PART III

APPENDICES

APPENDIX A: MANUFACTURER AND COMPENDIUM ABBREVIATIONS[7]

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

DOI 10.37573/9781585286720.PT3001

BPL	Bio Products Laboratories
BR	Bristol
BRD	Bracco Diagnostics
BRK	Breckenridge Pharmaceutical, Inc.
BRN	B. Braun
BRT	Britianna
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

F

FA	Farmitalia
FAN	Fandre Laboratories
FAU	Faulding
FC	Frosst & Cie
FED	Federa
FER	Ferring
FGN	Fagron
FI	Fisons
FL	Funk Labs
FLU	Fluka Co.
FOR	Forest Laboratories
FP	Faro Pharma
FRE	Fresenius
FRK	Fresenius Kabi
FUJ	Fujisawa

G

GAL	Galenova, Inc.
GEI	Geistich Pharma
GEM	Geneva-Marsam
GEN	Genentech
GG	Geigy
GIL	Gilead
GIU	Giulini
GL	Glaxo
GNS	Gensia-Sicor
GO	Goedecke
GRI	Grifols
GRP	Gruppo
GRU	Grunenthal S.A. Sint-Stevens-Woluwe
GSK	GlaxoSmithKline
GVA	Geneva
GW	Glaxo Wellcome
GZ	Genzyme

H

HAE	Haemonetics
HAG	Hanseler AG
HB	Hoechst-Biotika
HC	Hillcross
HE	Hengrui Medicine Co.
HER	Heritage
HIK	Hikma
HMR	Hoechst Marion Roussel
HO	Hoechst-Roussel
HOS	Hospira
HP	Hisun Pharmaceuticals
HQS	HQ Specialty Pharma
HR	Horner
HY	Hyland

I

ICI	ICI Pharmaceuticals
ICN	ICN Pharmaceuticals
ICU	ICU Medical, Inc.
IDX	Interstate Drug Exchange, Inc.
IMM	Immunex
IMS	IMS Ltd.
IN	Intra
INT	Intermune
IV	Ives
IVX	Ivex
IX	Invenex

J

JAZ	Jazz
JC	Janssen-Cilag
JHP	JHP Pharmaceuticals
JIH	Jiangsu Henfrui Medicine
JJ	Johnson & Johnson
JN	Janssen
JP	Jones Pharma

K

KA	Kabi
KED	Kedrion
KEY	Key Pharmaceuticals
KN	Knoll Pharmaceutical Company
KP	Kabi Pharmacia
KV	Kabi-Vitrum
KY	Kyowa

L

LA	Lagap
LAV	Lavoisier Pharmaceutical
LB	Leadiant Biosciences
LE	Lederle
LEI	Leiras, Finland
LEM	Lemmon
LEO	Leo Laboratories
LFB	Laboratorie Français du Fractionnement et des Biotechnologies

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
PP	Pharmaceutical Partners
PPC	Pharmaceutical Partners of Canada
PPR	Premier Pro Rx
PR	Pasadena Research
PRF	Pierre Fabre
PRK	Parkfields
PRM	Premier
PRP	Premier Pro
PS	ProStrakan Pharmaceuticals
PUR	Purdue Pharma, LP
PX	Pharmax

Q

QI	Qilu
QLM	Qualimed Labs
QU	Quad

R

RB	Robins
RBP	Ribosepharm
RC	Roche
REC	Recordati
REN	Renaudin
RI	Riker
RKB	Reckitt & Benckhiser
RKC	Reckitt & Colman
RMS	Repro-Med Systems
RNB	Ranbaxy Laboratories
ROR	Rorer
ROX	Roxane Labs
RP	Rhône-Poulenc
RPR	Rhône-Poulenc-Rorer
RR	Roerig
RS	Roussel
RU	Rugby

S

SA	Sankyo
SAA	Sanofi Aventis
SAB	Sabex
SAG	Sageant
SAN	Sanofi
SAO	Saol Therapeutics
SB	Sintetica Bioren
SC	Schering
SCI	Scios
SCN	Schein
SCS	SCS Pharmaceuticals
SE	Searle
SEQ	Sequus
SER	Servier
SGS	SangStat
SGT	Sagent
SH	Spectrum Healthcare
SHI	Shionogi
SHN	Shyndec Pharmaceutical Co.
SHP	Shanghai Harvest Pharma
SI	Sigma
SIA	Siam Pharmaceutical
SIC	Sicor
SIG	Sigma Tau
SJN	Samjin Pharmaceutical Co., Ltd.
SKB	SmithKline Beecham
SKF	Smith Kline & French
SM	Smith
SMX	SteriMax
SN	Smith + Nephew
SO	SoloPak
SP	Spectrum Pharmaceuticals
SQ	Squibb
SS	Sanofi-Synthelabo
ST	Sterilab
STE	Stella
STP	Sterop
STR	Sterling
STS	Steris
STU	Stuart
SUN	Sun
SV	Savage
SW	Sanofi Winthrop
SX	Sabex
SY	Syntex
SYN	Synergen
SYO	Synthelabo
SZ	Sandoz

T

TAK	Takeda
TAL	Talon Theraputics
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

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.[6]

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.[3]

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).[1]

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.[3]

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.[1]

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.[3]

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.[2]

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.[5] 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).[1]

DOI 10.37573/9781585286720.PT3002

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.[5]

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.[1]

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.[1]

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.[3]

Stability: The extent to which a product or preparation retains physical and chemical properties and characteristics within specified limits throughout its expiration or BUD.[1]

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.[4]

Sterility: The absence of viable microorganisms.[1]

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.

REFERENCES

1. USP <797> Pharmaceutical Compounding - Sterile Preparations. In: *2020: USP Compounding Compendium*. Rockville, MD: The United States Pharmacopeial Convention; 2020:40-74.
2. USP <381> Elastomeric Closures for Injections. In: *2020: USP Compounding Compendium*. Rockville, MD: The United States Pharmacopeial Convention; 2020:208-14.
3. Glossary. In: Buchanan EC, Schneider PJ, Forrey RA eds. *Compounding Sterile Preparations*. 4th ed. Bethesda, MD: American Society of Health-System Pharmacists; 2017:551-66.
4. USP <800> Hazardous Drugs - Handling in Healthcare Settings. In: *2020: USP Compounding Compendium*. Rockville, MD: The United States Pharmacopeial Convention; 2020:74-92.
5. USP <1151> Pharmaceutical Dosage Forms. In: *2020: USP Compounding Compendium*. Rockville, MD: The United States Pharmacopeial Convention; 2020:408-30.
6. Bing CD. Storage and beyond-use dating. In: Buchanan EC, Schneider PJ, Forrey RA eds. *Compounding Sterile Preparations*. 4th ed. Bethesda, MD: American Society of Health-System Pharmacists; 2017:213-26.
7. ASHP's Interactive Handbook on Injectable Drugs, 2020. Bethesda, MD: American Society of Health-System Pharmacists; Accessed February 2021.