CLINICAL AND LABORATORY STANDARDS INSTITUTE®

1st Edition

EP37

Supplemental Tables for Interference Testing in Clinical Chemistry

This document includes recommended testing concentrations for analytes and endogenous substances that may interfere in clinical chemistry measurement procedures and is intended for use with the evaluation procedures in the Clinical and Laboratory Standards Institute guideline EP07.

A CLSI supplement for global application.

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Supplemental Tables for Interference Testing in Clinical Chemistry

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Abstract

The supplemental tables presented in this document are intended for use with the evaluation procedures presented in CLSI document EP07—*Interference Testing in Clinical Chemistry*. EP07 describes protocols for manufacturers of *in vitro* diagnostic measurement procedures to screen potentially interfering substances, quantify interference effects, and confirm interference in patient samples. It also describes procedures for medical laboratories to verify interference claims and investigate discrepant results caused by unsuspected interfering substances. The supplemental tables in EP37 provide recommended test concentrations for analytes and endogenous substances that may interfere in clinical chemistry measurement procedures.

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Contents

Foreword

The interference testing process has remained relatively stable for many years. Recent updates were made to CLSI document EP07 to clarify the procedures and provide simpler options for data analysis. Because the interference testing process is stable, EP07 is unlikely to be updated frequently. However, medical therapies are constantly evolving. Therefore, to more frequently update the tables of possible interferents and their recommended testing concentrations, EP07's former Appendixes C and D have been removed from that guideline and placed into this supplement as Tables 1 and 2. Several changes were made to the information, including:

- Adding international units and the conversion factor
- For drugs, including the drug structure, molecular formula, and molar mass
- Including more drugs

NOTE: The content of this document is supported by the CLSI consensus process and does not necessarily reflect the views of any single individual or organization.

Key Words

Interference, interference testing, interferents, test concentrations

Abbreviations and Acronyms

AIDS	acquired immunodeficiency syndrome
ATP	adenosine triphosphate
CNS	central nervous system
DNA	deoxyribonucleic acid
EDTA	ethylenediaminetetraacetic acid
GABA	gamma-aminobutyric acid
GI	gastrointestinal
HIV	human immunodeficiency virus
ID-MS	isotope dilution mass spectrometry
INN	International Nonproprietary Name
LDL	low-density lipoprotein
MRSA	methicillin-resistant *Staphylococcus aureus*
pH	negative logarithm of hydrogen ion concentration
RNA	ribonucleic acid
SI	Système International d'Unités (International System of Units)

Supplemental Tables for Interference Testing in Clinical Chemistry

Instructions for Use of Table 1

Table 1 provides recommended test concentrations for many common drugs and some drug metabolites and anticoagulant agents. These concentrations are provided in both mg/dL and µmol/L units (except where indicated differently, eg, heparin in units/dL). The recommended test concentrations are typically three times the highest drug concentrations expected during treatment, except when such a high concentration is not achievable.

NOTE: Recommended test concentrations may be rounded for ease of preparation.

The conversion factor for converting from mass units to molar units is provided. In addition, the molecular formula and chemical structure are provided for most of the drugs. In some cases, the molecular formula or chemical structure is too complex to include.

NOTE 1: The numbers in Table 1 are reported differently than in previous editions of EP07. Concentrations are shown in exponential notation of base 10 to display values uniformly across the very wide range of concentrations.

NOTE 2: The compounds listed in Table 1 are listed using the International Nonproprietary Name (INN) and, when different, the name used by the United States Adopted Names (USAN) Council is also given. When the names are different, the USAN name is listed first, with the INN listed in parentheses.

Conversion of Exponential Notation Units

- **Positive exponent:** Move the decimal point to the right by the number of places specified by the exponent (ie, number after E). For example, to convert 5-aminosalicylic acid to the highest drug concentration under therapeutic treatment in µmol/L:

  1. Locate the value under the heading **Highest Drug Concentration Under Therapeutic Treatment, µmol/L:** 4.44E+01.

  2. As indicated by "01" after "+," move the decimal point in "4.44" one place to the right, ie, multiply by 10: 4.44 • 10 = 44.4 µmol/L.

- **Negative exponent:** Move the decimal point to the left by the number of places specified by the exponent (ie, number after E).

