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**Determination of metronidazole and norfloxacin in
toothpaste - High performance liquid chromatography
method**

牙膏中甲硝唑和诺氟沙星的测定 高效液相色谱法

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Determination of metronidazole and norfloxacin in toothpaste - High performance liquid chromatography method

1 Scope

This Standard specifies high performance liquid chromatography (HPLC) method for the content of forbidden antibiotic drugs - metronidazole and norfloxacin - in toothpaste.

This Standard is applicable to the determination of the content of forbidden antibiotic drugs - metronidazole and norfloxacin - in toothpaste.

The method detection limit of this Standard is 1mg/kg.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

GB/T 6682-2008, *Water for analytical laboratory use - Specification and test methods*

3 Principle

The sample is extracted by the extraction solution. The supernatant is filtered through a 0.45 μ m filter membrane. Use high performance liquid chromatography-ultraviolet detection method to determine. Use retention time to characterize. Use external standard peak area method to quantify.

4 Reagents and standard materials

Unless otherwise specified, all reagents used are analytically-pure AND water is grade one water specified in GB/T 6682-2008.

4.1 Extraction solution: 0.1% (volume fraction) formic acid aqueous solution: acetonitrile (95:5, volume ratio).

7 Determination by high performance liquid chromatography

7.1 Reference conditions of liquid chromatography

The reference conditions of liquid chromatography are as follows:

- a) Chromatographic column: C₁₈ stainless steel column (250mm×4.6mm×5μm).
- b) Detection wavelength: 290nm.
- c) Mobile phase: use triethylamine to adjust the pH value of 0.1% (volume fraction) phosphoric acid aqueous solution: acetonitrile (83:17, volume ratio) to 2.5~3.0.
- d) Flow rate: 1.0mL/min.
- e) Column temperature: 30°C.
- f) Injection volume: 10μL.

7.2 Preparation of standard working solution

Use mobile phase solution to gradually dilute 100mg/L mixed standard stock solution (4.7). Prepare into 50mg/L, 20mg/L, 10mg/L, 5mg/L standard working solutions. Use 0.45μm filter membrane to filter for future use. Under the set chromatographic conditions, respectively take 10μL for analysis. Take the mass concentration of the standard series of solutions as the abscissa (mg/L), the peak area of the reference substance as the ordinate to draw the calibration curve (linear correlation coefficient $R \geq 0.9990$). Refer to Figure A.1 in Annex A for the liquid chromatogram of metronidazole and norfloxacin mixed standard sample.

7.3 Determination steps

After the sample is processed according to the steps in Chapter 6, perform on-board testing according to the instrument conditions of 7.1. The response values of metronidazole and norfloxacin in the test sample solution shall be within the linear range of the standard curve. If it exceeds the linear range, it shall be diluted before injection for determination.

7.4 Blank test

Except for not adding specimen, the test is carried out according to the processing steps in Chapter 6 and the instrument conditions in 7.1.

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