

name: 7-(*R*)-[2-(2-amino-4-thiazol)acetamido]-3-[[[1-(2-dimethylamino)ethyl]-1*H*-tetrazol-5-yl]thio] methyl]-3-cephem-4-carboxylic acid.

(61) *Mupirocin*. Each of the antibiotic substances produced by the growth of *Pseudomonas fluorescens*, and each of the same substances produced by any other means, is a kind of mupirocin.

(62) *Cefmetazole*. Cefmetazole is an antibiotic substance having the chemical structure described by the following name: (6*R*-*cis*)-7-[[[cyanomethyl]thio]acetyl]amino]-7-methoxy-3-[[1-(methyl-1*H*-tetrazol-5-yl)thio]methyl]-8-oxo-5-thia-1-azabicyclo[4.2.0]oct-2-ene-2-carboxylic acid.

(63) *Cefpiramide*. Cefpiramide is an antibiotic substance having the chemical structure described by the following name: (6*R*, 7*R*)-7-[(*R*)-2-(4-hydroxy-6-methyl-nicotinamido)-2-(*p*-hydroxyphenyl)acetamido]-3-[[1-(methyl-1*H*-tetrazol-5-yl)thio]methyl]-8-oxo-5-thia-1-azabicyclo[4.2.0]oct-2-ene-2-carboxylic acid.

(64) *Clarithromycin*. Clarithromycin is 6-O-methylerythromycin A.

(65) *Azithromycin*. Azithromycin is an antibiotic substance having the chemical structure described by the following name: (2*R*,3*S*,4*R*,5*R*,8*R*,10*R*,11*R*,12*S*,13*S*,14*R*)-13-[(2,6-dideoxy-3-*C*-methyl-3-*O*-methyl- $\alpha$ -*L*-ribo-hexopyranosyl)oxy]-2-ethyl-3,4,10-trihydroxy-3,5,6,8,10,12,14-heptamethyl-11-[[3,4,6-trideoxy-3-(dimethylamino)- $\beta$ -*D*-xylo-hexopyranosyl]oxy]-1-oxa-6-azacyclopentadecan-15-one.

(66) *Cefprozil*. Cefprozil is an antibiotic substance having the chemical structure described by the following name: (6*R*,7*R*)-7-[(*R*)-2-amino-2-(*p*-hydroxyphenyl)acetamido]8-oxo-3-propenyl-5-thia-1-azabicyclo[4.2.0]oct-2-ene-2-carboxylic acid. It is a mixture of the *Z* (*cis*) and *E* (*trans*) isomers in an approximate ratio of 9:1, respectively.

(67) *Idarubicin*. Idarubicin is an anthracycline antibiotic substance having the chemical structure described by the following name: 5,12-Naphthacenedione, 9-acetyl-7-[(3-amino-2,3,6-trideoxy- $\alpha$ -*L*-lyxo-hexopyranosyl)oxy]-7,8,9,10-tetrahydro-6,9,11-trihydroxy-(7*S*-*cis*).

(68) *Loracarbef*. Loracarbef is an antibiotic substance having the chemical structure described by the following name: (6*R*,7*S*)-7-[(*R*)-2-amino-2-phenylacetamido]-3-chloro-8-oxo-1-azabicyclo[4.2.0]oct-2-ene-2-carboxylic acid.

(69) *Rifabutin*. Rifabutin is an antibiotic substance having the chemical structure described by the following name: (9*S*,12*E*,14*S*,15*R*,16*S*,17*R*,18*R*,19*R*,20*S*,21*S*,22*E*, 24*Z*)-6,16, 18,20-tetrahydroxy-1'-isobutyl-14-methoxy-7,9,15,17,19,21,25-heptamethylspiro[9,4-(epoxy-pentadeca[1,11,13]trienimino)-2*H*-furo[2',3':7,8]naphth[1,2-*d*]imidazole-2,4'-piperidine]-5,10,26-(3*H*,9*H*)-trione-16-acetate.

(70) *Cefpodoxime proxetil*. Cefpodoxime proxetil is an antibiotic substance having the chemical structure described by the following name: ( $\pm$ )-1-Hydroxyethyl(+)-(6*R*,7*R*)-7-[2-(2-amino-4-thiazolyl)glyoxylamido]-3-(methoxymethyl)-8-oxo-5-thia-1-azabicyclo[4.2.0]oct-2-ene-2-carboxylate,7<sup>2</sup>-(*Z*)-(O-methyloxime), isopropyl carbonate (ester).

(b) [Reserved]

[39 FR 18925, May 30, 1974]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 430.4, see the List of CFR Sections Affected in the Finding Aids section of this volume.

#### § 430.5 Definitions of master and working standards.

(a) *Master standards*—(1) *Penicillin and salts of penicillin*—(i) *Penicillin G* The term “penicillin G master standard” means a specific lot of crystalline penicillin G that is designated by the Commissioner as the standard of comparison in determining the potency of the penicillin G working standard.

(ii) [Reserved]

(iii) *Penicillin V*. The term “penicillin V master standard” means a specific lot of crystalline penicillin V that is designated by the Commissioner as the standard of comparison in determining the potency of the penicillin V working standard.

(iv)–(v) [Reserved]

(vi) *Methicillin*. The term “methicillin master standard” means a specific lot of crystalline methicillin that is designated by the Commissioner

as the standard of comparison in determining the potency of the methicillin working standard.

