



Azithromycin for Injection

Type of Posting	Notice of Intent to Revise
Posting Date	28-Jul-2023
Targeted Official Date	To Be Determined, Revision Bulletin
Expert Committee	Small Molecules 1

In accordance with the Rules and Procedures of the Council of Experts and the [Pending Monograph Guideline](#), this is to provide notice that the Small Molecules 1 Expert Committee intends to revise the Azithromycin for Injection monograph.

Based on the supporting data received from a manufacturer awaiting FDA approval, the Expert Committee proposes to revise the Azithromycin for Injection monograph to widen the *Acceptance criteria* in the *Assay* from 90.0%–110.0% to 90.0%–115.0%. The *Definition* in the Azithromycin for Injection monograph has also been revised to support the proposed change in the *Assay Acceptance criteria*.

The proposed revision is contingent on FDA approval of a product that meets the proposed monograph specifications. The proposed revision will be published as a Revision Bulletin and an official date will be assigned to coincide as closely as possible with the FDA approval of the associated product.

See below for additional information about the proposed text.¹

Should you have any questions, please contact Yanyin Yang, Senior Scientist II (301-692-3623 or yanyin.yang@usp.org).

¹ This text is not the official version of a *USP–NF* monograph and may not reflect the full and accurate contents of the currently official monograph. Please refer to the current edition of the *USP–NF* for official text.

USP provides this text to indicate changes that we anticipate will be made official once the product subject to this proposed revision under the Pending Monograph Program receives FDA approval. Once FDA approval is granted for the associated revision request, a Revision Bulletin will be posted that will include the changes indicated herein, as well as any changes indicated in the product's final approval, combined with the text of the monograph as effective on the date of approval. Any revisions made to a monograph under the Pending Monograph Program that are posted without prior publication for comment in the *Pharmacopeial Forum* must also meet the requirements outlined in the [USP Guideline on Use of Accelerated Processes for Revisions to the USP–NF](#).

Azithromycin for Injection

Change to read:

DEFINITION

Azithromycin for Injection is a sterile, dry mixture of azithromycin and a suitable stabilizing agent. It contains NLT 90.0% and NMT \blacktriangle 115.0% \blacktriangle (TBD) of the labeled amount of azithromycin ($C_{38}H_{72}N_2O_{12}$).

IDENTIFICATION

- **A.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the *Assay*.
- **B. [SPECTROSCOPIC IDENTIFICATION TESTS](#) (197), [Infrared Spectroscopy: 197A](#)**
 - Standard:** 25 mg/mL of [USP Azithromycin RS](#) in [acetonitrile](#). Pass the solution through a suitable filter, and remove the solvent by natural evaporation.
 - Sample:** Equivalent to 25 mg/mL of azithromycin from Azithromycin for Injection in [acetonitrile](#). Pass the solution through a suitable filter, and remove the solvent by natural evaporation.
 - Analysis:** Examine the spectra of the *Standard* and the *Sample* in the range between 3800 and 650 cm^{-1} .
 - Acceptance criteria:** The *Sample* exhibits bands at about 900, 995, 1165, 1376, 1456, 1725, and 2936 cm^{-1} similar to the spectrum from the *Standard* similarly obtained.

ASSAY

Change to read:

PROCEDURE

Buffer: 6.7 mg/mL of [dibasic potassium phosphate](#) in [water](#)

Mobile phase: [Acetonitrile](#) and *Buffer* (52:48). Adjust with 10 N [potassium hydroxide](#) to a pH of 11.0 \pm 0.1.

Diluent: [Acetonitrile](#) and [water](#) (52:48)

System suitability solution: 1 mg/mL each of [USP Azaerythromycin A RS](#) and [USP Azithromycin RS](#) in a mixture of [acetonitrile](#) and [water](#) (52:48). Dissolve first in [acetonitrile](#), and then dilute with [water](#) to volume.

Standard solution: 1 mg/mL of [USP Azithromycin RS](#) in a mixture of [acetonitrile](#) and [water](#) (52:48). Dissolve first in [acetonitrile](#), and dilute with [water](#) to volume.

