

## APPENDICES

APPENDIX A: Manufacturer and  
Compendium Abbreviations

APPENDIX B: Glossary of Terms

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## APPENDIX A: MANUFACTURER AND COMPENDIUM ABBREVIATIONS<sup>7</sup>

### A

AAB	Apoteket AB
AAP	AAPER Alcohol & Chemical Co
AB	Abbott
ABI	Abic Ltd.
ABV	AbbVie
ABX	Abraxis
ACC	American Critical Care
ACD	Accord Healthcare
ACN	Actelion
ACT	Actavis
AD	Adria
ADM	ADMA Biologics, Inc.
AGT	Aguettant
AH	Allen & Hanburys
AHP	Ascot Hospital Pharmaceuticals
AKN	Akorn
ALP	Alpharma
ALT	Altana-Nycomed
ALV	Alveda Pharma
ALZ	Alza
AM	ASTA Medica
AMB	Amneal Biosciences
AMD	Amdipharm
AMG	Amgen
AMP	Amphastar
AMR	American Regent
AMS	Amerisource
AND	Andromaco
ANT	Antigen
AP	Asta-Pharma
APC	Apothecon
APO	Apotex
APP	American Pharmaceutical Partners
APT	Aspen Triton
AQ	American Quinine
AR	Armour
ARD	Ardeapharm
AS	Arnar-Stone
ASC	Ascot

ASH	Ash-Stevens
ASM	AstraMedica
ASN	Aspen Pharmacare Holdings
ASP	Astellas Pharma
AST	Astra
ASZ	AstraZeneca
AT	Alpha Therapeutic
AUB	Aurobindo
AUR	Auromedics
AVD	Avadel Legacy Pharmaceuticals
AVE	Aventis
AVG	Alvogen
AW	Asta Werke
AY	Ayerst

### B

BA	Baxter
BAN	Banyu Pharmaceuticals
BAX	Baxalta, Inc.
BAY	Bayer
BB	B & B Pharmaceuticals
BC	Bencard
BCT	BioCryst Pharmaceuticals
BD	Becton, Dickinson and Company
BE	Beecham
BED	Bedford
BEH	Behring
BEL	R. Bellon
BFM	Bieffe Medital
BGD	Biogen-Idec
BI	Boehringer Ingelheim
BIO	Bioniche Pharma
BK	Berk
BKN	Baker Norton
BM	Boehringer Mannheim
BMS	Bristol-Myers Squibb
BN	Breon
BP	British Pharmacopeia
BPC	British Pharmaceutical Codex
BPH	Biotest Pharmaceuticals

BPL Bio Products Laboratories  
 BR Bristol  
 BRD Bracco Diagnostics  
 BRK Breckenridge Pharmaceutical, Inc.  
 BRN B. Braun  
 BRT Brianna  
 BT Boots  
 BTK Biotika  
 BV Ben Venue  
 BW Burroughs Wellcome  
 BX Berlex

**C**

CA Calmic  
 CAD Cadence Pharmaceuticals  
 CAN Cangene bioPharma, Inc.  
 CAR Cardinal Health  
 CBH CSL Behring  
 CE Carlo Erba  
 CEL Celltrion  
 CEN Centocor  
 CER Cerenex  
 CET Cetus  
 CG Ciba Geigy  
 CGC Ciba Geigy Canada, LTD  
 CH Lab. Choay Societe Anonyme  
 CHI Chiron  
 CHS Chiesi  
 CI Ciba  
 CIS CIS US  
 CL Clintec  
 CLA Claris Lifesciences  
 CMB Cumberland  
 CN Cannaught  
 CNF Centrafarm  
 CO Cole  
 COM CommScope  
 COR COR Therapeutics  
 COV Covis  
 CP Continental Pharma  
 CPF Coop. Pharmaceutique Francaise  
 CPP CP Pharmaceuticals  
 CR Critikon  
 CRC Caraco  
 CSL CSL Ltd.  
 CSP CSP Benelux

CTI Cell Therapeutics Inc.  
 CU Cutter  
 CUB Cubist  
 CUP Cura Pharmaceuticals  
 CUR Curomed  
 CY Cyanamid

