

**PHARMACOPOEIAL DISCUSSION GROUP
SIGN-OFF COVER SHEET**

CODE: E-17

NAME: ETHYLCELLULOSE

(Version 3 of sign-off cover sheet of Rev. 2 signed on May 26, 2016)

Amended Item: Add IP to the sign-off as new PDG member.

Harmonised attributes:

Attribute	EP	IP	JP	USP
Definition	+	+	+	+
Identification IR	+	+	+	+
Acidity/ Alkalinity	+	+	+	+
Viscosity	+	+	+	+
Acetaldehyde	+	+	+	+
Chlorides	+	+	+	+
Loss on drying	+	+	+	+
Sulphated Ash	+	+	+	+
Assay	+	+	+	+
Labelling	+	+	+ (1)	+

Legend

‘+’ will adopt and implement, ‘-’ will not stipulate

(1) JP will not stipulate ‘the name and concentration of any antioxidant’.

Non-harmonised parts

EP	Characters, Identification (it complies with the limits of assay). Functionality-Related Characteristics (Viscosity*, Degree of substitution*, Molecular mass distribution, Particle-size distribution, Powder flow)
IP	Category, Description, pH, Arsenic, Storage
JP	Description, Containers and storage
USP	Packaging and storage

* Viscosity and Degree of substitution (Assay) are harmonised attributes. They are also included in the Functionality-Related Characteristics section of the EP monograph.

E-17

Revision 2, Version 3 of sign-off cover sheet

July 2026

European Pharmacopoeia

Signé par :

5D202E6E19D1466...

C. Vielle

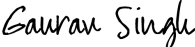
2 September 2026

Signature

Name

Date

Indian Pharmacopoeia

Signed by:

6CD705E38A2848B...

Gaurav Pratap Singh

August 18, 2026

Signature

Name

Date

Japanese Pharmacopoeia

署名者:

for T. Kishino
878995A356ED445...

Yoshiro Saito

Aug. 17, 2026

Signature

Name

Date

United States Pharmacopeia

Signed by:

A7467E52FCC94E9...

Kevin Moore

8/14/2026

Signature

Name

Date

E17 ETHYLCELLULOSE

DEFINITION

Ethylcellulose is a partly *O*-ethylated cellulose. It contains not less than 44.0 per cent and not more than 51.0 per cent of ethoxy ($-\text{OC}_2\text{H}_5$) groups, calculated with reference to the dried substance.

It may contain a suitable antioxidant.

IDENTIFICATION

Examine by infrared absorption spectrophotometry.

Preparation: dissolve 40 mg in 1 mL of *methylene chloride*; spread 2 drops of this solution between 2 sodium chloride plates, then remove one of the plates to evaporate the solvent.

TESTS

Acidity or alkalinity. To 0.5 g add 25 ml of *carbon dioxide-free water* and shake for 15 min. Filter through a sintered-glass filter (40). To 10 ml add 0.1 ml of *phenolphthalein solution* and 0.5 ml of 0.01 M *sodium hydroxide*. The solution is pink. To 10 ml add 0.1 ml of *methyl red solution* and 0.5 ml of 0.01 M *hydrochloric acid*. The solution is red.

Viscosity. Shake a quantity of the substance to be examined equivalent to 5.00 g of the dried substance with 95 g of a mixture of 20 g of *ethanol (96 per cent)* and 80 g of *toluene* until the substance is dissolved. Determine the viscosity using a capillary viscometer. The viscosity, determined at 25 °C and expressed in mPa·s, is not less than 80.0 per cent and not more than 120.0 per cent of that stated on the label for a nominal viscosity greater than 6 mPa·s; and not less than 75.0 per cent and not more than 140.0 per cent of that stated on the label for a nominal viscosity not greater than 6 mPa·s.