  For example, to convert abiraterone to the highest drug concentration under therapeutic treatment in mg/dL:

  1. Locate the value under the heading **Highest Drug Concentration Under Therapeutic Treatment, mg/dL:** 2.26E−02.

  2. As indicated by "02" after "−," move the decimal point two places to the left, ie, divide by 100: 2.26/ 100 = 0.0226 mg/dL.

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- **00 exponent:** Use the stated value with no adjustment.

  For example, to find the abacavir test concentration in mg/dL:

  1. Locate the value under the heading **Recommended Test Concentration, mg/dL:** 1.27E+00.

  2. As indicated by "00" after "+," the decimal point does not move and the value is used as shown: 1.27 mg/dL.

Conversion of Mass Concentration to Molar Concentration

To convert from mass concentration (eg, mg/dL) to molar concentration (eg, µmol/L), multiply the mass concentration by the conversion factor listed in Table 1. For example, the mass to molar concentration conversion for 5-aminosalicylic acid is: 6.80E−01 mg/dL • 6.54E+01 = 44.4E+01 µmol/L.

When a factor is not available, convert the units as shown in the following example:

millimoles = mmol/L

EXAMPLE: Convert 110 mg/dL glucose to molar units, then to millimoles, as follows:

The chemical formula for glucose is $C_6H_{12}O_6$.

1. Determine the gram molecular weight of $C_6H_{12}O_6$.
   The molecular weight is the sum of the atomic weights of carbon, hydrogen, and oxygen:
   C (carbon) = 12.01 g/mol • 6 = 72.06 g/mol
   H (hydrogen) = 1.01 g/mol • 12 = 12.12 g/mol
   O (oxygen) = 15.99 g/mol • 6 = 95.94 g/mol
   The sum of C + H + O = 72.06 + 12.12 + 95.94 = 180.12 g/mol.
   The gram molecular weight of glucose is 180.12 g/mol.

2. Determine the molar units for 110 mg/dL glucose.
   a) Use the gram molecular weight to convert the units:

$$\frac{110\,\text{mg}}{\text{dL}} \bullet \frac{10\,\text{dL}}{\text{L}} = \frac{1100\,\text{mg}}{\text{L}} \bullet \frac{1\,\text{g}}{1000\,\text{mg}} = \frac{1.10\,\text{g}}{\text{L}} \bullet \frac{1\,\text{mol}}{180.12\,\text{g}} = \frac{0.0061\,\text{mol}}{\text{L}}$$

   b) Convert to millimoles:

$$\frac{0.0061\,\text{mol}}{\text{L}} \bullet \frac{1000\,\text{mmol}}{\text{mol}} = \frac{6.105\,\text{mmol}}{\text{L}}$$

110 mg/dL glucose converted to molar units is 6.105 mmol/L.

Conversion of Molar Concentration to Mass Concentration

EXAMPLE: Convert 66.49 nmol/L of dopamine to mg/dL:

The chemical formula for dopamine is $C_8H_{11}NO_2$.

1. Determine the gram molecular weight of $C_8H_{11}NO_2$.
   The molecular weight is the sum of the atomic weights of carbon, hydrogen, nitrogen, and oxygen:

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C (carbon) = 12.01 g/mol • 8 = 96.08 g/mol
H (hydrogen) = 1.01 g/mol • 11 = 11.11 g/mol
N (nitrogen) = 14.01 g/mol • 1 = 14.01 g/mol
O (oxygen) = 15.99 g/mol • 2 = 31.98 g/mol
The sum of C + H + O = 96.087 + 11.11 + 14.01 + 31.98 = 153.18 g/mol.
The gram molecular weight of dopamine is 153.18 g/mol.

2. Determine the mass units for 66.49 nmol/L of dopamine.
   a) Determine the molar concentration:

$$\frac{66.49\,\text{nmol}}{\text{L}} \bullet \frac{1\,\mu\text{mol}}{1000\,\text{nmol}} = \frac{0.06649\,\mu\text{mol}}{\text{L}} \bullet \frac{1\,\text{mmol}}{1000\,\mu\text{mol}} = \frac{6.649\times10^{-5}\,\text{mmol}}{\text{L}} \bullet \frac{1\,\text{mol}}{1000\,\text{mmol}} = \frac{6.649\times10^{-8}\,\text{mol}}{\text{L}}$$

   b) Using the gram molecular weight, convert to mg/dL:

$$\frac{6.649\times10^{-8}\text{mol}}{\text{L}} \bullet \frac{153.18\text{g}}{\text{mol}} = \frac{1.018\times10^{-5}\text{g}}{\text{L}} \bullet \frac{1\text{L}}{10\text{dL}} = \frac{1.018\times10^{-6}\text{g}}{\text{dL}} \bullet \frac{1000\text{mg}}{\text{g}} = \frac{0.001\text{mg}}{\text{dL}} = \frac{1\times10^{-3}\text{mg}}{\text{dL}}$$

66.49 nmol/L dopamine converted to mass units is 0.001 mg/dL.