**D**

DAK Dakota  
 DB David Bull Laboratories  
 DCC Dupont Critical Care  
 DI Dista  
 DIA Diamant  
 DIO Diosynth  
 DM Dome  
 DME Dupont Merck Pharma  
 DMX Dumex  
 DRA Dr. Rentschler Arzneimittel  
 DRT Durata Therapeutics  
 DRX Draxis  
 DSM DSM Pharmaceuticals  
 DU DuPont  
 DUR Dura  
 DVL David Vult Laboratories  
 DW Delta West

**E**

EA Eaton  
 EBE Ebewe  
 ECL Éclat  
 EI Eisai  
 EL Enzon, Inc.  
 ELN Elan  
 EN Endo  
 ENZ Enzon  
 ERF Erfa  
 ERM Erempharma  
 ERS E. R. Squibb & Sons, LLC.  
 ES Elkins-Sinn  
 ESL ESI Lederie  
 ESP ESP Pharma  
 EST Esteve  
 EV Evans  
 EX Essex  
 EXL Exela

<b>F</b>			
FA	Farmitalia	HOS	Hospira
FAN	Fandre Laboratories	HP	Hisun Pharmaceuticals
FAU	Faulding	HQS	HQ Specialty Pharma
FC	Frosst & Cie	HR	Horner
FED	Federa	HY	Hyland
FER	Ferring	<b>I</b>	
FGN	Fagron	ICI	ICI Pharmaceuticals
FI	Fisons	ICN	ICN Pharmaceuticals
FL	Funk Labs	ICU	ICU Medical, Inc.
FLU	Fluka Co.	IDX	Interstate Drug Exchange, Inc.
FOR	Forest Laboratories	IMM	Immunex
FP	Faro Pharma	IMS	IMS Ltd.
FRE	Fresenius	IN	Intra
FRK	Fresenius Kabi	INT	Intermune
FUJ	Fujisawa	IV	Ives
<b>G</b>		IVX	Ivex
GAL	Galenova, Inc.	IX	Invenex
GEI	Geistich Pharma	<b>J</b>	
GEM	Geneva-Marsam	JAZ	Jazz
GEN	Genentech	JC	Janssen-Cilag
GG	Geigy	JHP	JHP Pharmaceuticals
GIL	Gilead	JIH	Jiangsu Henfrui Medicine
GIU	Giulini	JJ	Johnson & Johnson
GL	Glaxo	JN	Janssen
GNS	Gensia-Sicor	JP	Jones Pharma
GO	Goedecke	<b>K</b>	
GRI	Grifols	KA	Kabi
GRP	Gruppo	KED	Kedrion
GRU	Grunenthal S.A. Sint-Stevens-Woluwe	KEY	Key Pharmaceuticals
GSK	GlaxoSmithKline	KN	Knoll Pharmaceutical Company
GVA	Geneva	KP	Kabi Pharmacia
GW	Glaxo Wellcome	KV	Kabi-Vitrum
GZ	Genzyme	KY	Kyowa
<b>H</b>		<b>L</b>	
HAE	Haemonetics	LA	Lagap
HAG	Hanseler AG	LAV	Lavoisier Pharmaceutical
HB	Hoechst-Biotika	LB	Leadiant Biosciences
HC	Hillcross	LE	Lederle
HE	Hengrui Medicine Co.	LEI	Leiras, Finland
HER	Heritage	LEM	Lemmon
HIK	Hikma	LEO	Leo Laboratories
HMR	Hoechst Marion Roussel	LFB	Laboratoire Français du Fractionnement et des Biotechnologies
HO	Hoechst-Roussel		

LI Lilly  
 LME Laboratoire Meram  
 LUN Lundbeck  
 LY Lyphomed  
 LZ Labaz Laboratories

