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Dichlorphenamide Tablets

DEFINITION

Dichlorphenamide Tablets contain NLT 92.0% and NMT 108.0% of the labeled amount of dichlorphenamide ($C_6H_6Cl_2N_2O_4S_2$).

IDENTIFICATION

Change to read:

• **A.** ▲The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the *Assay*.▲2S *(USP41)*

Add the following:

▲• **B.** The UV spectrum of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the *Assay*.▲2S *(USP41)*

Change to read:

• ▲**C.**▲2S *(USP41)* **Identification Tests—General** ⟨191⟩, *Chemical Identification Tests, Sulfite*

Sample: Fuse a quantity of powdered Tablets, equivalent to 200 mg of dichlorphenamide, with 1 pellet of sodium hydroxide.

Acceptance criteria: The ammonia fumes produced cause moistened red litmus paper to turn blue. The fusion mixture meets the requirements of the test for *Sulfite*.

ASSAY

Change to read:

• **Procedure**

▲**Solution A:** 2.4 g/L of monobasic sodium phosphate and 2.8 g/L of dibasic sodium phosphate in water

Solution B: Acetonitrile

Mobile phase: See *Table 1*.

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	65	35
6	65	35
23	40	60
23.1	65	35
30	65	35

Diluent: Acetonitrile and water (1:1)

Standard solution: 0.5 mg/mL of USP Dichlorphenamide RS in *Diluent*. Sonicate if necessary.

Sample stock solution: Nominally 1 mg/mL of dichlorphenamide in *Diluent* prepared as follows. Transfer NLT 20 finely powdered Tablets, equivalent to 100 mg of dichlorphenamide, to a 100-mL volumetric flask. Fill the flask with 80 mL of *Diluent*, sonicate for 5 min, and mechanically shake for at least 30 min. Dilute with *Diluent* to volume, and centrifuge for 10 min.

Sample solution: Nominally 0.5 mg/mL of dichlorphenamide in *Diluent* from *Sample stock solution*

Chromatographic system

(See *Chromatography* ⟨621⟩, *System Suitability*.)

Mode: LC

Detector: UV 280 nm. For *Identification B*, use a diode array detector in the range of 220–400 nm.

Column: 4.6-mm × 15-cm; 2.7-µm packing L1

Flow rate: 0.4 mL/min

Injection volume: 10 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 2.0

Relative standard deviation: NMT 1.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of dichlorphenamide ($C_6H_6Cl_2N_2O_4S_2$) in the portion of Tablets taken:

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

r_U = peak response from the *Sample solution*

r_S = peak response from the *Standard solution*

C_S = concentration of USP Dichlorphenamide RS in the *Standard solution* (mg/mL)

C_U = nominal concentration of dichlorphenamide in the *Sample solution* (mg/mL)▲2S *(USP41)*

Acceptance criteria: 92.0%–108.0%

PERFORMANCE TESTS

Change to read:

• **Dissolution** ⟨711⟩

Medium: 0.1 M pH 8.0 phosphate buffer (see *Reagents, Indicators, and Solutions—Buffer Solutions*); 900 mL

Apparatus 2: 75 rpm

Time: 60 min

Standard solution: USP Dichlorphenamide RS in *Medium*

Sample solution: Use filtered portions of the solution under test, suitably diluted with *Medium* in comparison with the *Standard solution*.

Instrumental conditions

Mode: UV

Analytical wavelength: Maximum absorbance at about 285 nm

Analysis

▲**Samples:** *Standard solution* and *Sample solution*▲2S *(USP41)*

Calculate the percentage of the labeled amount of dichlorphenamide ($C_6H_6Cl_2N_2O_4S_2$) dissolved:

▲$$\text{Result} = (A_U/A_S) \times C_S \times D \times (V/L) \times 100$$

A_U = absorbance of the *Sample solution*

A_S = absorbance of the *Standard solution*

C_S = concentration of the *Standard solution* (mg/mL)

D = dilution factor for the *Sample solution*, if needed

V = volume of *Medium*, 900 mL

L = label claim (mg/Tablet)▲2S *(USP41)*

Tolerances: NLT 80% (*Q*) of the labeled amount of dichlorphenamide ($C_6H_6Cl_2N_2O_4S_2$) is dissolved.

• **Uniformity of Dosage Units** ⟨905⟩**:** Meet the requirements

IMPURITIES

Add the following:

▲• **Organic Impurities**

Solution A, Solution B, Diluent, and **Chromatographic system:** Proceed as directed in the *Assay*.

Standard solution: 0.004 mg/mL of USP Dichlorphenamide RS in *Diluent*

Sample solution: Nominally 2 mg/mL of dichlorphenamide in *Diluent* prepared as follows. Transfer NLT 20 finely powdered Tablets, equivalent to 50 mg of dichlorphenamide, to a 25-mL volumetric flask. Fill the flask with 20 mL of *Diluent*. Sonicate for 5 min and mechanically shake for at least 30 min. Dilute with *Diluent* to volume, and centrifuge for 10 min.

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 1.5

Relative standard deviation: NMT 5.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of each degradation product in the portion of Tablets taken:

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

r_U = peak response of each individual degradation product from the *Sample solution*

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

C_S = concentration of USP Dichlorphenamide RS in the *Standard solution* (mg/mL)

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

Acceptance criteria

Individual degradation product: NMT 0.20%

Total degradation products: NMT 1.0%▲2S *(USP41)*

ADDITIONAL REQUIREMENTS

Change to read:

• **Packaging and Storage:** Preserve in well-closed containers. ▲Store at controlled room temperature.▲2S *(USP41)*

• **USP Reference Standards** ⟨11⟩

USP Dichlorphenamide RS

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
DICHLORPHENAMIDE TABLETS	Documentary Standards Support	SM32020 Small Molecules 3

Chromatographic Database Information: Chromatographic Database

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