NOTE: The atomic weights have been rounded to hundredths.

Determination of the Highest Drug Concentration Under Therapeutic Treatment

The "highest drug concentration under therapeutic treatment" is the highest drug concentration (known as peak concentration and shown in Figure 1) in the blood or plasma during therapeutic treatment that has been measured and published in the literature. It is not the therapeutic concentration.

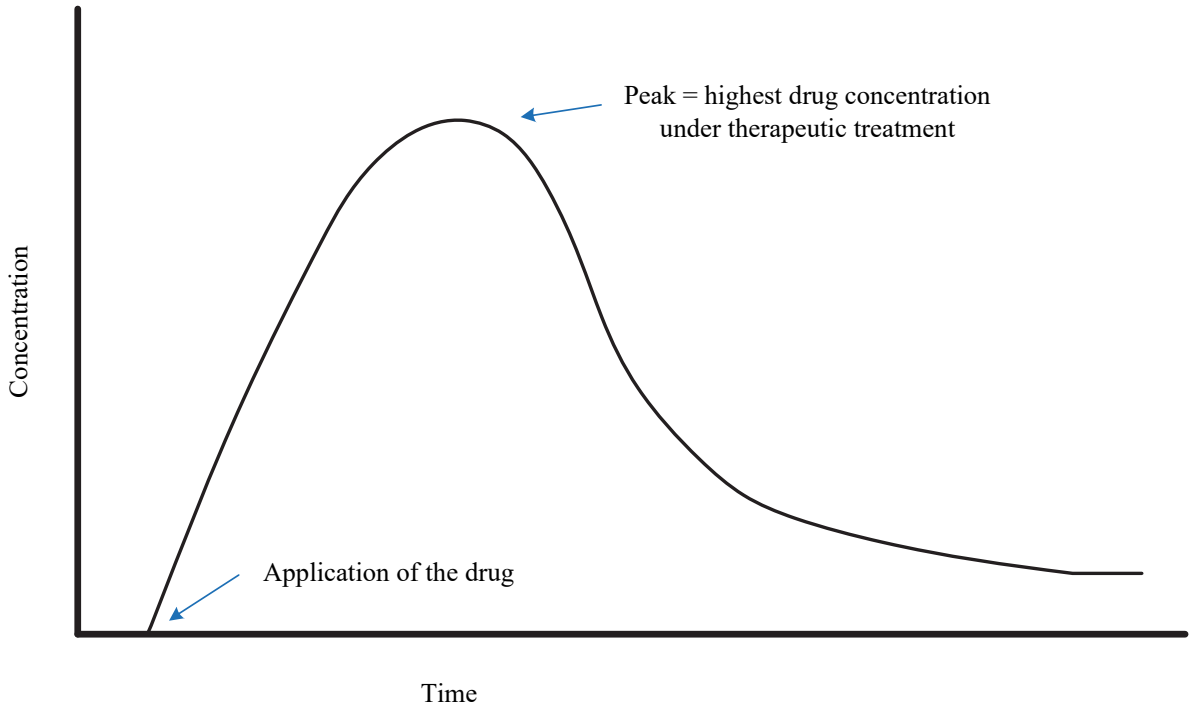

Figure 1. Typical Pharmacokinetics of a Drug

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Table 1. Testing Concentrations for Exogenous Interferents