(vii) *Oxacillin*. The term "oxacillin master standard" means a specific lot of crystalline oxacillin that is designated by the Commissioner as the standard of comparison in determining the potency of the oxacillin working standard.

(viii) *Ampicillin*. The term "ampicillin master standard" means a specific lot of crystalline ampicillin that is designated by the Commissioner as the standard of comparison in determining the potency of the ampicillin working standard.

(ix) *Nafcillin*. The term "nafcillin master standard" means a specific lot of crystalline nafcillin that is designated by the Commissioner as the standard of comparison in determining the potency of the nafcillin working standard.

(x) *Cloxacillin*. The term "cloxacillin master standard" means a specific lot of crystalline cloxacillin that is designated as the standard of comparison in determining the potency of the cloxacillin working standard.

(xi) *Dicloxacillin*. The term "dicloxacillin master standard" means a specific lot of dicloxacillin that is designated by the Commissioner as the standard of comparison in determining the potency of the dicloxacillin working standard.

(xii) The term "hetacillin working standard" means a specific lot of homogenous preparation of hetacillin.

(2) *Streptomycin*. The term "streptomycin master standard" means a specific lot of streptomycin that is designated by the Commissioner as the standard of comparison in determining the potency of the streptomycin working standard.

(3) *Dihydrostreptomycin*. The term "dihydrostreptomycin master standard" means a specific lot of crystalline dihydrostreptomycin that is designated by the Commissioner as the standard of comparison in determining the potency of the dihydrostreptomycin working standard.

(4) *Chlortetracycline*. The term "chlortetracycline master standard" means a specific lot of crystalline chlortetracycline hydrochloride that is

designated by the Commissioner as the standard of comparison in determining the potency of the chlortetracycline working standard.

(5) *Demeclocycline*. The term "demeclocycline master standard" means a specific lot of crystalline demeclocycline hydrochloride that is designated by the Commissioner as the standard of comparison in determining the potency of the demeclocycline working standard.

(6) *Tetracycline*. The term "tetracycline master standard" means a specific lot of crystalline tetracycline hydrochloride that is designated by the Commissioner as the standard of comparison in determining the potency of the tetracycline working standard.

(7) *Rolitetracycline*. The term "rolitetracycline master standard" means a specific lot of crystalline rolitetracycline that is designated by the Commissioner as the standard of comparison in determining the potency of the rolitetracycline working standard.

(8) *Chloramphenicol*. The term "chloramphenicol master standard" means a specific lot of crystalline chloramphenicol that is designated by the Commissioner as the standard of comparison in determining the potency of the chloramphenicol working standard.

(9) *Bacitracin*. The term "bacitracin master standard" means a specific lot of bacitracin that is designated by the Commissioner as the standard of comparison in determining the potency of the bacitracin working standard.

(10) [Reserved]

(11) *Amphotericin*. The term "amphotericin A master standard" means a specific lot of amphotericin A designated by the Commissioner as the standard of comparison in determining the potency of the amphotericin A working standard. The term "amphotericin B master standard" means a specific lot of amphotericin B designated by the Commissioner as the standard of comparison in determining the potency of the amphotericin B working standard.

(12) *Colistin*. The term "colistin master standard" means a specific lot of colistin designated by the Commissioner as the standard of comparison in

determining the potency of the colistin working standard.

(13) *Colistimethate*. The term “colistimethate master standard” means a specific lot of colistimethate designated by the Commissioner as the standard of comparison in determining the potency of the colistimethate working standard.

(14) *Cycloserine*. The term “cycloserine master standard” means a specific lot of cycloserine designated by the Commissioner as the standard of comparison in determining the potency of the cycloserine working standard.

(15) *Erythromycin*. The term “erythromycin master standard” means a specific lot of erythromycin designated by the Commissioner as the standard of comparison in determining the potency of the erythromycin working standard.

(16) *Gramicidin*. The term “gramicidin master standard” means a specific lot of gramicidin designated by the Commissioner as the standard of comparison in determining the potency of the gramicidin working standard.

(17) *Griseofulvin*. The term “griseofulvin master standard” means a specific lot of griseofulvin designated by the Commissioner as the standard of comparison in determining the potency of the griseofulvin working standard.

(18) *Kanamycin*. The term “kanamycin master standard” means a specific lot of kanamycin designated by the Commissioner as the standard of comparison in determining the potency of the kanamycin working standard.

(19) *Neomycin*. The term “neomycin master standard” means a specific lot of neomycin designated by the Commissioner as the standard of comparison in determining the potency of the neomycin working standard.

(20) *Novobiocin*. The term “novobiocin master standard” means a specific lot of novobiocin designated by the Commissioner as the standard of comparison in determining the potency of the novobiocin working standard.

(21) *Nystatin*. The term “nystatin master standard” means a specific lot of nystatin designated by the Commissioner as the standard of comparison in determining the potency of the nystatin working standard.

(22) *Oleandomycin*. The term “oleandomycin master standard”

means a specific lot of oleandomycin designated by the Commissioner as the standard of comparison in determining the potency of the oleandomycin working standard.

(23) *Oxytetracycline*. The term “oxytetracycline master standard” means a specific lot of oxytetracycline designated by the Commissioner as the standard of comparison in determining the potency of the oxytetracycline working standard.

(24) *Paromomycin*. The term “paromomycin master standard” means a specific lot of paromomycin designated by the Commissioner as the standard of comparison in determining the potency of the paromomycin working standard.

(25) *Polymyxin B*. The term “polymyxin B master standard” means a specific lot of polymyxin B designated by the Commissioner as the standard of comparison in determining the potency of the polymyxin B working standard.

