

Status: Currently Official on 16-Feb-2025
 Official Date: Official Prior to 2013
 Document Type: NF Monographs
 DocId: GUID-2C15F250-6717-4F62-B372-F7878F191D69_1_en-US
 DOI: https://doi.org/10.31003/USPNF_M66975_01_01
 DOI Ref: tr9it

© 2025 USPC
 Do not distribute

Polyvinyl Acetate Phthalate

DEFINITION

Polyvinyl Acetate Phthalate is a reaction product of phthalic anhydride and a partially hydrolyzed polyvinyl acetate. It contains NLT 55.0% and NMT 62.0% of phthalyl (o-carboxybenzoyl, $C_8H_5O_3$) groups, calculated on the anhydrous, acid-free basis.

IDENTIFICATION

• **A.** The *Sample solution* in the Assay exhibits a maximum at 277 ± 3 nm.

• **B.**

Sample: 10 mg

Analysis: Place the *Sample* in a small test tube, add 10 mg of resorcinol, and mix. Add 0.5 mL of sulfuric acid, and heat in a liquid bath at 160° for 3 min. Cool, and pour the solution into a mixture of 25 mL of 1 N sodium hydroxide and 200 mL of water.

Acceptance criteria: The solution shows a vivid green fluorescence.

• **C.**

Sample solution: 100 mg/mL of Polyvinyl Acetate Phthalate in methanol

Analysis: Pour 1 mL of the *Sample solution* onto a clear glass plate.

Acceptance criteria: A film is deposited as the methanol evaporates.

ASSAY

• PHTHALYL CONTENT

Standard solution: 0.05 mg/mL of phthalic anhydride in alcohol, prepared as follows. Transfer 50 mg of phthalic anhydride to a 1000-mL volumetric flask. Dissolve with heat in 100 mL of alcohol, dilute with alcohol to volume, and mix.

Sample solution: 0.1 mg/mL of Polyvinyl Acetate Phthalate in alcohol, prepared as follows. Transfer 100 mg of Polyvinyl Acetate Phthalate to a 1000-mL volumetric flask, dissolve in alcohol, and dilute with alcohol to volume.

Instrumental conditions

Mode: UV

Cell: 1 cm

Analytical wavelength: 275 nm

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate, on the acid-free basis, the percentage of phthalyl taken:

$$\text{Result} = (A_U/A_S) \times (C_S/C_U) \times 100$$

A_U = absorbance of the *Sample solution*

A_S = absorbance of the *Standard solution*

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

C_U = concentration of Polyvinyl Acetate Phthalate in the *Sample solution* (mg/mL)

Acceptance criteria: 55.0%–62.0% of phthalyl (o-carboxybenzoyl, $C_8H_5O_3$) groups on the anhydrous, acid-free basis

IMPURITIES

• **RESIDUE ON IGNITION (281):** NMT 1.0%

• **FREE PHTHALIC ACID**

Standard solution: 0.05 mg/mL of phthalic anhydride

Sample solution: 6 mg/mL of polyvinyl acetate phthalate in water prepared as follows. Dissolve 1500 mg of Polyvinyl Acetate Phthalate in 50 mL of a mixture of methylene chloride and methanol (4:1). Transfer the solution to a separator with the aid of 75 mL of water, and swirl, taking care not to shake. Add 100 mL of hexanes, shake, and allow the mixture to stand until it separates into two layers. Transfer the water layer to a 250-mL volumetric flask. Add 100 mL of water to the separator, shake, and allow to stand until the layers separate. Transfer the water layer to the same volumetric flask, and dilute with water to volume. If the solution is cloudy, centrifuge a portion until clear.

Instrumental conditions

Mode: UV

Cell: 1 cm

Analytical wavelength: 277 nm

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of free phthalic acid in the portion taken:

$$\text{Result} = (A_U/A_S) \times (C_S/C_U) \times (M_{r1}/M_{r2}) \times 100$$

A_U = absorbance of the *Sample solution*

A_S = absorbance of the *Standard solution*

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

C_U = concentration of Polyvinyl Acetate Phthalate in the *Sample solution* (mg/mL)

M_{r1} = molecular weight of phthalic acid, 166.13

M_{r2} = molecular weight of phthalic anhydride, 148.12

Acceptance criteria: NMT 0.6% on the anhydrous basis

• FREE ACID OTHER THAN PHTHALIC

Sample solution: Proceed as directed for *Sample solution* in *Impurities, Free Phthalic Acid*, but instead of transferring the water extracts to a volumetric flask, transfer them to a 400-mL beaker.

Titrimetric system

(See [Titrimetry \(541\)](#).)

Mode: Direct titration

Titrant: 0.1 N sodium hydroxide VS

Endpoint detection: Visual

Analysis: Titrate the *Sample solution* with *Titrant* to a phenolphthalein endpoint.

Calculate the volume, V_p , in mL, of 0.1 N sodium hydroxide consumed by the free phthalic acid in the sample taken:

$$V_p = (1/M_r) \times (1/N) \times P \times W$$

M_r = equivalent weight of phthalic acid, 83.065 mg/mEq

N = actual normality of the *Titrant* (mEq/mL)

P = percentage of free phthalic acid, previously determined, in decimal form

W = sample weight of Polyvinyl Acetate Phthalate on the anhydrous basis (mg)

Calculate the percentage of free acid other than phthalic, as acetic acid, in the portion taken:

$$\text{Result} = [(V - V_p) \times M_{r3} \times N]/W \times 100$$

V = total volume of 0.1 N sodium hydroxide used (mL)

M_{r3} = equivalent weight of acetic acid, 60.05 mg/mEq

N = actual normality of the *Titrant*

W = sample weight on the anhydrous basis (mg)