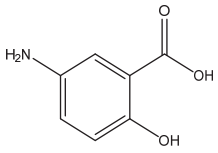
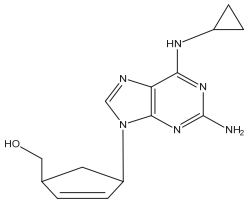
Exogenous Potential Interferent (Drug INN)	Chemical Structure	Comments	Highest Drug Concentration Under Therapeutic Treatment, mg/dL	Conversion Factor	Highest Drug Concentration Under Therapeutic Treatment, µmol/L	Molecular Formula	Molar Mass, g/mol	Recommended Test Concentration, mg/dL	Recommended Test Concentration, µmol/L
5-Aminosalicylic acid		• Used to treat ulcerative colitis • Anti-inflammatory agent • Low acute oral toxicity	6.80E−01	6.54E+01	4.44E+01	$C_7H_7NO_3$	1.53E+02	2.04E+00	1.33E+02
Abacavir		• HIV reverse transcriptase inhibitor • Antiviral agent • Shows anti-HIV activity	4.24E−01	3.49E+01	1.48E+01	$C_{14}H_{18}N_6O$	2.86E+02	1.27E+00	4.44E+01
Abatacept	—	• Selective costimulation modulator • Binds to the B7 family of molecules expressed on antigen-presenting cells • Used to treat autoimmune diseases such as rheumatoid arthritis • Composed of 2 homologous glycosylated polypeptide chains of CTLA4Ig of approximately 46 kDa, each of which are held together by 1 disulfide bond and noncovalent interactions	2.95E+01	1.09E−01	3.21E+00	$C_{3498}H_{5458}N_{922}O_{1090}S_{32}$	9.20E+04	8.85E+01	9.62E+00

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Table 1. (Continued)

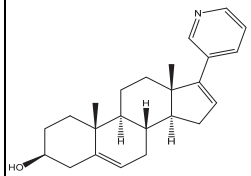
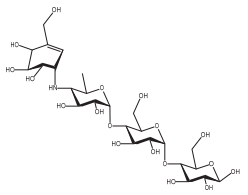
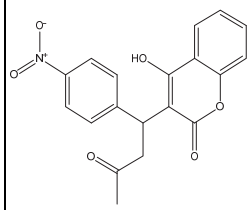
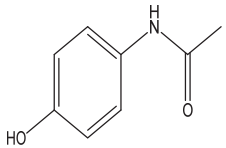
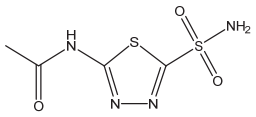
Exogenous Potential Interferent (Drug INN)	Chemical Structure	Comments	Highest Drug Concentration Under Therapeutic Treatment, mg/dL	Conversion Factor	Highest Drug Concentration Under Therapeutic Treatment, µmol/L	Molecular Formula	Molar Mass, g/mol	Recommended Test Concentration, mg/dL	Recommended Test Concentration, µmol/L
Abiraterone		• Inhibitor of cytochrome P450 • Inhibits androgen synthesis, particularly testosterone • Used to treat hormone-dependent prostatic cancers	2.26E−02	2.86E+01	6.47E−01	$C_{24}H_{31}NO$	3.50E+02	6.78E−02	1.94E+00
Acarbose		• A potent inhibitor of α-glucosidases and saccharases • Used to treat diabetes, hyperlipidemia, and obesity	1.00E−02	1.55E+01	1.55E−01	$C_{25}H_{43}NO_{18}$	6.46E+02	3.00E−02	4.65E−01
Acenocoumarol		• Antithrombotic agent, vitamin K antagonist, anticoagulant agent, coumarin derivate	4.00E−02	2.83E+01	1.13E+00	$C_{19}H_{15}NO_6$	3.53E+02	1.20E−01	3.40E+00
Acetaminophen (paracetamol)		• Widely used analgesic and antipyretic agent	5.20E+00	6.62E+01	3.44E+02	$C_8H_9NO_2$	1.51E+02	1.56E+01	1.03E+03
Acetazolamide		• Potent carbonic anhydrase inhibitor • Used to treat glaucoma • Diuretic, sulfonamide diuretic agent	1.90E+00	4.50E+01	8.56E+01	$C_4H_6N_4O_3S_2$	2.22E+02	5.70E+00	2.57E+02

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Table 1. (Continued)