(26) [Reserved]

(27) *Vancomycin*. The term “vancomycin master standard” means a specific lot of vancomycin designated by the Commissioner as the standard of comparison in determining the potency of the vancomycin working standard.

(28) [Reserved]

(29) *Troleandomycin*. The term “troleandomycin master standard” means a specific lot of troleandomycin designated by the Commissioner as the standard of comparison in determining the potency of the troleandomycin working standard.

(30) *Gentamicin*. The term “gentamicin master standard” means a specific lot of gentamicin designated by the Commissioner as the standard of comparison in determining the potency of the gentamicin working standard.

(31) *Dactinomycin*. The term “dactinomycin master standard” means a specific lot of dactinomycin designated by the Commissioner as the standard of comparison in determining the potency of the dactinomycin working standard.

(32) *Candidin*. The term “candidin master standard” means a specific lot of candidin that is designated by the Commissioner as the standard of comparison in determining the potency of the candidin working standard.

(33) *Cephalothin*. The term “cephalothin master standard” means a specific lot of cephalothin designated by the Commissioner as the standard of comparison in determining the potency of the cephalothin working standard.

(34) *Lincomycin*. The term “lincomycin master standard” means a specific lot of lincomycin designated by the Commissioner as the standard of comparison in determining the potency of the lincomycin working standard.

(35) *Methacycline*. The term “methacycline master standard” means a specific lot of methacycline designated by the Commissioner as the standard of comparison in determining the potency of the methacycline working standard.

(36) *Doxycycline*. The term “doxycycline master standard” means a specific lot of  $\alpha$ -6-deoxyoxytetracycline designated by the Commissioner as the standard of comparison in determining the potency of the doxycycline working standard.

(37) *Cephaloridine*. The term “cephaloridine master standard” means a specific lot of cephaloridine that is designated by the Commissioner as the standard of comparison in determining the potency of the cephaloridine working standard.

(38) *Plicamycin*. The term “plicamycin master standard” means a specific lot of plicamycin designated by the Commissioner as the standard of comparison in determining the potency of the plicamycin working standard.

(39) *Clindamycin*. The term “clindamycin master standard” means a specific lot of clindamycin designated by the Commissioner as the standard of comparison in determining the potency of the clindamycin working standard.

(40) *Cephaloglycin*. The term “cephaloglycin master standard” means a specific lot of cephaloglycin designated by the Commissioner as the standard of comparison in determining the potency of the cephaloglycin working standard.

(41) *Carbenicillin*. The term “carbenicillin master standard” means a specific lot of carbenicillin designated by the Commissioner as the standard of comparison in determining the potency of the carbenicillin working standard.

(42) *Cephalexin*. The term “cephalexin master standard” means a specific lot of cephalexin that is designated by the Commissioner as the standard of comparison in determining the potency of the cephalexin working standard.

(43) [Reserved]

(44) *Capreomycin*. The term “capreomycin master standard” means a specific lot of capreomycin designated by the Commissioner as the standard of comparison in determining the potency of the capreomycin working standard.

(45) *Rifampin*. The term “rifampin master standard” means a specific lot of rifampin designated by the Commissioner as the standard of comparison in determining the potency of the rifampin working standard.

(46) *Minocycline*. The term “minocycline master standard” means a specific lot of minocycline designated by the Commissioner as the standard of comparison in determining the potency of the minocycline working standard.

(47) *Spectinomycin*. The term “spectinomycin master standard” means a specific lot of spectinomycin designated by the Commissioner as the standard of comparison in determining the potency of the spectinomycin working standard.

(48) *Clindamycin palmitate hydrochloride*. The term “clindamycin palmitate hydrochloride master standard” means a specific lot of clindamycin palmitate hydrochloride designated by the Commissioner as the standard of comparison in determining the potency of the clindamycin palmitate hydrochloride working standard.

(49) *Carbenicillin indanyl*. The term “carbenicillin indanyl master standard” means a specific lot of carbenicillin indanyl designated by the Commissioner as the standard of comparison in determining the potency of the carbenicillin indanyl working standard.

(50) *Cephapirin*. The term “cephapirin master standard” means a specific lot of cephapirin that is designated by the Commissioner as the standard of comparison in determining the potency of the cephapirin working standard.

(51) *Cefazolin*. The term “cefazolin master standard” means a specific lot

of cefazolin that is designated by the Commissioner as the standard of comparison in determining the potency of the cefazolin working standard.

(52) *Mitomycin*. The term “mitomycin master standard” means a specific lot of crystalline mitomycin that is designated by the Commissioner as the standard of comparison in determining the potency of the mitomycin working standard.

(53) *Amoxicillin*. The term “amoxicillin master standard” means a specific lot of amoxicillin that is designated by the Commissioner as the standard of comparison in determining the potency of the amoxicillin working standard.

(54) [Reserved]

(55) *Cephadrine*. The term “cephadrine master standard” means a specific lot of cephradine that is designated by the Commissioner as the standard of comparison in determining the potency of the cephradine working standard.

(56) *Doxorubicin*. The term “doxorubicin master standard” means a specific lot of crystalline doxorubicin that is designated by the Commissioner as the standard of comparison in determining the potency of the doxorubicin working standard.

(57) *Bleomycin*. The term “bleomycin master standard” means a specific lot of bleomycin designated by the Commissioner as the standard of comparison in determining the potency of the bleomycin working standard.