Acetaldehyde. Introduce 3.0 g into a 250 ml conical flask with a ground-glass stopper, add 10 ml of *water* and stir mechanically for 1 h. Allow to stand for 24 h, filter and dilute the filtrate to 100.0 ml with *water*. Transfer 5.0 ml to a 25 ml volumetric flask, add 5 ml of a 0.5 g/l solution of *methylbenzothiazolone hydrazone hydrochloride* ($\text{C}_8\text{H}_{10}\text{ClN}_3\text{S}\cdot\text{H}_2\text{O}$) and heat in a water-bath at 60 °C for 5 min. Add 2 ml of *ferric chloride-sulphamic acid reagent* and heat again at 60 °C for 5 min. Cool and dilute to 25.0 ml with *water*. The solution is not more intensely coloured than a standard prepared at the same time and in the same manner using instead of the 5.0 ml of filtrate, 5.0 ml of a reference solution prepared by diluting 3.0 ml of *acetaldehyde standard solution (100 ppm $\text{C}_2\text{H}_4\text{O}$)* to 100.0 ml with *water* (100 ppm).

Chlorides (0.1 per cent). Disperse 0.250 g in 50 ml of *water*, heat to boiling and allow to cool, shaking occasionally. Filter and discard the first 10 ml of the filtrate. Dilute 10 ml of the filtrate to 15 ml with *water*. Add 1 ml of *dilute nitric acid* and pour the mixture as a single addition into a test-tube containing 1 ml of a 17 g/l solution of *silver nitrate*. Prepare a standard in the same manner using 10 ml of *chloride standard solution (5 ppm Cl)* and 5 ml

of *water*. Examine the tubes laterally against a black background. After standing for 5 min protected from light, any opalescence in the test solution is not more intense than that in the standard.

Loss on drying. Not more than 3.0 per cent, determined on 1.000 g by drying in an oven at 105 °C for 2 h.

Sulfated ash. Not more than 0.5 per cent, determined on 1.0 g.

ASSAY

Gas chromatography (2.2.28).

Internal standard solution. To 10 mL of *o*-xylene add 0.5 mL of *n*-octane and dilute to 100.0 mL with *o*-xylene.

Test solution. To 30.0 mg of the substance to be examined (dried substance), add 60 mg of *adipic acid* in a 5-mL pressure-tight reaction vial equipped with a pressure-tight membrane stopper coated with polytetrafluoroethylene and secured with an aluminium crimped cap or any other sealing system providing a sufficient air-tightness¹. Add 2.00 mL of internal standard solution and 1.0 mL of *hydroiodic acid* and close immediately. Accurately weigh the vial (total mass before heating). Do not mix the contents of the vial by hand before heating. Place the vial in an oven or heat in a suitable heater, with continuous mechanical agitation², maintaining the internal temperature of the vial at 115 ± 2 °C for 70 min. Allow to cool and weigh accurately the vial (total mass after heating). If the difference of the total mass before heating to the total mass after heating is more than 10 mg, prepare a new test solution. After phase separation, pierce through the septum of the vial with a cooled syringe and withdraw a sufficient volume of the upper phase as the test solution.

Reference solution. Place 60 mg of *adipic acid* and 2.00 mL of internal standard solution in another 5-mL reaction vial, add 1.0 mL of *hydroiodic acid* and close immediately. Weigh accurately the vial then inject 25 µL of *iodoethane* through the septum in the vial, weigh again accurately and mix. After phase separation, pierce through the septum of the vial with a cooled syringe and withdraw a sufficient volume of the upper phase as reference solution.

Column:

— *material* : fused silica,

— *size*: $l = 30$ m, $\varnothing = 0.53$ mm,

— *stationary phase*: *poly(dimethyl)siloxane* (3 µm)³.

¹ 5 ml Reacti Vial (thick glass wall, sealable) e.g. PIERCE, Cat. No. 13223 and Reacti Vial Caps Mininert Valve e. g. PIERCE, Cat. No. 10135 or other appropriate pressure resistant caps

² Wedge magnetic stirrer PIERCE cat no. 16000

³ RTX-1 Restek, DB-1 or HP-1

1 *Carrier gas : helium for chromatography.*

2 *Flow rate: 4.2 mL/min.*

3 *Split ratio: 1:40.*

4 *Temperature:*

5 — *temperature programme as follows:*

6

	Time (min)	Temperature (°C)
Column	0-3	50
	3-8	50 → 100
	8-12.3	100 → 250
	12.3-20.3	250
Injection port		250
Detector		280

7 *Detection: flame ionisation.*

8 *Injection: 1 µL.*

9 *Relative retention* with reference to *n*-octane (retention time = about 10 min): iodoethane:
10 about = 0.6.