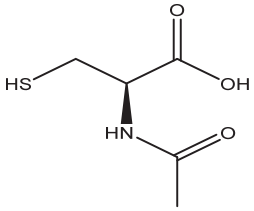
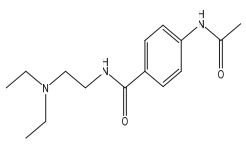
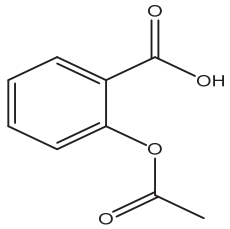
Exogenous Potential Interferent (Drug INN)	Chemical Structure	Comments	Highest Drug Concentration Under Therapeutic Treatment, mg/dL	Conversion Factor	Highest Drug Concentration Under Therapeutic Treatment, µmol/L	Molecular Formula	Molar Mass, g/mol	Recommended Test Concentration, mg/dL	Recommended Test Concentration, µmol/L
N-acetylcysteine		• When used as an antidote to acetaminophen (paracetamol) poisoning, the loading dose is 140 mg/kg orally; this dosage did not lead to blood concentrations higher than 1.6 mg/dL. Intravenously, this occurs over 1 hour. The observed drug concentration does not exceed 8.0 mg/dL for 15-minute infusions. **NOTE:** When used as a mucolytic agent, concentrations are far lower.	5.00E+00	6.13E+01	3.07E+02	$C_5H_9NO_3S$	1.63E+02	1.50E+01	9.20E+02
N-acetylprocain-amide		• Metabolite	1.00E+00	3.61E+01	3.61E+01	$C_{15}H_{23}N_3O_2$	2.77E+02	3.00E+00	1.08E+02
Acetylsalicylic acid†		• Analgesic agent • Antipyretic agent • Anti-inflammatory agent	1.00E+00	5.55E+01	5.55E+01	$C_9H_8O_4$	1.80E+02	3.00E+00	1.67E+02

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Table 1. (Continued)

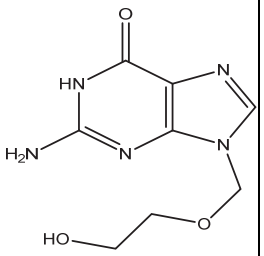
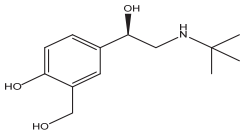
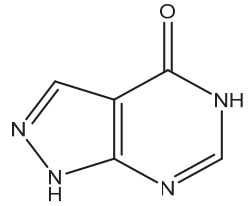
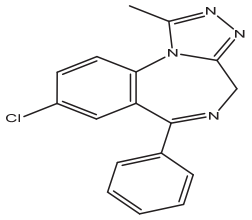
Exogenous Potential Interferent (Drug INN)	Chemical Structure	Comments	Highest Drug Concentration Under Therapeutic Treatment, mg/dL	Conversion Factor	Highest Drug Concentration Under Therapeutic Treatment, µmol/L	Molecular Formula	Molar Mass, g/mol	Recommended Test Concentration, mg/dL	Recommended Test Concentration, µmol/L
Acyclovir		• Nucleoside derivative • Antiviral agent used to treat herpes	2.20E+00	4.44E+01	9.77E+01	$C_8H_{11}N_5O_3$	2.25E+02	6.60E+00	2.93E+02
Albuterol (salbutamol)		• β-adrenoceptor agonist • Antiasthmatic agent, bronchodilator, muscle relaxant, topical anti-inflammatory agent	1.50E−03	4.18E+01	6.27E−02	$C_{13}H_{21}NO_3$	2.39E+02	4.50E−03	1.88E−01
Allopurinol		• Xanthine oxidase inhibitor • Used to treat chronic gout and related diseases • Inhibitor of ATP synthesis from guanine and of RNA biosynthesis • Also shows antithrombotic and antiparasitic activities	2.00E+00	7.35E+01	1.47E+02	$C_5H_4N_4O$	1.36E+02	6.00E+00	4.41E+02
Alprazolam		• Benzodiazepine receptor agonist • Tranquilizer, muscle relaxant	8.60E−03	3.24E+01	2.78E−01	$C_{17}H_{13}ClN_4$	3.09E+02	2.58E−02	8.35E−01

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Table 1. (Continued)