(58) *Tobramycin*. The term “tobramycin master standard” means a specific lot of tobramycin designated by the Commissioner as the standard of comparison in determining the potency of the tobramycin working standard.

(59) *Amikacin*. The term “amikacin master standard” means a specific lot of amikacin designated by the Commissioner as the standard of comparison in determining the potency of the amikacin working standard.

(60) *Vidarabine*. The term “vidarabine master standard” means a specific lot of vidarabine that is designated by the Commissioner as the standard of comparison in determining the potency of the vidarabine working standard.

(61) *Ticarcillin*. The term “ticarcillin master standard” means a specific lot

of ticarcillin designated by the Commissioner as the standard of comparison in determining the potency of the ticarcillin working standard.

(62) *Cefadroxil*. The term “cefadroxil master standard” means a specific lot of cefadroxil that is designated by the Commissioner as the standard of comparison in determining the potency of the cefadroxil working standard.

(63) *Natamycin*. The term “natamycin master standard” means a specific lot of natamycin designated by the Commissioner as the standard of comparison in determining the potency of the natamycin working standard.

(64) *Cefoxitin*. The term “cefoxitin master standard” means a specific lot of cefoxitin that is designated by the Commissioner as the standard of comparison in determining the potency of the cefoxitin working standard.

(65) *Cefamandole*. The term “cefamandole master standard” means a specific lot of cefamandole that is designated by the Commissioner as the standard of comparison in determining the potency of the cefamandole working standard.

(66) *Cefaclor*. The term “cefaclor master standard” means a specific lot of cefaclor that is designated by the Commissioner as the standard of comparison in determining the potency of the cefaclor working standard.

(67) *Cyclacillin*. The term “cyclacillin master standard” means a specific lot of cyclacillin that is designated by the Commissioner as the standard of comparison in determining the potency of the cyclacillin working standard.

(68) *Daunorubicin*. The term “daunorubicin master standard” means a specific lot of daunorubicin that is designated by the Commissioner as the standard of comparison in determining the potency of the daunorubicin working standard.

(69) *Sisomicin*. The term “sisomicin master standard” means a specific lot of sisomicin that is designated by the Commissioner as the standard of comparison in determining the potency of the sisomicin working standard.

(70) *Meclocycline*. The term “meclocycline master standard” means a specific lot of meclocycline that is designated by the Commissioner as the standard of comparison in determining

the potency of the meclocycline working standard.

(71) *Cefotaxime*. The term “cefotaxime master standard” means a specific lot of cefotaxime that is designated by the Commissioner as the standard of comparison in determining the potency of the cefotaxime working standard.

(72) *Mezlocillin*. The term “mezlocillin master standard” means a specific lot of mezlocillin that is designated by the Commissioner as the standard of comparison in determining the potency of the mezlocillin working standard.

(73) *Moxalactam*. The term “moxalactam master standard” means a specific lot of moxalactam that is designated by the Commissioner as the standard of comparison in determining the potency of the moxalactam working standard.

(74) *Piperacillin*. The term “piperacillin master standard” means a specific lot of piperacillin that is designated by the Commissioner as the standard of comparison in determining the potency of the piperacillin working standard.

(75) *Azlocillin*. The term “azlocillin master standard” means a specific lot of azlocillin that is designated by the Commissioner as the standard of comparison in determining the potency of the azlocillin working standard.

(76) *Cefoperazone*. The term “cefoperazone master standard” means a specific lot of cefoperazone that is designated by the Commissioner as the standard of comparison in determining the potency of the cefoperazone working standard.

(77) *Netilmicin*. The term “netilmicin master standard” means a specific lot of netilmicin that is designated by the Commissioner as the standard of comparison in determining the potency of the netilmicin working standard.

(78) *Cefuroxime*. The term “cefuroxime master standard” means a specific lot of cefuroxime that is designated by the Commissioner as the standard of comparison in determining the potency of the cefuroxime working standard.

(79) *Ceftizoxime*. The term “ceftizoxime master standard” means a specific lot of ceftizoxime that is designated by the Commissioner as the standard of comparison in determining

the potency of the ceftizoxime working standard.

(80) *Cyclosporine*. The term “cyclosporine master standard” means a specific lot of cyclosporine that is designated by the Commissioner as the standard of comparison in determining the potency of the cyclosporine working standard.

(81) *Ceforanide*. The term “ceforanide master standard” means a specific lot of ceforanide that is designated by the Commissioner as the standard of comparison in determining the potency of the ceforanide working standard.

(82) *Cefonidic*. The term “cefonicid master standard” means a specific lot of cefonidic that is designated by the Commissioner as the standard of comparison in determining the potency of the cefonidic working standard.

(83) *Clavulanic acid*. The term “clavulanic acid master standard” means a specific lot of clavulanic acid or a salt thereof that is designated by the Commissioner as the standard of comparison in determining the potency of the clavulanic acid working standard.

(84) *Amdinocillin*. The term “amdinocillin master standard” means a specific lot of amdinocillin that is designated by the Commissioner as the standard of comparison in determining the potency of the amdinocillin working standard.

(85) *Ceftriaxone*. The term “ceftriaxone master standard” means a specific lot of ceftriaxone that is designated by the Commissioner as the standard of comparison in determining the potency of the ceftriaxone working standard.

(86) *Ceftazidime*. The term “ceftazidime master standard” means a specific lot of ceftazidime that is designated by the Commissioner as the standard of comparison in determining the potency of the ceftazidime working standard.

