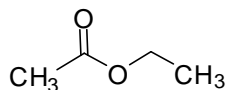


## Ethyl Acetate



C<sub>4</sub>H<sub>8</sub>O<sub>2</sub>

Mol. Wt. 88.1

Ethyl acetate is Acetic acid, ethyl ester.

Ethyl acetate contains not less than 98.0 per cent and not more than 102.0 per cent of C<sub>4</sub>H<sub>8</sub>O<sub>2</sub>.

**Category.** Excipient.

**Description.** A transparent, colourless liquid.

### Identification

Determine by infrared absorption spectrophotometry (2.4.6). Compare the spectrum with that obtained with *ethyl acetate RS* or with the reference spectrum of ethyl acetate.

### Test

**Specific gravity** (2.4.29). 0.894 to 0.898.

**Acidity.** To 2.0 ml of substance in 10 ml of neutralized alcohol, add 2 drops of *phenolphthalein* solution. Neutralize with 0.1 M sodium hydroxide. Not more than 0.1 ml of 0.1 M sodium hydroxide is required to change the colour of the solution.

**Readily carbonizable substances.** Add 2.0 ml of substance to 10.0 ml of *sulphuric acid* to form separate layers. No dark zone is developed within 15 minutes.

**Limit of nonvolatile residue.** Not more than 0.02 per cent, determined by evaporating 100 g of the substance to dryness in a tared porcelain dish on a steam-bath and dry at 105° for 1 hour.

**Related substance.** Determine by gas chromatography (2.4.13).

*Test solution.* Dissolve 1.6 g of the substance under examination in 10.0 ml of *N,N-dimethylacetamide*.

*Reference solution (a).* A mixture of solution containing 0.016 per cent w/v of each *acetaldehyde* and *methanol*, 16.0 per cent w/v solution of *ethyl acetate RS* and 0.16 per cent w/v solution of *methyl ethyl ketone RS* in *N,N-dimethylacetamide*.

*Reference solution (b).* A 0.016 per cent w/v solution each of *acetaldehyde*, *ethyl acetate RS*, and *1-Ethoxy-2-methylpropane RS* in *N,N-dimethylacetamide*.

*Reference solution (c).* A 0.016 per cent w/v solution each of *methanol*, *methyl acetate*, and *methyl isobutyrate* in *N,N-dimethylacetamide* (For identification of Methyl compounds).

*Reference solution (d).* Dilute 5.0 ml of reference solution (b) to 10.0 ml with *N,N-dimethylacetamide*.

### Chromatographic system

- a fused-silica capillary column 60 m x 0.32 mm coated with 6 per cent cyanopropylphenyl- 94 per cent dimethylpolysiloxane (film thickness 1.8 µm) (Such as DB624),
- flame ionisation detector,
- temperature:
  - column. 40° for 15 minutes, 40° to 200° @ 12° per minute and hold at 200° for 2 minutes,
  - inlet port at 210° and detector at 250°,
- flow rate: 3.0 ml per minute using nitrogen as carrier gas,
- split ratio of 30:1,
- injection volume: 1 µl.

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Name

Relative  
retention time

Acetaldehyde	0.29
Methanol	0.31
Methyl ethyl ketone	0.97
Ethyl acetate	1.0
1-ethoxy-2-methylpropane	1.1

Inject reference solution (a), (b) and (d). The test is not valid unless the resolution between the peaks due to acetaldehyde and methanol is not less than 2.0 and between the peaks due to methyl ethyl ketone and ethyl acetate is not less than 2.0 in the chromatogram obtained with reference solution (a), the relative standard deviation for acetaldehyde, ethyl acetate, and 1-ethoxy-2-methylpropane peaks is not more than 5.0 per cent and the tailing factor is not more than 1.5 for acetaldehydes ethyl acetate and 1-ethoxy-2-methylpropane peaks in the chromatogram obtained with reference solution (b) and signal-to-noise ratio for acetaldehyde, ethyl acetate, and 1-ethoxy-2-methylpropane peaks is not less than 20 in the chromatogram obtained with reference solution (d).

Inject reference solution (c) to identify the peaks due to methanol, methyl acetate and methyl isobutyrate in the test solution.

Inject reference solution (b) and the test solution. In the chromatogram obtained with the test solution the area of any peak corresponding to acetaldehyde and 1-ethoxy-2-methylpropane, each of is not more than the area of the corresponding peak in the in the chromatogram obtained with reference solution (d) (0.1per cent). The sum of the areas of the peaks corresponding to methyl compound (methanol, methyl acetate and methyl isobutyrate) multiplied by correction factor 0.1 is not more than the area of the ethyl acetate peck in the in the chromatogram obtained with reference solution (b) (0.1per cent) and the sum of the areas of all the secondary peaks other than acetaldehyde, 1-ethoxy-2-methylpropane and methyl compounds is not more than 3 times the area of the ethyl acetate peak in the chromatogram obtained with reference solution (b) (0.3 per cent).

**Bacterial endotoxins** (2.2.3). .....

**Assay.** Determine by gas chromatography (2.4.13).

*Test solution.* Dissolve 50 mg of the substance under examination in 25.0 ml of *N,N*-dimethylacetamide.

*Reference solution (a).* A solution containing 0.2 per cent w/v of *ethyl acetate RS* and 0.002 per cent w/v of *methyl ethyl ketone RS* in the *N,N*-dimethylacetamide.

*Reference solution (b).* A 0.2 per cent w/v solution of *ethyl acetate RS* in the *N,N*-dimethylacetamide.

Use chromatographic system as described under Related substances.

The relative retention time with reference to ethyl acetate for methyl ethyl ketone is about 0.97.

Inject reference solution (a), (b). The test is not valid unless the resolution between the peaks due to methyl ethyl ketone and ethyl acetate is not less than 2.0 in the chromatogram obtained with reference solution (a), the tailing factor is not more than 1.5 and the relative standard deviation for replicate injections is not more than 2.0 per cent in the chromatogram obtained with reference solution (b).

Inject reference solution (b) and the test solution.

Calculate the content of  $C_4H_8O_2$ .

**Storage.** Store protected from moisture, at a temperature not exceeding 30°.

**Solubility.** Soluble in *water*, miscible with *alcohol*, *ether*, fixed oils and with volatile oils.

## 4.2. General reagent

**Methyl isobutyrate:**  $C_5H_{10}O_2 = 102.13$

General laboratory reagent grade of commerce.