11 *System suitability: reference solution:*

12 — *resolution: minimum 5.0 between the peaks due to n-octane and iodoethane;*

13 — *relative standard deviation of the response factor of the principal peak: maximum 2.0 per*
14 *cent determined on 6 injections.*

15 Calculate the response factor (*R*) from the following expression:

16
$$(A_1 \times W_1 \times C) / (A_2 \times 100)$$

17 *A*₁ = area of the peak due to the internal standard in the chromatogram obtained with the
18 reference solution;

19 *A*₂ = area of the peak due to iodoethane in the chromatogram obtained with the reference
20 solution;

21 *W*₁ = mass of iodoethane in the reference solution, in milligrams;

1 C = percentage content of *iodoethane*.

2 Calculate the percentage content m/m of ethoxy groups from the following expression:

$$3 \quad (A_4 \times R \times M_1 \times 100) / (A_3 \times W_2 \times M_2)$$

4

5 A_3 = area of the peak due to the internal standard in the chromatogram obtained with the test
6 solution;

7 A_4 = area of the peak due to the iodoethane in the chromatogram obtained with the test
8 solution;

9 R = response factor of iodoethane;

10 M_1 = molar mass of ethoxy group (45.1);

11 M_2 = molar mass of iodoethane (156.0);

12 W_2 = mass of the sample (dried substance) in the test solution, in milligrams.

13

14 LABELLING

15 The label states:

16 - the nominal viscosity in millipascal seconds for a 5 per cent m/m solution;

17 - the name and concentration of any added antioxidant.

18

19 Reagents

20

21 **Phenolphthalein solution.**

22 Dissolve 0.1 g of *phenolphthalein* in 80 ml of *ethanol (96 per cent)* and dilute to 100 ml with
23 *water*.

24

25 **Methyl red solution.**

26 Dissolve 50 mg in a mixture of 1.86 ml of *0.1 M sodium hydroxide* and 50 ml of *ethanol*
27 *(96 per cent)* and dilute to 100 ml with *water*.

28

29 **Ferric chloride-sulphamic acid reagent.**

30 A solution containing 10 g/l of *ferric chloride* ($\text{FeCl}_3 \cdot 6\text{H}_2\text{O}$) and 16 g/l of *sulphamic acid*.

31

32 **Acetaldehyde standard solution (100 ppm $\text{C}_2\text{H}_4\text{O}$).**

1 Dissolve 1.0 g of *acetaldehyde* in *water* and dilute to 100.0 ml with the same solvent. Dilute
2 5.0 ml of the solution to 500.0 ml with *water*. Prepare immediately before use.

3
4 **Nitric acid, dilute.**

5 Contains about 125 g/l of HNO₃ (*M*_r 63.0).

6
7 **Chloride standard solution (5 ppm Cl).**

8 Immediately before use, dilute with *water* to 100 times its volume a solution containing
9 *sodium chloride* equivalent to 0.824 g of NaCl in 1000.0 ml.

10
11 **Iodoethane.** C₂H₅I. (*M*_r 155.9). [75-03-6].

12 Colourless or slightly yellowish liquid, darkening on exposure to air and light, miscible with
13 ethanol (96 per cent) and most organic solvents.

14 n_{D}^{20} : about 1.95.

15 n_{D}^{20} : about 1.513.

16 bp: about 72 °C.

17 *Storage*: in an airtight container.

18 *Content*: minimum 99 per cent.

19
20 **Octane.** C₈H₁₈. (*M*_r 114.2). [111-65-9]. *n*-Octane.

21 *Content*: minimum 99 per cent.