Sample solution: Nominally equivalent to 1 mg/mL of azithromycin from Azithromycin for Injection in *Diluent* prepared as follows. Reconstitute 3 vials individually as directed in the labeling. Mix the contents of all the reconstituted vials. Dilute a portion of the mixture with *Diluent*.

Chromatographic system

(See [Chromatography](#) (621), [System Suitability](#).)

Mode: LC

Detector: UV 215 nm

Columns

Guard: 4.6-mm \times 1-cm; 5- μ m packing [L67](#)

Analytical: 4.6-mm × 15-cm; 5-μm packing [L67](#)

Temperatures

Autosampler: 15°

Column: 40°

Flow rate: 1 mL/min

Injection volume: 15 μL

System suitability

Samples: *System suitability solution* and *Standard solution*

[NOTE—The relative retention times for azaerythromycin A and azithromycin are 0.68 and 1.0, respectively.]

Suitability requirements

Resolution: NLT 2.5 between azaerythromycin A and azithromycin, *System suitability solution*

Tailing factor: NLT 0.9 and NMT 1.5, *Standard solution*

Relative standard deviation: NMT 2%, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of azithromycin ($C_{38}H_{72}N_2O_{12}$) in the portion of Azithromycin for Injection taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times P \times F \times 100$$

r_U = peak response from the *Sample solution*

r_S = peak response from the *Standard solution*

C_S = concentration of [USP Azithromycin RS](#) in the *Standard solution* (mg/mL)

C_U = nominal concentration of azithromycin in the *Sample solution* (mg/mL)

P = potency of [USP Azithromycin RS](#) (μg/mg)

F = conversion factor, 0.001 mg/μg

Acceptance criteria: 90.0%–▲115.0%▲ (TBD)

PERFORMANCE TESTS

- [UNIFORMITY OF DOSAGE UNITS](#) (905): Meets the requirements

IMPURITIES

[NOTE—The test for *Limit of Azithromycin N-Oxide, Desosaminylazithromycin, and N-Demethylazithromycin* does not quantify aminoazithromycin, formamido analog, methylformamido analog, and 3'-de(dimethylamino)-3'-oxoazithromycin. If these impurities are part of the impurity profile, the *Limit of Aminoazithromycin, Formamido Analog, Methylformamido Analog, and 3'-De(dimethylamino)-3'-oxoazithromycin* test is recommended in addition to the test for *Limit of Azithromycin N-Oxide, Desosaminylazithromycin, and N-Demethylazithromycin*.]

- **LIMIT OF AZITHROMYCIN N-OXIDE, DESOSAMINYLAZITHROMYCIN, AND N-DEMETHYLAZITHROMYCIN**

Buffer: 3.5 g/L of [dibasic potassium phosphate](#)

Mobile phase: [Acetonitrile](#) and *Buffer* (23:77). Adjust with 5 N [potassium hydroxide](#) to a pH of 10.55 ± 0.05.

Standard stock solution: 0.05 mg/mL of [USP Azithromycin N-oxide RS](#), 45 μg/mL of [USP Desosaminylazithromycin RS](#), and 160 μg/mL each of [USP N-Demethylazithromycin RS](#) and [USP](#)

[Azithromycin RS](#) in [acetonitrile](#). Sonicate if necessary to dissolve.

Standard solution: 0.001 mg/mL of azithromycin *N*-oxide, 0.9 µg/mL of desosaminylazithromycin, and 3.2 µg/mL each of *N*-demethylazithromycin and azithromycin from *Standard stock solution* in *Mobile phase*

Sample solution: Nominally equivalent to 0.3 mg/mL of azithromycin in *Mobile phase* from Azithromycin for Injection

Chromatographic system

(See [Chromatography \(621\)](#), [System Suitability](#).)