**M**

MA Mallinckrodt  
 MAC Maco Pharma  
 MAR Marsam  
 MAY Mayne Pharma  
 MB May & Baker  
 MCD Merck Chibret Dohme  
 MCO Monico spa  
 MDI Medimmune  
 MDX Medex  
 ME Merck  
 MED Medac Pharma, Inc.  
 MEL Melinta Therapeutics  
 MG McGaw  
 MGI MGI Pharma  
 MI Miles  
 MIL Millimed  
 MJ Mead Johnson  
 MM Merrimack  
 MMD Marion Merrell Dow  
 MMT Meridian Medical Technologies  
 MN McNeil  
 MOL Molteni Farmaceutici  
 MON Monarch  
 MRD Merrell-Dow  
 MRN Merrell-National  
 MSD Merck Sharp & Dohme  
 MTN Marathon  
 MUN Mundi Pharma  
 MY Maney  
 MYL Mylan  
 MYR Mayrhofer Pharmazeutika

**N**

NA National  
 NAB Nabi  
 NAP NAPP Pharmaceuticals  
 NCI National Cancer Institute  
 NE Norwich-Eaton  
 NF National Formulary

NIN Ningbo Team  
 NL Normon Laboratories  
 NO Nordic  
 NOP Novopharm  
 NOV Novo Pharm  
 NP Nycomed-Pharma  
 NVA Novartis  
 NVC Novocol Chemical Mfg. Co., Inc.  
 NVN Novo Nordisk  
 NVP Nova Plus  
 NVX Novex Pharma  
 NYC Nycomed

**O**

OB Ortho Biotech  
 OCT Octapharma  
 OHM Ohmeda  
 OM Omega  
 OMJ OMJ Pharmaceuticals  
 OMN Ortho-McNeil  
 ON Orion  
 OR Organon  
 ORC Orchid  
 ORP Orphan Medical  
 ORT Ortho  
 OTS Otsuka

**P**

PAD Paddock  
 PAL Paladin  
 PAN Panpharma Laboratory  
 PAR Par  
 PB Pohl-Boskamp  
 PCC Piramal Critical Care, Inc.  
 PD Parke-Davis  
 PE Pentagone  
 PF Pfizer  
 PFM Pfrimmer  
 PH Pharmacia  
 PHC Pharmachemie  
 PHS Pharmascience  
 PHT Pharma-Tek  
 PHU Pharmacia & Upjohn  
 PHX Phoenix  
 PNN Pantheon  
 PNT Parenta

PO	Poulenc	SCI	Scios
PP	Pharmaceutical Partners	SCN	Schein
PPC	Pharmaceutical Partners of Canada	SCS	SCS Pharmaceuticals
PPR	Premier Pro Rx	SE	Searle
PR	Pasadena Research	SEQ	Sequus
PRF	Pierre Fabre	SER	Servier
PRK	Parkfields	SGS	SangStat
PRM	Premier	SGT	Sagent
PRP	Premier Pro	SH	Spectrum Healthcare
PS	ProStrakan Pharmaceuticals	SHI	Shionogi
PUR	Purdue Pharma, LP	SHN	Shyndec Pharmaceutical Co.
PX	Pharmax	SHP	Shanghai Harvest Pharma
<b>Q</b>		SI	Sigma
QI	Qilu	SIA	Siam Pharmaceutical
QLM	Qualimed Labs	SIC	Sicor
QU	Quad	SIG	Sigma Tau
<b>R</b>		SJN	Samjin Pharmaceutical Co., Ltd.
RB	Robins	SKB	SmithKline Beecham
RBP	Ribosepharm	SKF	Smith Kline & French
RC	Roche	SM	Smith
REC	Recordati	SMX	SteriMax
REN	Renaudin	SN	Smith + Nephew
RI	Riker	SO	SoloPak
RKB	Reckitt & Benckhiser	SP	Spectrum Pharmaceuticals
RKC	Reckitt & Colman	SQ	Squibb
RMS	Repro-Med Systems	SS	Sanofi-Synthelabo
RNB	Ranbaxy Laboratories	ST	Sterilab
ROR	Rorer	STE	Stella
ROX	Roxane Labs	STP	Sterop
RP	Rhône-Poulenc	STR	Sterling
RPR	Rhône-Poulenc-Rorer	STS	Steris
RR	Roerig	STU	Stuart
RS	Roussel	SUN	Sun
RU	Rugby	SV	Savage
<b>S</b>		SW	Sanofi Winthrop
SA	Sankyo	SX	Sabex
SAA	Sanofi Aventis	SY	Syntex
SAB	Sabex	SYN	Synergen
SAG	Sageant	SYO	Synthelabo
SAN	Sanofi	SZ	Sandoz
SAO	Saol Therapeutics	<b>T</b>	
SB	Sintetica Bioren	TAK	Takeda
SC	Schering	TAL	Talon Therapeutics
		TAP	TAP Holdings
		TAR	Targanta Therapeutics

