amount, and use this solution as the sample solution. Separately, weigh accurately about 0.01 g of Estriol Reference Standard, previously dried at 105°C for 3 hours, dissolve in methanol to make exactly 100 mL, then pipet 5 mL of this solution, and add water to make exactly 100 mL. Pipet 2 mL of this solution, add water to make exactly 100 mL, and use this solution as the standard solution. Perform the test with 100 μL each of the sample solution and the standard solution according to the operating conditions as directed in the Assay under Estriol, and determine the peak areas of estriol, A₁ and A₅, from these solutions.

The dissolution rate of Estriol Tablets in 30 minutes is not less than 80%.

Dissolution rate (٪) with respect to the labeled amount of estriol (C₁₃H₂₄O₃)

\[ \text{Dissolution rate} = \frac{W_5 \times A_5}{A_0 \times V \times \frac{1}{C} \times \frac{9}{10}} \]

W₅: Amount (mg) of Estriol Reference Standard.
C: Labeled amount (mg) of estriol (C₁₃H₂₄O₃) in 1 tablet.

Assay Weigh accurately and powder not less than 20 Estriol Tablets. Weigh accurately a portion of the powder, equivalent to about 1 mg of estriol (C₁₃H₂₄O₃), add exactly 5 mL of water, disperse the fine particles with ultrasonic wave, shake with 25 mL of methanol for 10 minutes, centrifuge, and take the supernatant liquid. Add 25 mL of methanol, repeat the above procedure twice, combine the supernatant liquid, add exactly 5 mL of the internal standard solution, then add methanol to make 100 mL, and use this solution as the sample solution. Separately, weigh accurately about 0.025 g of Estriol Reference Standard, previously dried at 105°C for 3 hours, and dissolve in methanol to make exactly 100 mL. Pipet 4 mL of this solution, add exactly 5 mL of internal standard solution, then add methanol to make 100 mL, and use this solution as the standard solution. Proceed with 20μL each of the sample solution and the standard solution as directed in the Assay under Estriol.

Amount (mg) of estriol (C₁₃H₂₄O₃)

\[ = \frac{Q_5 \times Q_1 \times 1}{25} \]

Internal standard solution—A solution of methyl benzoate for estriol limit test in methanol (1 in 5000).

Containers and storage Containers—Tight containers.

Etacrylic Acid

エタクリリン酸

\[ \text{C₁₃H₁₈Cl₂O₄: 303.14} \]

[2,3-Dichloro-4-(2-ethylacryloyl)phenoxy]acetic acid
[58-54-8]

Etacrylic Acid, when dried, contains not less than 98.0% of C₁₂H₁₂Cl₂O₄.

Description Etacrylic Acid occurs as a white, crystalline powder. It is odorless, and has a slightly bitter taste.

It is very soluble in methanol, freely soluble in ethanol (95), in acetic acid (100) and in diethyl ether, and very slightly soluble in water.

Identification (1) Dissolve 0.2 g of Etacrylic Acid in 10 mL of acetic acid (100), and to 5 mL of this solution add 0.1 mL of bromine TS: the color of the test solution disappears. To the remaining 5 mL of the solution add 0.1 mL of potassium permanganate TS: the color of the test solution changes to light orange immediately.

(2) To 0.01 g of Etacrylic Acid add 1 mL of sodium hydroxide TS, and heat in a water bath for 3 minutes. After cooling, add 1 mL of disodium chloromotrate TS, and heat in a water bath for 10 minutes: a deep purple color develops.

(3) Determine the absorption spectrum of a solution of Etacrylic Acid in methanol (1 in 20,000) as directed under the Ultraviolet-visible Spectrophotometry, and compare the spectrum with the Reference Spectrum: both spectra exhibit similar intensities of absorption at the same wavelengths.

(4) Perform the test with Etacrylic Acid as directed under the Flame Coloration Test (2): a green color appears.

Melting point 121–125°C

Purity (1) Clarity and color of solution—Dissolve 1.0 g of Etacrylic Acid in 10 mL of methanol: the solution is clear and colorless.