Mode: LC

Detector: Amperometric electrochemical

Electrodes: Dual series glassy carbon

Mode: Oxidative screen

Electrode 1: +0.70 ± 0.05 V

Electrode 2: +0.82 ± 0.05 V

Column: 4.6-mm × 15-cm; 3-µm packing [L49](#)

Autosampler temperature: 5°

Flow rate: 1 mL/min

Injection volume: 50 µL

System suitability

Sample: *Standard solution*

[NOTE—See [Table 1](#) for relative retention times.]

Suitability requirements

Tailing factor: NMT 2.0 for azithromycin and NMT 2.6 for *N*-demethylazithromycin

Relative standard deviation: NMT 10.0% for azithromycin *N*-oxide, desosaminylazithromycin, *N*-demethylazithromycin, and azithromycin

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of each specified impurity in the portion of Azithromycin for Injection taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times P \times 100$$

r_U = peak response of each specified impurity from the *Sample solution*

r_S = peak response of each specified impurity from the *Standard solution*

C_S = concentration of the relevant impurity Reference Standard in the *Standard solution* (mg/mL)

C_U = nominal concentration of azithromycin in the *Sample solution* (mg/mL)

P = potency of the relevant Reference Standard (mg/mg)

Acceptance criteria: See [Table 1](#). The reporting threshold is 0.05%.

Table 1

Name	Relative Retention Time	Acceptance Criteria, NMT (%)
Azithromycin <i>N</i> -oxide ^a	0.17	1.0
Desosaminylazithromycin ^b	0.27	0.3
Erythromycin A oxime ^{c,d}	0.35	—
<i>N</i> -Demethylazithromycin ^e	0.50	1.0
Azaerythromycin A ^{c,f}	0.85	—
Azithromycin	1.00	—

^a (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- α -*L*-ribo-hexopyranosyl)oxy]-2-ethyl-3,4,10-trihydroxy-3,5,6,8,10,12,14-heptamethyl-11-[[3,4,6-trideoxy-3-(dimethylazinoyl)- β -*D*-xylo-hexopyranosyl]oxy]-1-oxa-6-azacyclopentadecan-15-one.

^b (2*R*,3*S*,4*R*,5*R*,8*R*,10*R*,11*R*,12*S*,13*S*,14*R*)-2-Ethyl-3,4,10,13-tetrahydroxy-3,5,6,8,10,12,14-heptamethyl-11-[[3,4,6-trideoxy-3-dimethylamino- β -*D*-xylo-hexopyranosyl]oxy]-1-oxa-6-azacyclopentadecan-15-one.

^c Process impurities that are controlled in the drug substance are not to be reported. They are listed here for information only.

^d (3*R*,4*S*,5*S*,6*R*,7*R*,9*R*,11*S*,12*R*,13*S*,14*R*,*E*)-6-[[3,4,6-Trideoxy-3-(dimethylamino)- β -*D*-xylo-hexopyranosyl]oxy]-14-ethyl-7,12,13-trihydroxy-4-[(2,6-dideoxy-3-*C*-methyl-3-*O*-methyl- α -*L*-ribo-hexopyranosyl)oxy]-10-(hydroxyimino)-3,5,7,9,11,13-hexamethyloxacyclotetradecan-2-one.

^e (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- α -*L*-ribo-hexopyranosyl)oxy]-2-ethyl-3,4,10-trihydroxy-3,5,6,8,10,12,14-heptamethyl-11-[[3,4,6-trideoxy-3-methylamino- β -*D*-xylo-hexopyranosyl]oxy]-1-oxa-6-azacyclopentadecan-15-one.

^f 9-Deoxo-9a-aza-9a-homoerythromycin A.

• **LIMIT OF AMINOAZITHROMYCIN, FORMAMIDO ANALOG, METHYLFORMAMIDO ANALOG, AND 3'-DE(DIMETHYLAMINO)-3'-OXOAZITHROMYCIN** (if present)

Buffer: 3.5 g/L of [dibasic potassium phosphate](#) in [water](#)

Mobile phase: [Acetonitrile](#) and *Buffer* (46:54). Adjust with 10 N [potassium hydroxide](#) to a pH of 11.0 ± 0.1.