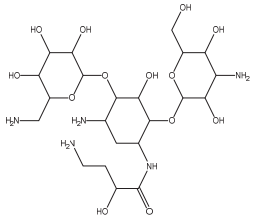
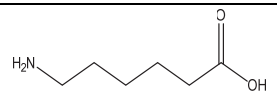
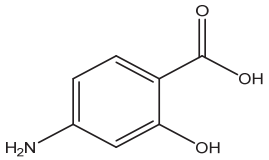
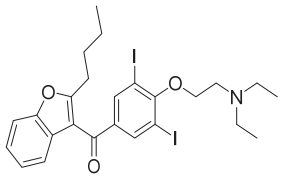
Exogenous Potential Interferent (Drug INN)	Chemical Structure	Comments	Highest Drug Concentration Under Therapeutic Treatment, mg/dL	Conversion Factor	Highest Drug Concentration Under Therapeutic Treatment, µmol/L	Molecular Formula	Molar Mass, g/mol	Recommended Test Concentration, mg/dL	Recommended Test Concentration, µmol/L
Amikacin		• Shows antimicrobial activity, including synergism with third-generation cephalosporins • Used especially against multidrug-resistant bacterial strains • Protein biosynthesis inhibitor by binding to bacterial ribosomes	4.80E+00	1.71E+01	8.19E+01	$C_{22}H_{43}N_5O_{13}$	5.86E+02	1.44E+01	2.46E+02
Aminocaproic acid		• Hemostatic, antifibrinolytic agent	3.00E−01	7.63E+01	2.29E+01	$C_6H_{13}NO_2$	1.31E+02	9.00E−01	6.87E+01
p-Aminosalicylic acid		• Tuberculostatic antibacterial agent often administered as sodium, potassium, or calcium salt • Reserved for tuberculosis treatment following resistance to first-line therapy	1.55E+01	6.54E+01	1.01E+03	$C_7H_7NO_3$	1.53E+02	4.65E+01	3.04E+03
Amiodarone		• Antiarrhythmic (class III) agent	1.40E+00	1.55E+01	2.17E+01	$C_{25}H_{29}I_2NO_3$	6.45E+02	4.20E+00	6.51E+01

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Table 1. (Continued)

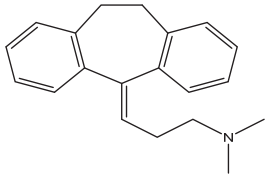
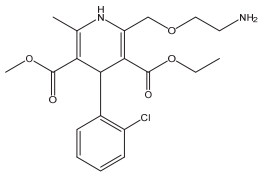
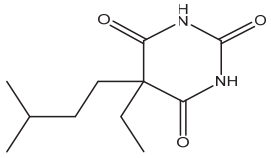
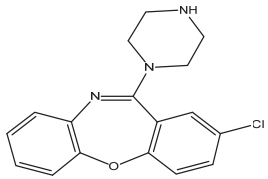
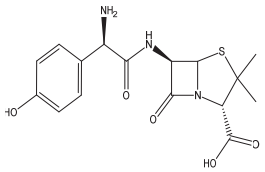
Exogenous Potential Interferent (Drug INN)	Chemical Structure	Comments	Highest Drug Concentration Under Therapeutic Treatment, mg/dL	Conversion Factor	Highest Drug Concentration Under Therapeutic Treatment, µmol/L	Molecular Formula	Molar Mass, g/mol	Recommended Test Concentration, mg/dL	Recommended Test Concentration, µmol/L
Amitriptyline		• Antidepressant agent • Noradrenaline and 5-hydroxytryptamine uptake inhibitor	1.60E−02	3.61E+01	5.78E−01	$C_{20}H_{23}N$	2.77E+02	4.80E−02	1.73E+00
Amlodipine		• Calcium channel blocking agent • Antianginal, antihypertensive agent	2.50E−03	2.44E+01	6.11E−02	$C_{20}H_{25}ClN_2O_5$	4.09E+02	7.50E−03	1.83E−01
Amobarbital		• Barbiturate • Sedative agent • Hypnotic agent	1.20E+00	4.42E+01	5.31E+01	$C_{11}H_{18}N_2O_3$	2.26E+02	3.60E+00	1.59E+02
Amoxapine		• Antidepressant agent	9.30E−03	3.18E+01	2.96E−01	$C_{17}H_{16}ClN_3O$	3.14E+02	2.79E−02	8.89E−01
Amoxicillin		• Active against gram-positive and gram-negative bacteria • Antibacterial activity similar to ampicillin with superior oral absorption • β-lactamase inhibitor	1.80E+00	2.74E+01	4.93E+01	$C_{16}H_{19}N_3O_5S$	3.65E+02	5.40E+00	1.48E+02

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Table 1. (Continued)

