Personal computer
PCP	Promotion, communication and publication
PI	Product information
PMA	Pre- market application
PPC	Peripheral Pharmacovigilance centre
PSUR	Periodic safety update reports
PSVT	Paroxysmal supra ventricular tachycardia
Pv	Pharmacovigilance
PvPI	Pharmacovigilance program of India
QA	Quality assurance
QC	Quality control
QM	Quality manual

QMS	Quality management system
QRP	Quality review panel
RNTCP	Revised national TB control programme
RPC	Regional Pharmacovigilance centre
RTC	Regional training centres
SADRRF	Suspected adverse drug reaction reporting form
SAE	Serious adverse event
SD	Signal detection
SGOT	Serum glutamic oxaloacetic transaminase
SGPT	Serum glutamic pyruvic transaminase
SmPC	Summary of product characteristics
SMQs	Standardized MedDRA Queries
SMS	Safety management system
SOP	Standard operating procedure
SRP	Signal review panel
STN	Submission tracking number
SUSAR	Suspected unexpected serious adverse drug reaction
TB	Tuberculosis
TE	Training and education
TEN	Toxic epidermal necrolysis
TGA	Therapeutic goods administration
TID	Ter in die
UF	User facility
UK	United kingdom
ULN	Upper limit of normal

UMC	Uppsala monitoring centre
UNESCO	United nation educational, scientific and cultural organization
UNK	Unknown
US	United states
USC	United states code
VAERS	Vaccine adverse event reporting systems
WBC	White blood cells
WHO	World health organization
WHO-ART	World health organization adverse reaction terminology
XML	Extensible markup language
ZPC	Zonal Pharmacovigilance centre

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