Diluent: [Acetonitrile](#) and [water](#) (46:54)

Standard stock solution: 0.09 mg/mL of [USP Desosaminylazithromycin RS](#), 0.21 mg/mL of [USP N-Demethylazithromycin RS](#), and 0.30 mg/mL of [USP Azithromycin RS](#) in [acetonitrile](#)

Standard solution: 0.0018 mg/mL of desosaminylazithromycin, 0.0042 mg/mL of *N*-demethylazithromycin, and 0.006 mg/mL of azithromycin in *Diluent*

Sample solution: Nominally equivalent to 0.6 mg/mL of azithromycin from Azithromycin for Injection in *Diluent*. Reconstitute 3 vials individually, as directed in the labeling. Mix the contents of all the reconstituted vials. Dilute a portion of the mixture with *Diluent*. The *Sample solution* must be injected immediately after preparation.

Blank: Use the *Diluent*.

Chromatographic system

(See [Chromatography](#) (621), [System Suitability](#).)

Mode: LC

Detector: Amperometric electrochemical

Electrodes: Dual series glassy carbon

Mode: Oxidative screen

Electrode 1: +0.70 ± 0.05 V

Electrode 2: +0.82 ± 0.05 V

Columns

Guard: 4.6-mm × 1-cm; 5-µm packing [L67](#)

Analytical: 4.6-mm × 25-cm; 5-µm packing [L67](#)

Temperatures

Autosampler: 15°

Column: 40°

Flow rate: 1 mL/min

Injection volume: 25 µL

System suitability

Sample: *Standard solution*

[NOTE—See [Table 2](#) for relative retention times.]

Suitability requirements

Resolution: NLT 1.5 between desosamylazithromycin and *N*-demethylazithromycin

Tailing factor: NMT 1.5 for azithromycin

Relative standard deviation: NMT 5% for azithromycin

Analysis

Samples: *Standard solution*, *Sample solution*, and *Blank*

Disregard any peaks corresponding to those obtained from the *Blank*.

Calculate the percentage of each impurity in the portion of Azithromycin for Injection taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times P \times F \times 100$$

r_U = peak response of each impurity from the *Sample solution*

r_S = peak response of azithromycin from the *Standard solution*

C_S = concentration of [USP Azithromycin RS](#) in the *Standard solution* (mg/mL)

C_U = nominal concentration of azithromycin in the *Sample solution* (mg/mL)

P = potency of [USP Azithromycin RS](#) (µg/mg)

F = conversion factor, 0.001 mg/µg

Acceptance criteria: See [Table 2](#).

Table 2

Name	Relative Retention Time	Acceptance Criteria, NMT (%)
Erythromycin A iminoether ^{a,b}	0.20	—
3'-(<i>N,N</i> -Didemethyl)azithromycin (aminoazithromycin) ^c + 3'-(<i>N,N</i> -didemethyl)-3'- <i>N</i> -formylazithromycin (formamido analog) ^d	0.25	1.0
Azithromycin F ^{a,e}	0.30	—
Desosamylazithromycin ^{f,g}	0.31	—

Name	Relative Retention Time	Acceptance Criteria, NMT (%)
3'-N-Demethyl-3'-N-formylazithromycin (methylformamido analog) ^h	0.32	1.0
N-Demethylazithromycin ^{f,i}	0.35	—
Erythromycin A oxime ^{a,j}	0.42	—
Azaerythromycin A ^{a,k}	0.63	—
3'-De(dimethylamino)-3'-oxoazithromycin ^l	0.72	1.0
3'-N-Demethyl-3'-N-[(4-methylphenyl)sulfonyl]azithromycin ^{a,m}	0.85	—
Azithromycin	1.00	—
Azithromycin B (3-deoxyazithromycin) ^{a,n}	1.64	—
Any other unspecified impurity	—	0.2
Total impurities ^o	—	3.0

^a Process impurities that are controlled in the drug substance are not to be reported. They are listed here for information only.