(87) *Imipenem*. The term “imipenem master standard” means a specific lot of imipenem that is designated by the Commissioner as the standard of comparison in determining the potency of the imipenem working standard.

(88) *Cefotetan*. The term “cefotetan master standard” means a specific lot of cefotetan that is designated by the

Commissioner as the standard of comparison in determining the potency of the cefotetan working standard.

(89) *Aztreonam*. The term “aztreonam master standard” means a specific lot of aztreonam that is designated by the Commissioner as the standard of comparison in determining the potency of the aztreonam working standard.

(90) *Sulbactam*. The term “sulbactam master standard” means a specific lot of sulbactam that is designated by the Commissioner as the standard of comparison in determining the potency of the sulbactam working standard.

(91) *Cefuroxime axetil*. The term “cefuroxime axetil master standard” means a specific lot of cefuroxime axetil that is designated by the Commissioner as the standard of comparison in determining the potency of the cefuroxime axetil working standard.

(92) *Cefmenoxime*. The term “cefmenoxime master standard” means a specific lot of cefmenoxime that is designated by the Commissioner as the standard of comparison in determining the potency of the cefmenoxime working standard.

(93) *Cefixime*. The term “cefixime master standard” means a specific lot of cefixime that is designated by the Commissioner as the standard of comparison in determining the potency of the cefixime working standard.

(94) *Cefotiam*. The term “cefotiam master standard” means a specific lot of cefotiam that is designated by the Commissioner as the standard of comparison in determining the potency of the cefotiam working standard.

(95) *Clindamycin phosphate*. The term “clindamycin phosphate master standard” means a specific lot of clindamycin phosphate that is designated by the Commissioner as the standard for comparison in determining the potency of the clindamycin phosphate standard.

(96) *Mupirocin*. The term “mupirocin master standard” means a specific lot of mupirocin or a salt thereof that is designated by the Commissioner as the standard of comparison in determining the potency of the mupirocin working standard.

(97) *Cefmetazole*. The term “cefmetazole master standard” means a specific lot of cefmetazole that is des-

ignated by the Commissioner as the standard of comparison in determining the potency of the cefmetazole working standard.

(98) *Cefpiramide*. The term “cefpiramide master standard” means a specific lot of cefpiramide that is designated by the Commissioner as the standard of comparison in determining the potency of the cefpiramide working standard.

(99) *Clarithromycin*. The term “clarithromycin master standard” means a specific lot of clarithromycin that is designated by the Commissioner as the standard of comparison in determining the potency of the clarithromycin working standard.

(100) *Azithromycin*. The term “azithromycin master standard” means a specific lot of azithromycin that is designated by the Commissioner as the standard of comparison in determining the potency of the azithromycin working standard.

(101) *Cefprozil*. The term “cefprozil master standard” means a specific lot of the (Z) isomer of cefprozil and a specific lot of the (E) isomer of cefprozil that are designated by the Commissioner as the standard of comparison in determining the potency of the cefprozil working standard.

(102) *Idarubicin*. The term “idarubicin master standard” means a specific lot of idarubicin that is designated by the Commissioner as the standard of comparison in determining the potency of the idarubicin working standard.

(103) *Loracarbef*. The term “loracarbef master standard” means a specific lot of loracarbef that is designated by the Commissioner as the standard of comparison in determining the potency of the loracarbef working standard.

(104) *Rifabutin*. The term “rifabutin master standard” means a specific lot of rifabutin that is designated by the Commissioner as the standard of comparison in determining the potency of the rifabutin working standard.

(105) *Cefpodoxime proxetil*. The term “cefpodoxime proxetil master standard” means a specific lot of the (R) isomer of cefpodoxime proxetil that is designated by the Commissioner as the standard of comparison in determining the potency of the cefpodoxime proxetil working standard.

(b) *Working standards.* The potency or purity of each preparation has been determined by comparison with its master standard, and each has been designated by the Commissioner as working standards for use in determining the potency or purity of antibiotic substances subject to the regulations in this chapter. Unless otherwise noted, the working standard and the U.S.P. reference standard for the antibiotic drug named are identical.

(1) *Penicillin.* (i) The term "penicillin G working standard" means a specific lot of a homogeneous preparation of penicillin G.

(ii) [Reserved]

(iii) The term "penicillin V working standard" means a specific lot of a homogeneous preparation of penicillin V.

(iv) [Reserved]

(v) The term "methicillin working standard" means a specific lot of a homogeneous preparation of methicillin.

(vi) The term "oxacillin working standard" means a specific lot of a homogeneous preparation of oxacillin.

(vii) The term "ampicillin working standard" means a specific lot of a homogeneous preparation of ampicillin.

(viii) The term "nafcillin working standard" means a specific lot of a homogeneous preparation of nafcillin.

(ix) The term "cloxacillin working standard" means a specific lot of a homogeneous preparation of cloxacillin.

(x) The term "penicillin G procaine working standard" means a specific lot of a homogeneous preparation of penicillin G procaine.

(xi) The term "dicloxacillin working standard" means a specific lot of a homogeneous preparation of dicloxacillin.

(xii) The term "bacampicillin hydrochloride working standard" means a specific lot of a homogeneous preparation of bacampicillin hydrochloride.

(2) *Amphotericin A.* The term "amphotericin A working standard" means a specific lot of a homogeneous preparation of amphotericin A.

(3) *Amphotericin B.* The term "amphotericin B working standard" means a specific lot of a homogeneous preparation of amphotericin B.