TAS	Talecris
TAY	Taylor
TE	Teva
TEC	Teclapharm
TES	Tesaro
TL	Tillotts
TLP	Therabel Lucien Pharma
TMC	The Medicines Company
TO	Torigian
TPI	Tetraphase Pharmaceuticals, Inc.
TR	Travenol
TYS	Tayside Pharmaceuticals

**U**

UCB	UCB
UN	Unknown
UP	Upjohn
USB	US Bioscience
USP	United States Pharmacopeia
USV	USV Pharmaceuticals
UT	United Therapeutics

**V**

VFP	Vifor Pharma
VHA	VHA Plus
VI	Vitarine
VIC	Vicuron Pharmaceuticals
VT	Vitrum

**W**

WAS	Wasserman
WAT	Watson
WAY	Wyeth-Ayerst
WB	Winthrop-Breon
WC	Warner-Chilcott
WED	Weddel
WEL	Wellcome
WG	WG Critical Care
WI	Winthrop
WL	Warner Lambert
WOC	Wockhardt
WW	West-Ward
WY	Wyeth

**X**

XGN	X-Gen
XU	Xudong Pharmaceutical Co.

**Y**

YAM	Yamanouchi
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**Z**

ZEN	Zeneca
ZLB	ZLB Biopharma
ZNS	Zeneus Pharma
ZY	ZyGenerics

## APPENDIX B: GLOSSARY OF TERMS

**Absorption:** Form of sorption where there is diffusion and retention of a drug molecule within the matrix of the container or administration set material.<sup>6</sup>

**Accuracy:** A measure of the volume or weight of an ingredient to determine that the correct quantities of nutrients, electrolytes, or other components are delivered.<sup>3</sup>

**Adsorption:** Form of sorption where there is a weak and reversible interaction between a drug in solution and the container surface that causes the drug to bind to the surface of the container or administration set.

**Aggregation:** Process by which dispersed droplets come together but do not fuse. May be redispersed with gentle agitation.

**Agitation:** Mixing to evenly disperse a drug or solution.

**Antibiotic lock technique (ALT):** Instillation of a high concentration of antibiotic, usually at least 1000-times higher than the pathogen minimum inhibitory concentration, as a means to penetrate or disrupt biofilms and eradicate or prevent the growth of bacteria in a central venous catheter.

**Beyond-use date:** The date, or the hour and date, beyond which the preparation must not be used and must be discarded. The beyond-use date or BUD is determined from the date/time that preparation of the CSP is initiated. The BUD is not intended to limit the time during which the CSP is administered (e.g., infused).<sup>1</sup>

**Central venous access device (CVAD):** A central venous access device (CVAD) is a catheter whose tip terminates in the lower segment of the superior vena cava. CVADs may be utilized for administration of any type of infusion therapy. The large diameter and high flow of blood permits administration of medications with high osmolality, concentration and/or viscosity, parenteral nutrition, chemotherapy, blood products, and medications with vesicant properties.

**Closure:** Seal on a sterile container that prevents leakage, tampering, or entry of contaminants. A closure is part of a container.<sup>3</sup>

**Coalescence:** The fusion of droplets leading to a decreased number of droplets and an increase in droplet size.

**Commercial product:** A drug product manufactured in large quantities intended for commercial sale.

**Compounded sterile preparation (CSP):** A preparation intended to be sterile that is created by combining, admixing, diluting, pooling, reconstituting, repackaging, or otherwise altering a drug product or bulk drug substance.<sup>1</sup>

**Compounding record:** A detailed record that provides specific compounding instructions, describes how the CSP was prepared, and documents the entire process. Compounding records are specific to each compounding event.