^b (3*R*,4*R*,5*S*,6*R*,9*R*,10*S*,11*S*,12*R*,13*S*,15*R*,Z)-12-[[3,4,6-Trideoxy-3-(dimethylamino)-β-D-xylo-hexopyranosyl]oxy]-6-ethyl-4,5-dihydroxy-10-[(2,6-dideoxy-3-C-methyl-3-O-methyl-α-L-ribo-hexopyranosyl)oxy]-3,5,9,11,13,15-hexamethyl-7,16-dioxa-2-azabicyclo[11.2.1]hexadec-1-en-8-one.

^c (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-α-L-ribo-hexopyranosyl)oxy]-2-ethyl-3,4,10-trihydroxy-3,5,6,8,10,12,14-heptamethyl-11-[[3-amino-3,4,6-trideoxy-β-D-xylo-hexopyranosyl]oxy]-1-oxa-6-azacyclopentadecan-15-one.

^d (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-α-L-ribo-hexopyranosyl)oxy]-2-ethyl-3,4,10-trihydroxy-3,5,6,8,10,12,14-heptamethyl-11-[[3-formamido-3,4,6-trideoxy-β-D-xylo-hexopyranosyl]oxy]-1-oxa-6-azacyclopentadecan-15-one.

^e (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-α-L-ribo-hexopyranosyl)oxy]-2-ethyl-3,4,10-trihydroxy-3,5,6,8,10,12-hexamethyl-14-hydroxymethyl-11-[[3-dimethylamino-3,4,6-trideoxy-β-D-xylo-hexopyranosyl]oxy]-1-oxa-6-azacyclopentadecan-15-one.

^f These impurities are controlled using the *Limit of Azithromycin N-Oxide, Desosaminylazithromycin, and N-Demethylazithromycin* test. They are listed here for information only.

^g (2*R*,3*S*,4*R*,5*R*,8*R*,10*R*,11*R*,12*S*,13*S*,14*R*)-2-Ethyl-3,4,10,13-tetrahydroxy-3,5,6,8,10,12,14-heptamethyl-11-[[3,4,6-trideoxy-3-dimethylamino-β-D-xylo-hexopyranosyl]oxy]-1-oxa-6-azacyclopentadecan-15-one.

^h (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-α-L-ribo-hexopyranosyl)oxy]-2-ethyl-3,4,10-trihydroxy-3,5,6,8,10,12,14-heptamethyl-11-[[3-(N-methyl)formamido-3,4,6-trideoxy-β-D-xylo-hexopyranosyl]oxy]-1-oxa-6-azacyclopentadecan-15-one.

ⁱ (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-α-L-ribo-hexopyranosyl)oxy]-2-ethyl-3,4,10-trihydroxy-3,5,6,8,10,12,14-heptamethyl-11-[[3,4,6-trideoxy-3-methylamino-β-D-xylo-hexopyranosyl]oxy]-1-oxa-6-azacyclopentadecan-15-one.

^j (3*R*,4*S*,5*S*,6*R*,7*R*,9*R*,11*S*,12*R*,13*S*,14*R*,E)-6-[[3,4,6-Trideoxy-3-(dimethylamino)-β-D-xylo-hexopyranosyl]oxy]-14-ethyl-7,12,13-trihydroxy-4-[(2,6-dideoxy-3-C-methyl-3-O-methyl-α-L-ribo-hexopyranosyl)oxy]-10-(hydroxyimino)-3,5,7,9,11,13-hexamethylloxacyclotetradecan-2-one.

^k 9-Deoxy-9a-aza-9a-homoerythromycin A.

^l (2R,3S,4R,5R,8R,10R,11R,12S,13S,14R)-13-[(2,6-Dideoxy-3,3-dimethyl- α -L-ribo-hexopyranosyl)oxy]-2-ethyl-3,4,10-trihydroxy-3,5,6,8,10,12,14-heptamethyl-11-[[3,4,6-trideoxy-3-oxo- β -D-xylo-hexopyranosyl]oxy]-1-oxa-6-azacyclopentadecan-15-one.