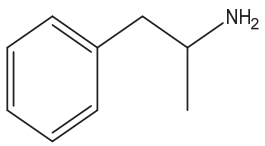
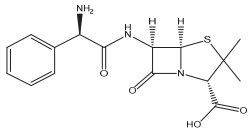
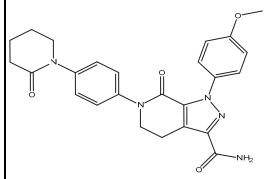
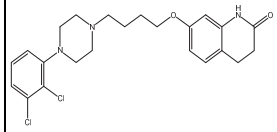
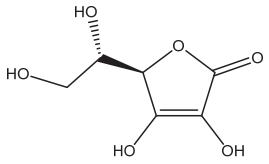
Exogenous Potential Interferent (Drug INN)	Chemical Structure	Comments	Highest Drug Concentration Under Therapeutic Treatment, mg/dL	Conversion Factor	Highest Drug Concentration Under Therapeutic Treatment, µmol/L	Molecular Formula	Molar Mass, g/mol	Recommended Test Concentration, mg/dL	Recommended Test Concentration, µmol/L
Amphetamine		• A mixture of amphetamine salts is used to treat attention-deficit hyperactivity disorder	1.10E−02	7.41E+01	8.15E−01	$C_9H_{13}N$	1.35E+02	3.30E−02	2.44E+00
Ampicillin		• Orally absorbed antimicrobial agent active against gram-positive and some gram-negative bacteria	2.50E+00	2.87E+01	7.16E+01	$C_{16}H_{19}N_3O_4S$	3.49E+02	7.50E+00	2.15E+02
Apixaban		• Anticoagulant, antithrombotic agent • Factor Xa inhibitor	1.05E−02	2.18E+01	2.29E−01	$C_{25}H_{25}N_5O_4$	4.60E+02	3.15E−02	6.86E−01
Aripiprazole		• Shows presynaptic dopamine autoreceptor agonist activity and postsynaptic dopamine D_2 receptor antagonist activity • Antipsychotic agent • Used to treat schizophrenia	4.52E−02	2.23E+01	1.01E+00	$C_{23}H_{27}Cl_2N_3O_2$	4.48E+02	1.36E−01	3.02E+00
Ascorbic acid		• Used as a reducing agent, antioxidant agent, nutrient, preservative • Enzymatic browning inhibitor	1.75E+00	5.68E+01	9.94E+01	$C_6H_8O_6$	1.76E+02	5.25E+00	2.98E+02

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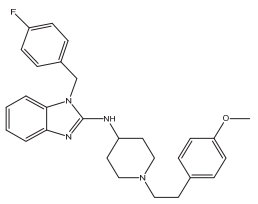
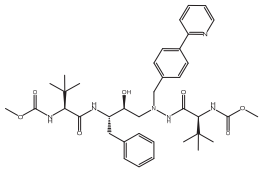
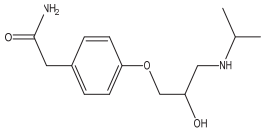
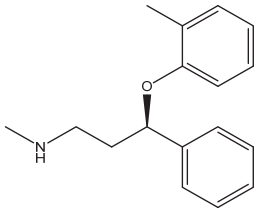
Table 1. (Continued)

Exogenous Potential Interferent (Drug INN)	Chemical Structure	Comments	Highest Drug Concentration Under Therapeutic Treatment, mg/dL	Conversion Factor	Highest Drug Concentration Under Therapeutic Treatment, µmol/L	Molecular Formula	Molar Mass, g/mol	Recommended Test Concentration, mg/dL	Recommended Test Concentration, µmol/L
Astemizole		• Histamine H_1 receptor antagonist	1.00E−02	2.18E+01	2.18E−01	$C_{28}H_{31}FN_4O$	4.59E+02	3.00E−02	6.54E−01
Atazanavir		• Used to treat HIV infection • HIV-1 protease inhibitor	6.50E−01	1.42E+01	9.22E+00	$C_{38}H_{52}N_6O_7$	7.05E+02	1.95E+00	2.77E+01
Atenolol		• β-adrenergic blocking agent • Antihypertensive agent	3.00E−01	3.75E+01	1.13E+01	$C_{14}H_{22}N_2O_3$	2.66E+02	9.00E−01	3.38E+01
Atomoxetine		• Reverse transcriptase inhibitor • Antiviral agent	2.61E−01	3.92E+01	1.02E+01	$C_{17}H_{21}NO$	2.55E+02	7.83E−01	3.07E+01

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