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WS

**INDUSTRY STANDARD OF THE
PEOPLE'S REPUBLIC OF CHINA**

WS/T 686-2020

**Detection methods and evaluation requirements of antiviral
drugs in disinfectants and antibacterial agents
(English Translation)**

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Foreword

This standard was drafted in accordance with the rules given in GB/T 1.1-2009.

Drafting organizations of this standard. Beijing Municipal Center for Disease Control and Prevention, Chinese Academy of Metrology, Beijing Physical and Chemical Analysis and Testing Center, China National Institute for Food and Drug Control, Jiangsu Provincial Center for Disease Control and Prevention, Chinese Center for Disease Control and Prevention, Shandong Provincial Center for Disease Control and Prevention.

1 Scope

This standard specifies the testing methods and evaluation requirements for antiviral drugs in disinfectants and antibacterial agents.

This standard applies to ganciclovir, acyclovir, penciclovir, ribavirin and other antiviral drugs in disinfectants and antibacterial agents Measurement and evaluation.

2 Normative references

The following documents are indispensable for the application of this standard. For dated reference documents, only the dated version applies to this document.

For undated references, the latest version (including all amendments) applies to this

document.

GB/T 6682 Analyze laboratory water specifications and test methods.

Pharmacopoeia of the People's Republic of China

3 Terms and definitions

The following terms and definitions apply to this document.

Antiviral drugs

Drugs used to prevent and treat viral infections.

4.1.1 Principle

The ganciclovir, acyclovir and penciclovir in the sample were ultrasonically extracted with a mixed solution of acetic acid and methanol, and the extract was centrifuged and filtered.

C18 column separation, UV detector or diode array detector detection, external standard method for quantification.

4.1.2 Reagents and materials

Unless otherwise specified, the reagents used in this method are all analytically pure, and the water is the first grade water specified in GB/T 6682.

4.1.2.1 Reagents

4.1.2.1.1

Methanol (CH_3OH). chromatographically pure.

4.1.2.1.2

Glacial acetic acid (CH_3COOH).

4.1.2.1.3

Ammonium acetate ($\text{CH}_3\text{COONH}_4$).

4.1.2.2 Reagent preparation

4.1.2.2.1

Sample extraction solution. Pipette 80 mL of methanol and 10 mL of glacial acetic acid respectively, place them in a reagent bottle, add 10 mL of water, and mix.

4.1.2.2.2

Ammonium acetate acetic acid buffer solution. Weigh 0.77 g of ammonium acetate, place it in a reagent bottle, add 400 mL of water to dissolve, and then add 2 mL of glacial acetic

acid, add water to 500 mL, and mix well.

4.1.2.3 Standard product

The purity of ganciclovir, acyclovir and penciclovir are all greater than 97% or the standard substances certified and granted by the country. For other relevant information, see Appendix A.

4.1.2.4 Standard solution preparation

4.1.2.4.1

Standard stock solution. accurately weigh 25.0 mg each of ganciclovir, acyclovir and penciclovir, and place them in a 50 mL volume respectively Add about 40 mL of sample extraction solution to the bottle, sonicate for 10 minutes, dissolve, dilute the volume with the sample extraction solution to the mark, and prepare the mass concentration both are 500 mg/L standard stock solutions. Keep refrigerated, the validity period is 3 months.

4.1.2.4.2

Mixed standard intermediate solution. Pipette the standard stock solutions of ganciclovir, acyclovir and penciclovir respectively, and extract the solution with the sample Dilute into a mixed standard intermediate solution with a mass concentration of 50 mg/L. Keep refrigerated, valid for 1 month.

4.1.2.4.3

Mixed standard series solution. take different volumes of mixed standard intermediate solution and dilute with sample extraction solution to form mixed standard series Solution, such as 0.5 mg/L, 2.5 mg/L, 5.0 mg/L, 10.0 mg/L, 20.0 mg/L. Now equipped for temporary use.

4.1.2.5 Materials

4.1.2.5.1

Organic filter membrane. the pore size is 0.45 μ m.

4.1.2.5.2

Glass beads. $\Phi < 5$ mm.

4.1.3 Apparatus and equipment

4.1.3.1

High performance liquid chromatograph. with diode array detector or ultraviolet detector.

4.1.3.2

Analytical balance. the smallest division value is 0.1 mg.

4.1.3.3

Centrifuge. $\geq 3\,000$ r/min.

4.1.3.4

Vortex mixer.

4.1.3.5

Ultrasonic cleaner.

4.1.4.1.1 Liquid dosage form

Weigh 0.5 g (accurate to 1 mg) of the sample into a 10 mL centrifuge tube (colorimetric tube) with a stopper and add the sample extraction solution to 10 mL Graduation, vortex and mix for 1 min, ultrasonic for 10 min, filter through a filter membrane, and set aside.

4.1.4.1.2 Other dosage forms

Weigh 0.5 g (accurate to 1 mg) sample into a 10 mL centrifuge tube (colorimetric tube) with a stopper and add the sample extraction solution to 10 mL scale, add 1 to 2 glass beads, vortex to mix until the solution is uniform, sonicate for 10 minutes, centrifuge for 5 minutes, and take the supernatant Filter through a filter membrane and set aside.

4.1.4.2 HPLC reference conditions

The reference conditions of HPLC are as follows.

- a) Chromatographic column. C18 column (column length 250 mm, inner diameter 4.6 mm, particle size 5 μ m), or equivalent;
- b) Mobile phase. Phase A is methanol, phase B is ammonium acetate acetic acid buffer solution;
- c) Flow rate. 1.0 mL/min;
- d) Column temperature. 30°C;
- e) Injection volume. 5 μ L;
- f) Detection wavelength. 254 nm;
- g) Gradient elution procedure. see Appendix B.1.