^m (2R,3S,4R,5R,8R,10R,11R,12S,13S,14R)-13-[(2,6-Dideoxy-3-C-methyl-3-O-methyl- α -L-ribo-hexopyranosyl)oxy]-2-ethyl-3,4,10-trihydroxy-3,5,6,8,10,12,14-heptamethyl-11-[[3-[N-(4-acetamidophenylsulfonyl)-N-methylamino]-3,4,6-trideoxy- β -D-xylo-hexopyranosyl]oxy]-1-oxa-6-azacyclopentadecan-15-one.

ⁿ (2R,3R,4S,5R,8R,10R,11R,12S,13S,14R)-13-[(2,6-Dideoxy-3-C-methyl-3-O-methyl- α -L-ribo-hexopyranosyl)oxy]-2-ethyl-4,10-dihydroxy-3,5,6,8,10,12,14-heptamethyl-11-[[3,4,6-trideoxy-3-(dimethylamino)- β -D-xylo-hexopyranosyl]oxy]-1-oxa-6-azacyclopentadecan-15-one.

^o Total impurities include desosaminylazithromycin and N-demethylazithromycin.

SPECIFIC TESTS

- **BACTERIAL ENDOTOXINS TEST** (85): Meets the requirements
- **STERILITY TESTS** (71): Meets the requirements
- **PARTICULATE MATTER IN INJECTIONS** (788): Meets the requirements
- **PH** (791): 6.4–6.8, determined in a solution constituted as directed in the labeling
- **WATER DETERMINATION** (921), *Method I*: NMT 2.0%
- **OTHER REQUIREMENTS**: It meets the requirements under [Injections and Implanted Drug Products](#) (1).

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE**: Preserve as described under [Packaging and Storage Requirements](#) (659), [Injection Packaging](#), [Packaging for Constitution](#). Store at controlled room temperature.
- **LABELING**: It meets the requirements for [Labeling](#) (7), [Labels and Labeling for Injectable Products](#).
- **USP REFERENCE STANDARDS** (11).

[USP Azaerythromycin A RS](#)

9-Deoxy-9a-aza-9a-homoerythromycin A.

$C_{37}H_{70}N_2O_{12}$ 734.96

[USP Azithromycin RS](#)

[USP Azithromycin N-oxide RS](#)

(2R,3S,4R,5R,8R,10R,11R,12S,13S,14R)-13-[(2,6-Dideoxy-3-C-methyl-3-O-methyl- α -L-ribo-hexopyranosyl)oxy]-2-ethyl-3,4,10-trihydroxy-3,5,6,8,10,12,14-heptamethyl-11-[[3,4,6-trideoxy-3-(dimethylazinoyl)- β -D-xylo-hexopyranosyl]oxy]-1-oxa-6-azacyclopentadecan-15-one.

$C_{38}H_{72}N_2O_{13}$ 764.98

[USP N-Demethylazithromycin RS](#)

(2R,3S,4R,5R,8R,10R,11R,12S,13S,14R)-13-[(2,6-Dideoxy-3-C-methyl-3-O-methyl- α -L-ribo-hexopyranosyl)oxy]-2-ethyl-3,4,10-trihydroxy-3,5,6,8,10,12,14-heptamethyl-11-[[3,4,6-trideoxy-3-methylamino- β -D-xylo-hexopyranosyl]oxy]-1-oxa-6-azacyclopentadecan-15-one.

$C_{37}H_{70}N_2O_{12}$ 734.96

[USP Desosaminylazithromycin RS](#)

(2R,3S,4R,5R,8R,10R,11R,12S,13S,14R)-2-Ethyl-3,4,10,13-tetrahydroxy-3,5,6,8,10,12,14-heptamethyl-11-[[3,4,6-trideoxy-3-dimethylamino- β -D-xylo-hexopyranosyl]oxy]-1-oxa-6-azacyclopentadecan-15-one.

$C_{30}H_{58}N_2O_9$ 590.79

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