**Concentration:** Amount of active ingredient in a volume of solution (e.g., mg/mL).

**Container:** That which holds the preparation and is or may be in direct contact with the preparation. The closure is part of the container.<sup>3</sup>

**Cracking:** Coalescence of an emulsion continues to a point of complete separation and an oily layer is seen at the top.

**Creaming:** Formation of a layer of aggregates at the emulsion surface.

**Degradation:** Chemical and physical changes of a drug during storage resulting in modified pharmacological outcomes, altering the therapeutic or toxic profile.

**Diluent:** Ingredient in a compounded sterile preparation that lacks pharmacologic activity but is necessary for the dissolution of drug(s) to be administered parenterally.

**Dissolution:** The process of dissolving one substance into another. A dissolution test measures the amount of drug that goes into solution over time.

**Elastomeric container:** Containers made of materials obtained by vulcanization (cross-linking) polymerization, polyaddition, or polycondensation of macromolecular organic substances (elastomers). Formulations contain natural or synthetic elastomers and inorganic and organic additives to aid or control vulcanization, impart physical and chemical properties or color, or stabilize the container formulation.<sup>2</sup>

**Emulsion:** A dosage form consisting of a two-phase system composed of at least two immiscible liquids, one of which is dispersed as droplets with the other liquid, generally stabilized with one or more emulsifying agents.<sup>5</sup> Oil-in-water mixture requiring an emulsifying agent to disperse the oil phase into the aqueous phase.

**Evaporation:** Loss of water through the container material.

**Expiration date:** Date that identifies the time during which a conventionally manufactured drug product, active ingredient, or added substance can be expected to meet the requirements of a compendial monograph, if one exists, or maintain expected quality provided it is kept under the specified storage conditions. Expiration dates are assigned by manufacturers and are not the same as beyond-use dates (BUDs).<sup>1</sup>