(4) *Streptomycin.* The term "streptomycin working standard" means a specific lot of a homogeneous preparation of streptomycin.

(5) *Dihydrostreptomycin.* The term "dihydrostreptomycin working standard" means a specific lot of a homogeneous preparation of dihydrostreptomycin.

(6) *Chlortetracycline.* The term "chlortetracycline working standard" means a specific lot of a homogeneous preparation of chlortetracycline.

(7) *Demeclocycline.* The term "demeclocycline working standard" means a specific lot of a homogeneous preparation of demeclocycline.

(8) *Tetracycline.* The term "tetracycline working standard" means a specific lot of a homogeneous preparation of tetracycline.

(9) *Rolitetetracycline.* The term "rolitetetracycline working standard" means a specific lot of a homogeneous preparation of rolitetetracycline.

(10) *Chloramphenicol.* The term "chloramphenicol working standard" means a specific lot of a homogeneous preparation of chloramphenicol.

(11) *Bacitracin.* The term "bacitracin working standard" means a specific lot of a homogeneous preparation of bacitracin.

(12) [Reserved]

(13) *Colistin.* The term "colistin working standard" means a specific lot of a homogeneous preparation of colistin.

(14) *Colistimethate.* The term "colistimethate working standard" means a specific lot of a homogeneous preparation of colistimethate.

(15) *Cycloserine.* The term "cycloserine working standard" means a specific lot of a homogeneous preparation of cycloserine.

(16) *Erythromycin.* The term "erythromycin working standard" means a specific lot of a homogeneous preparation of erythromycin.

(17) *Gramicidin.* The term "gramicidin working standard" means a specific lot of a homogeneous preparation of gramicidin.

(18) *Griseofulvin.* The term "griseofulvin working standard" means a specific lot of a homogeneous preparation of griseofulvin.

(19) *Kanamycin.* The term "kanamycin working standard" means a specific lot of a homogeneous preparation of kanamycin.

(20) *Neomycin.* The term "neomycin working standard" means a specific lot

of a homogeneous preparation of neomycin.

(21) *Novobiocin*. The term “novobiocin working standard” means a specific lot of a homogeneous preparation of novobiocin.

(22) *Nystatin*. The term “nystatin working standard” means a specific lot of a homogeneous preparation of nystatin.

(23) *Oleandomycin*. The term “oleandomycin working standard” means a specific lot of a homogeneous preparation of oleandomycin.

(24) *Troleandomycin*. The term “troleandomycin working standard” means a specific lot of a homogeneous preparation of troleandomycin.

(25) *Oxytetracycline*. The term “oxytetracycline working standard” means a specific lot of a homogeneous preparation of oxytetracycline.

(26) *Paromomycin*. The term “paromomycin working standard” means a specific lot of a homogeneous preparation of paromomycin.

(27) *Polymyxin B*. The term “polymyxin B working standard” means a specific lot of a homogeneous preparation of polymyxin B.

(28) *Vancomycin*. The term “vancomycin working standard” means a specific lot of a homogeneous preparation of vancomycin.

(29) [Reserved]

(30) *Gentamicin*. The term “gentamicin working standard” means a specific lot of a homogeneous preparation of gentamicin.

(31) *Dactinomycin*. The term “dactinomycin working standard” means a specific lot of a homogeneous preparation of dactinomycin.

(32) *Candididin*. The term “candididin working standard” means a specific lot of a homogeneous preparation of candididin.

(33) *Cephalothin*. The term “cephalothin working standard” means a specific lot of a homogeneous preparation of cephalothin.

(34) *Lincomycin*. The term “lincomycin working standard” means a specific lot of a homogeneous preparation of lincomycin.

(35) *Methacycline*. The term “methacycline working standard”

means a specific lot of homogeneous preparation of methacycline.

(36) *Doxycycline*. The term “doxycycline working standard” means a specific lot of homogeneous preparation of  $\alpha$ -6-deoxyoxytetracycline.

(37) *Cephaloridine*. The term “cephaloridine working standard” means a specific lot of homogeneous preparation of cephaloridine.

(38) *Plicamycin*. The term “plicamycin working standard” means a specific lot of a homogeneous preparation of plicamycin.

(39) *Clindamycin*. The term “clindamycin working standard” means a specific lot of a homogeneous preparation of clindamycin.

(40) *Cephaloglycin*. The term “cephaloglycin working standard” means a specific lot of homogeneous preparation of cephaloglycin.

(41) *Carbenicillin*. The term “carbenicillin working standard” means a specific lot of homogeneous preparation of carbenicillin.

(42) *Cephalexin*. The term “cephalexin working standard” means a specific lot of a homogeneous preparation of cephalexin.

(43) [Reserved]

(44) *Capreomycin*. The term “capreomycin working standard” means a specific lot of a homogeneous preparation of capreomycin.

(45) *Rifampin*. The term “rifampin working standard” means a specific lot of a homogeneous preparation of rifampin.

(46) *Minocycline*. The term “minocycline working standard” means a specific lot of a homogeneous preparation of minocycline.

(47) *Spectinomycin*. The term “spectinomycin working standard” means a specific lot of a homogeneous preparation of spectinomycin.

(48) *Clindamycin palmitate hydrochloride*. The term “clindamycin palmitate hydrochloride working standard” means a specific lot of a homogeneous preparation of clindamycin palmitate hydrochloride.

(49) *Carbenicillin indanyl*. The term “carbenicillin indanyl working standard” means a specific lot of a homogeneous preparation of carbenicillin indanyl.