(2) Heavy metals—Proceed with 1.0 g of Etacrylic Acid according to Method 4, and perform the test. Prepare the control solution with 2.0 mL of Standard Lead Solution (not more than 20 ppm).

(3) Arsenic—Prepare the test solution with 1.0 g of Etacrylic Acid according to Method 3, and perform the test using Apparatus B. Add 10 mL of a solution of magnesium nitrate hexahydrate in ethanol (95) (1 in 50), then add 1.5 mL of hydrogen peroxide (30), and fire to burn (not more than 2 ppm).

(4) Related substances—Dissolve 0.20 g of Etacrylic Acid in 10 mL of ethanol (95), and use this solution as the sample solution. Pipet 3 mL of the sample solution, add ethanol (95) to make exactly 200 mL, and use this solution as the standard solution. Perform the test with these solutions as directed under the Thin-layer Chromatography. Spot 10 μL each of the sample solution and the standard solution on a plate of silica gel with fluorescent indicator for thin-layer chromatography. Develop the plate with a mixture of chloroform, ethyl acetate and acetic acid (100:6:5:2) to a distance of about 15 cm, and air-dry the plate.

Examine under ultraviolet light (main wavelength: 254 nm): the spots other than the principal spot from the sample solution are not more intense than the spot from the standard solution.

Loss on drying Not more than 0.25% (1 g, in vacuum, 60°C, 2 hours).

Residue on ignition Not more than 0.10% (1 g).

Assay Weigh accurately about 0.1 g of Etacrylic Acid, previously dried, place in an iodine bottle, dissolve in 20 mL of acetic acid (100), and add exactly 20 mL of 0.05 mol/L bromine VS. To this solution add 3 mL of hydrochloric
Etacrylic Acid Tablets

Ethambutol Hydrochloride

Assay
Weigh accurately and powder not less than 20 Etacrylic Acid Tablets. Weigh accurately a portion of the powder, equivalent to about 0.1 g of etacrylic acid (C₁₃H₁₂Cl₂O₄), add 25 mL of 0.1 mol/L hydrochloric acid TS, and extract with three 30-mL portions of dichloromethane. Filter the dichloromethane extract through a pledget of absorbent cotton into an iodine bottle. Wash the pledget of absorbent cotton with a small amount of dichloromethane, and combine the washing with the extracts. Evaporate this solution on a water bath to dryness in a current of air, to the residue add 20 mL of acetic acid (100), and proceed as directed in the Assay under Etacrylic Acid.

Containers and storage
Containers—Well-closed containers.

Ethambutol Hydrochloride, when dried, contains not less than 98.5% of C₁₀H₁₉N₂O₅⋅2HCl.

Description
Ethambutol Hydrochloride occurs as white crystals or crystalline powder. It is odorless, and has a bitter taste.

It is very soluble in water, soluble in methanol and in ethanol (95), and practically insoluble in diethyl ether.

The pH of a solution of Ethambutol Hydrochloride (1 in 20) is between 3.4 and 4.0.

Identification
(1) To 10 mL of a solution of Ethambutol Hydrochloride (1 in 100) add 0.5 mL of copper (II) sulfate TS and 2 mL of sodium hydroxide TS: a deep blue color is produced.

(2) Dissolve 0.1 g of Ethambutol Hydrochloride in 40 mL of water, add 20 mL of 2,4,6-trinitrophenol TS, and allow to stand for 1 hour. Collect the precipitate, wash with 50 mL of water, and dry at 105°C for 2 hours: the precipitate melts between 193°C and 197°C.

(3) A solution of Ethambutol Hydrochloride (1 in 30) responds to the Qualitative Tests for chloride.

Optical rotation
[a]₁₀ = +5.5° + 6.1° (after drying, 5 g, water, 50 mL, 200 mm).

Melting point
200–204°C

Purity
(1) Clarity and color of solution—Dissolve 1.0 g of Ethambutol Hydrochloride in 10 mL of water: the solution is clear and colorless.

(2) Heavy metals—Proceed with 2.0 g Ethambutol