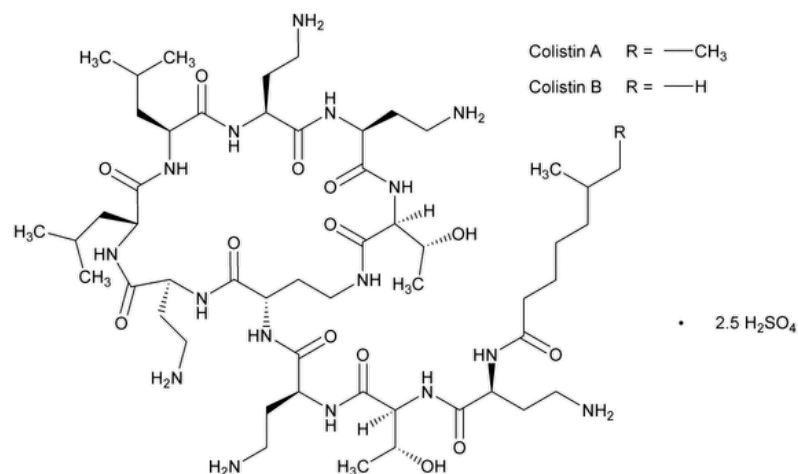


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Colistin Sulfate



Colistin, sulfate;
 Colistins sulfate

CAS RN[®]: 1264-72-8; UNII: WP15DXU577.

DEFINITION

Colistin Sulfate is the sulfate salt of an antibacterial substance produced by the growth of *Bacillus polymyxa* var. *colistinus*. It has a potency equivalent to NLT 500 µg of colistin/mg.

IDENTIFICATION

Delete the following:

▲ **A. PROCEDURE** ▲ (USP 1-Dec-2022)

Add the following:

▲ **A. SPECTROSCOPIC IDENTIFICATION TESTS (197), Infrared Spectroscopy**: 197A or 197K ▲ (USP 1-Dec-2022)

• **B. IDENTIFICATION TESTS—GENERAL (191), Chemical Identification Tests, Sulfate**: Meets the requirements

Delete the following:

▲ **C. LIQUID CHROMATOGRAPHIC IDENTIFICATION TEST** ▲ (USP 1-Dec-2022)

Add the following:

▲ **C.** The retention times of the colistin A and colistin B peaks of the *Sample solution* correspond to those of the *Standard solution*, as obtained in the test for *Composition*. ▲ (USP 1-Dec-2022)

ASSAY

Change to read:

• **PROCEDURE**

Analysis: Proceed as directed for *Colistin* in [Antibiotics—Microbial Assays \(81\)](#).

Acceptance criteria: NLT 500 µg ▲ of colistin ▲ (USP 1-Dec-2022) /mg

Add the following:

▲ **IMPURITIES**

• **ORGANIC IMPURITIES**

Solution A: 4.5 g of [anhydrous sodium sulfate](#) in 900 mL of [water](#), adjusted with [diluted phosphoric acid](#) to a pH of 2.4 and diluted with [water](#) to 1000 mL

Mobile phase: *Solution A* and [acetonitrile](#) (78:22)

Diluent: [Water](#) and [acetonitrile](#) (80:20)

Sensitivity solution: 5 µg/mL of [USP Colistin Sulfate RS](#) in *Diluent*

Standard solution: 0.5 mg/mL of [USP Colistin Sulfate RS](#) in *Diluent*

Sample solution: 0.5 mg/mL of Colistin Sulfate in *Diluent*

Chromatographic system

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

Mode: LC

Detector: UV 215 nm

Column: 4.6-mm × 25-cm; 3-µm packing L1

Column temperature: 50°

Flow rate: 1.0 mL/min

Injection volume: 20 µL

System suitability

Samples: *Sensitivity solution* and *Standard solution*

[NOTE—See [Table 1](#) for the relative retention times. Use the reference chromatogram provided with the lot of [USP Colistin Sulfate RS](#) to identify the peaks.]

Suitability requirements

Peak-to-valley ratio: NLT 1.1 for the ratio of the height of the peak that immediately follows the colistin B peak to the height of the valley between the two peaks, *Standard solution*

Resolution: NLT 2.0 between polymyxin E6 and 7-L-isooleucinepolymyxin E2; NLT 3.0 between 2,3-dehydro colistin A and colistin A, *Standard solution*

Signal-to-noise ratio: NLT 10 for the colistin A peak, *Sensitivity solution*

Analysis

Sample: *Sample solution*

Calculate the percentage of each individual impurity (for peaks other than colistin A; colistin B; polymyxins E3, E4, E6, E7; 7-L-valinepolymyxin E2; 7-L-isooleucinepolymyxin E2; 7-L-norvalinepolymyxin E1; colistin III; and 2,3-dehydro colistin A) in the portion of Colistin Sulfate taken:

$$\text{Result} = (r_U/r_T) \times (1/F) \times 100$$

r_U = peak response of each individual impurity

r_T = sum of all the peak responses

F = relative response factor

Acceptance criteria: See [Table 1](#). The reporting threshold is 0.35%.

Table 1

Name	Relative Retention Time	Relative Response Factor	Acceptance Criteria (%)
7-L-Valinepolymyxin E2 ^a and polymyxin E4 ^b	0.28	1.0	—
Polymyxin E6 ^c	0.39	1.0	NMT 4.5
7-L-Isooleucinepolymyxin E2 ^d	0.42	1.0	NMT 2.5
Colistin B ^e	0.50	1.0	—



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