(50) *Cephapirin*. The term “cephapirin working standard” means a specific lot of a homogeneous preparation of cephapirin.

(51) *Cefazolin*. The term “cefazolin working standard” means a specific lot of a homogeneous preparation of cefazolin.

(52) *Mitomycin*. The term “mitomycin working standard” means a specific lot of a homogeneous preparation of mitomycin.

(53) *Amoxicillin*. The term “amoxicillin working standard” means a specific lot of a homogeneous preparation of amoxicillin.

(54) [Reserved]

(55) *Cephradine*. The term “cephradine working standard” means a specific lot of a homogeneous preparation of cephradine.

(56) *Doxorubicin*. The term “doxorubicin working standard” means a specific lot of a homogeneous preparation of doxorubicin.

(57) *Bleomycin*. The term “bleomycin working standard” means a specific lot of a homogeneous preparation of bleomycin.

(58) *Tobramycin*. The term “tobramycin working standard” means a specific lot of a homogeneous preparation of tobramycin.

(59) *Amikacin*. The term “amikacin working standard” means a specific lot of a homogeneous preparation of amikacin.

(60) *Vidarabine*. The term “vidarabine working standard” means a specific lot of a homogeneous preparation of vidarabine.

(61) *Ticarcillin*. The term “ticarcillin working standard” means a specific lot of a homogeneous preparation of ticarcillin.

(62) *Cefadroxil*. The term “cefadroxil working standard” means a specific lot of a homogeneous preparation of cefadroxil.

(63) *Natamycin*. The term “natamycin working standard” means a specific lot of a homogeneous preparation of natamycin.

(64) *Cefoxitin*. The term “cefoxitin working standard” means a specific lot of a homogeneous preparation of cefoxitin.

(65) *Cefamandole*. The term “cefamandole working standard”

means a specific lot of a homogeneous preparation of cefamandole.

(66) *Cefaclor*. The term “cefaclor working standard” means a specific lot of a homogeneous preparation of cefaclor.

(67) *Cyclacillin*. The term “cyclacillin working standard” means a specific lot of a homogeneous preparation of cyclacillin.

(68) *Daunorubicin*. The term “daunorubicin working standard” means a specific lot of a homogeneous preparation of daunorubicin.

(69) *Sisomicin*. The term “sisomicin working standard” means a specific lot of a homogeneous preparation of sisomicin.

(70) *Meclocycline*. The term “meclocycline working standard” means a specific lot of a homogeneous preparation of meclocycline.

(71) *Cefotaxime*. The term “cefotaxime working standard” means a specific lot of a homogeneous preparation of cefotaxime.

(72) *Mezlocillin*. The term “mezlocillin working standard” means a specific lot of a homogeneous preparation of mezlocillin.

(73) *Moxalactam*. The term “moxalactam working standard” means a specific lot of a homogeneous preparation of moxalactam.

(74) *Piperacillin*. The term “piperacillin working standard” means a specific lot of a homogeneous preparation of piperacillin.

(75) *Azlocillin*. The term “azlocillin working standard” means a specific lot of a homogeneous preparation of azlocillin.

(76) *Cefoperazone*. The term “cefoperazone working standard” means a specific lot of a homogeneous preparation of cefoperazone.

(77) *Netilmicin*. The term “netilmicin working standard” means a specific lot of a homogeneous preparation of netilmicin.

(78) *Cefuroxime*. The term “cefuroxime working standard” means a specific lot of a homogeneous preparation of cefuroxime.

(79) *Ceftizoxime*. The term “ceftizoxime working standard” means a specific lot of a homogeneous preparation of ceftizoxime.

(80) *4-Epitetracycline*. The term “4-epitetracycline working standard” means a specific lot of a homogeneous preparation of 4-epitetracycline.

(81) *Chloramphenicol palmitate*. The term “chloramphenicol palmitate working standard” means a specific lot of a homogeneous preparation of chloramphenicol palmitate.

(82) *Cyclosporine*. The term “cyclosporine working standard” means a specific lot of a homogeneous preparation of cyclosporine.

(83) *Ceforanide*. The term “ceforanide working standard” means a specific lot of a homogeneous preparation of ceforanide.

(84) *Cefonicid*. The term “cefonicid working standard” means a specific lot of a homogeneous preparation of cefonicid.

(85) *Clavulanic acid*. The term “clavulanic acid working standard” means a specific lot of a homogeneous preparation of clavulanic acid or a salt thereof.

(86) *Amdinocillin*. The term “amdinocillin working standard” means a specific lot of a homogeneous preparation of amdinocillin.

(87) *Ceftriaxone*. The term “ceftriaxone working standard” means a specific lot of a homogeneous preparation of ceftriaxone.

(88) *Ceftazidime*. The term “ceftazidime working standard” means a specific lot of a homogeneous preparation of ceftazidime.

(89) *Imipenem*. The term “imipenem working standard” means a specific lot of a homogeneous preparation of imipenem.

(90) *Cefotetan*. The term “cefotetan working standard” means a specific lot of a homogeneous preparation of cefotetan.

(91) *Aztreonam*. The term “aztreonam working standard” means a specific lot of a homogeneous preparation of aztreonam.

(92) *Sulbactam*. The term “sulbactam working standard” means a specific lot of a homogeneous preparation of sulbactam.

(93) *Cefuroxime axetil*. The term “cefuroxime axetil working standard” means a specific lot of a homogeneous preparation of cefuroxime axetil.

