

## ABBREVIATIONS & ACRONYMS RELEVANT TO APIs - May 2000

AAPS	American Association of Pharmaceutical Scientists
AESGP	Association Européenne des Spécialités Grand Public
ANDA	Abbreviated New Drug Application
APIC	Active Pharmaceutical Ingredients Committee
BP	British Pharmacopoeia
BSE	Bovine Spongiform Encephalopathy
CEO	Chief/Corporate Executive Officer
CEFIC	European Chemical Industry Council
CPMP	Committee of Proprietary Medicinal Products (EU)
CVMP	Committee of Proprietary Veterinary Products (EU)
CRO	Contract Research Organization
CTD	Common Technical Document (Register ICH)
DIA	Drug Information Association (USA)
DOE	Department of Energy (USA)
DSHEA	Dietary Supplement Health and Education Act (USA)
GCP	Good Clinical Practice
GMO	Genetically Modified Organisms
GMP	Good Manufacturing Practice
GLP	Good Laboratory Practice (For Safety Evaluation)
EDQM	European Directorate for the Quality of Medicines
EGA	European Generics Association
EMEA	European Medicines Evaluation Agency
EFPIA	European Federation of Pharmaceutical Industries Associations
EUR PH	European Pharmacopoeia (Commission)
FDA	Food and Drug Administration (USA)
FEDESA	Fédération Européenne de la Santé Animale
GPIA	Generic Pharmaceutical Industry Association
ICH	International Conference of Harmonization
IFPMA	International Federation of Pharmaceutical Manufacturers Associations
IGPA	International Generic Pharmaceutical Association
IPEC	International Pharmaceutical Excipients Council
ISPE	International Society for Pharmaceutical Engineering
MCA	Medicines Control Agency (UK)
NAFTA	North American Free Trade Agreement
NAPM	National Association of Pharmaceutical Manufacturers
NAS	National Academy of Sciences (USA)
NCE	New Chemical Entity
NDA	New Drug Application
NIST	National Institute of Science and Technology (USA)
NPA	National Pharmaceutical Alliance
OC	Oral Contraceptive
OEM	Original Equipment Manufacturer
PCR	Polymerase Chain Reaction
PDUFA	Prescription Drug User Fee Act (USA, 1992)
PEFRAS	Pan European Federation of Regulatory Affairs Society
PhARMA	Pharmaceutical Association of Research-based Manufacturers (PMA, USA)
PIC	Pharmaceutical Inspection Convention (EFTA)
PICS	Pharmaceutical Inspection Cooperation Scheme

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PTO	Patent and Trademark Office (USA)
SMO	Site Management Organization
SPC	Summary of Product Characteristics (EU, DMF per Mutual Recognition Procedure) /// Statistical Process Control
SRM	Specified Risk Material (EU)
TSE	Transmissible Spongiform Encephalopathies (Veure BSE)
USP	United States Pharmacopoeia
VFA	Verband der Forschender Arzneimittelherstellern
VOC	Volatile Organic Compound
WHO	World Health Organization (OMS)
WTO	World Trade Organization