- Extended stability:** The maximum time period in which 90% or greater of a labeled active ingredient is measurable in the solution and container specified, under the stated storage conditions. An exception applies to coagulation factors, which are considered stable when at least 80% of the factor activity is retained.
- Extrapolation:** The prediction or estimation of a variable beyond the given data set by observing its relation with other variables in the existing data set.
- Flocculation:** Process by which dispersed droplets come together, but do not fuse, and may be redispersed with gentle agitation.
- Hydrolysis:** The chemical process of drug degradation by water. For aqueous solutions, pH, presence of acids or bases, drug concentration, and temperature are all factors that could affect the rate of hydrolysis.
- Inert:** Chemically inactive, and does not contain additives or other compounds that may potentially migrate into the finished preparation.
- Infusate:** A fluid given parenterally for a therapeutic purpose.
- Leaching:** Components of the plastic formulation (such as from a container) migrate into the infusate, contaminating the drug solution.
- Lipophilic:** The ability of a compound to dissolve in lipid-containing solutions.
- Lock:** The final step in intravenous therapy administration when the vascular access device (VAD) will remain in place for future therapy to prevent occlusion or infection of a catheter between uses.
- Master formulation record:** A detailed record that provides specific compounding instructions and describes how the CSP was prepared. Master formulation records should contain sufficient detail to be used on their own without additional verbal explanation.
- Microbial contamination:** Introduction of infectious material into a sterile solution.
- Midline catheter:** Midline catheters measure 38 inches with the tip terminating in veins located between the elbow and shoulder. Midline catheter duration of therapy is typically 1 to 4 weeks. This type of catheter is an alternative to PICCs for certain indications, and intravenous solutions appropriate for administration into the peripheral vasculature.
- Osmolality:** The measure of particles of solute per kilogram of solvent (mOsm/kg), and contributes to the osmotic pressure of a solution.
- Osmolarity:** The measure of particles of solute per liter of solution (mOsm/L), and contributes to the osmotic pressure of a solution.
- Overfill:** Addition of a sufficient amount of excess solution to allow for water vapor transmission losses out of the container over the shelf life of the product, and to account for the variation in the amount of solution dispensed by compounding or administration devices. USP <1151>, *Pharmaceutical Dosage Forms*, recommends an excess volume of 2% of the labeled container size for mobile liquids.<sup>5</sup>
- Oxidation:** The chemical process of drug degradation by oxygen. Factors that affect the rate of oxidation include the presence of oxygen, light, heavy metal ions, temperature, pH, and the presence of other drugs or chemicals that act as oxidizing agents.
- Parenteral nutrition:** Intravenous administration of nutrition, which may include protein, carbohydrates, fats, minerals, electrolytes, and vitamins.
- Peripheral catheter:** Peripheral catheters are usually 1 to 1.5 inches in length with the tip terminating in a peripheral vein. This type of catheter should not be used for continuous infusions of vesicants, parenteral nutrition, or infusates > 900 mOsm/L. The anticipated duration of therapy is generally less than 6 days.
- Peripherally inserted central catheter (PICC):** A peripherally inserted central catheter (PICC) is a type of non-tunneled CVAD that is inserted in the antecubital space into the basilic, brachial, or cephalic veins and advanced within the blood vessel to achieve central placement.
- Permeation:** Loss of container contents by allowing vapor, water, or drug molecules to migrate through the wall of the container.
- Peroxidation:** Peroxidation of lipids occurs as a free radical-mediated chain of reactions that results in an oxidative degradation of lipid emulsions.
- Plasticizer:** Component added to a plastic material to make it softer and more flexible.
- Precipitation:** Reaction upon mixing of drugs or solutions resulting in insoluble particulates that may be observed as crystals, haziness, or turbidity.
- Preservative:** A substance added to inhibit microbial growth.<sup>1</sup>
- Product:** A commercially manufactured sterile drug or nutrient that has been evaluated for safety and efficacy by the US Food and Drug Administration (FDA). Products are accompanied by full prescribing information, which is commonly known as the FDA-approved manufacturer's labeling or product package insert.
- Ready-to-use (RTU):** Commercially manufactured product that does not require additional compounding prior to administration.
- Reconstitution:** The process of adding a diluent to a conventionally manufactured product to prepare a sterile solution or suspension.<sup>1</sup>
- Shearing:** Occurs from differences of fluid velocity in moving liquids between the solution and the surface, such as a solution going through syringes

and administration sets. It may promote interfacial reactions for solid-liquid (adsorption, leaching), gas-liquid (air-bubble entrapment), and oil-water (silicon lubricants).

**Sorption:** Drug loss from a solution intended to be administered by adsorption to the surface or absorption into the matrix of the container material, administration set, or filter.<sup>3</sup>

**Stability:** The extent to which a product or preparation retains physical and chemical properties and characteristics within specified limits throughout its expiration or BUD.<sup>1</sup>

**Standard operating procedure (SOP):** Written procedures describing operations, testing, sampling, interpretation of results, and corrective actions that relate to the operations that are taking place.<sup>4</sup>

**Sterility:** The absence of viable microorganisms.<sup>1</sup>

**Temperature excursion:** Occurs when a temperature reading is outside the recommended range for the medication as defined in the manufacturer's package insert.

**Turbidity:** Cloudiness or haziness of a solution caused by large numbers of individual particles.

**Vascular access device (VAD):** Vascular access devices are flexible catheters inserted into a vein to deliver infusion therapy.

**Vial-bag connector:** Specialized point-of-care activated devices and bags that allow for the connection of a vial of medication to a small volume infusion container.

**Visual inspection:** Immediately after compounding, and as a condition of release, each CSP unit, where possible, should be inspected against a lighted white or black

background or both for evidence of visible particulates or other foreign matter. Prerelease inspection also includes container-closure integrity and any other apparent visual defect. When CSPs are not distributed promptly after preparation, a pre-distribution inspection is conducted to ensure that a CSP with defects, such as precipitation, cloudiness, and leakage, which may develop between the time of release and the time of distribution, is not released.

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