(94) *Cefmenoxime*. The term “cefmenoxime working standard” means a specific lot of a homogeneous preparation of cefmenoxime.

(95) *Cefixime*. The term “cefixime working standard” means a specific lot of a homogeneous preparation of cefixime.

(96) *Cefotiam*. The term “cefotiam working standard” means a specific lot of a homogeneous preparation of cefotiam.

(97) *Clindamycin phosphate*. The term “clindamycin phosphate working standard” means a specific lot of a homogeneous preparation of clindamycin phosphate.

(98) *Mupirocin*. The term “mupirocin working standard” means a specific lot of a homogeneous preparation of mupirocin or a salt thereof.

(99) *Cefmetazole*. The term “cefmetazole working standard” means a specific lot of a homogeneous preparation of cefmetazole.

(100) *Cefpiramide*. The term “cefpiramide working standard” means a specific lot of a homogeneous preparation of cefpiramide.

(101) *Clarithromycin*. The term “clarithromycin working standard” means a specific lot of a homogeneous preparation of clarithromycin.

(102) *Azithromycin*. The term “azithromycin working standard” means a specific lot of a homogeneous preparation of azithromycin.

(103) *Cefprozil*. The term “cefprozil (Z) working standard” means a specific lot of a homogeneous preparation of cefprozil (Z). The term “cefprozil (E) working standard” means a specific lot of a homogeneous preparation of cefprozil (E).

(104) *Idarubicin*. The term “idarubicin working standard” means a specific lot of a homogeneous preparation of idarubicin.

(105) *Loracarbef*. The term “loracarbef working standard” means a specific lot of a homogeneous preparation of loracarbef.

(106) *Rifabutin*. The term “rifabutin working standard” means a specific lot of a homogeneous preparation of rifabutin.

(107) *Cefpodoxime proxetil*. The term "cefpodoxime proxetil working standard" means a specific lot of a homogeneous preparation of cefpodoxime proxetil.

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EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 430.5, see the List of CFR Sections Affected appearing in the Finding Aids section of this volume.

**§ 430.6 Definitions of the terms "unit" and "microgram" as applied to antibiotic substances.**

Unless it has been otherwise specified in the individual definitions in this section, the activity assigned to each "unit" or "microgram" is equivalent to an International Unit, if such has been defined by the World Health Organization.

(a) "Unit"—(1) *Penicillin*—(i) *Penicillin G*. The term "unit" applies to penicillin G means the penicillin activity (potency) contained in 0.600 microgram of the penicillin G master standard.

(ii) [Reserved]

(iii) *Penicillin V*. The term "unit" applied to penicillin V means the penicillin activity (potency) contained in 0.590 microgram of the penicillin V master standard.

(2) *Bacitracin*. The term "unit" applied to bacitracin means a bacitracin activity (potency) contained in 13.51 micrograms of the bacitracin master standard, except that when the activity (potency) of bacitracin is expressed in terms of its weight, as in the feed and drinking water of animals, 1 gram of activity is equivalent to 42,000 units.

(3) *Nystatin*. The term "unit" applied to nystatin means the nystatin activity (potency) contained in 0.2817 microgram of the nystatin master standard when dried for 2 hours at 40° C. and a pressure of 5 millimeters or less.

(4) *Polymyxin B*. The term "unit" applied to polymyxin B means the polymyxin activity (potency) contained in 0.1274 microgram of the polymyxin B master standard when dried for 3 hours at 60° C. and a pressure of 5 millimeters or less.

(5) *Bleomycin*. The term "unit" applied to bleomycin means the bleomycin activity (potency) contained

in 0.637 milligram of the bleomycin master standard.

(b) "Microgram"—(1) *Streptomycin*. The term "microgram" applied to streptomycin means the streptomycin activity (potency) contained in 1.250 micrograms of the streptomycin master standard after it is dried for 3 hours at 60° C. and a pressure of 5 millimeters or less.

(2) *Dihydrostreptomycin*. The term "microgram" applied to dihydrostreptomycin means the dihydrostreptomycin activity (potency) contained in 1.25 micrograms of the dihydrostreptomycin master standard after it is dried for 4 hours at 100° C. and a pressure of 50 microns or less.

(3) *Chlortetracycline*. The term "microgram" applied to chlortetracycline means the chlortetracycline activity (potency) contained in 1.0 microgram of the chlortetracycline master standard.

(4) *Demeclocycline*. The term "microgram" applied to demeclocycline means the demeclocycline activity (potency) contained in 1.0 microgram of the demeclocycline master standard after it is dried for 3 hours at 60° C. and a pressure of 5 millimeters or less.

(5) *Tetracycline*. The term "microgram" applied to tetracycline means the tetracycline activity (potency) contained in 1.0 microgram of tetracycline master standard.

(6) *Rolitetracycline*. The term "microgram" applied to rolitetracycline means the rolitetracycline activity (potency) contained in 1.0 microgram of the rolitetracycline master standard when dried for 3 hours at 60° C. and a pressure of 5 millimeters or less.

(7) *Chloramphenicol*. The term "microgram" applied to chloramphenicol means the chloramphenicol activity (potency) contained in 1.0 microgram of the chloramphenicol master standard.

(8) *Methicillin*. The term "microgram" applied to methicillin means the methicillin activity (potency) contained in 1.105 micrograms of the methicillin master standard.

(9) *Oxacillin*. The term "microgram" applied to oxacillin means the oxacillin activity (potency) contained in 1.111