PHARMACOPOEIAL DISCUSSION GROUP

CODE: E-11
NAME: CELLULOSE, POWDERED

Correction 1 (Previous Rev. 1 sign-off on 2016-05-26)

Item to be corrected:

- Loss on Drying: specified sample amount 1.0 g
- Residue on Ignition: specified sample amount 1.0 g
- Labeling: removed from the global text because it is a non-harmonized attribute.

Harmonised Attributes

Attribute	**EP**	**JP**	**USP**
Definition	+	+	+
Identification A B	 + +	 + +	 + +
pH	+	+	+
Loss on drying	+	+	+
Residue on ignition	+	+	+
Water-soluble substances	+	+	+
Ether-soluble substances	+	+	+

Legend
+: will adopt and implement
–: will not stipulate

Non-harmonised attributes

Characters/Description, Microbial limits, Containers and storage/Packaging and storage, Labelling

Local requirements

EP	JP	USP
Solubility, Functionality-Related Characteristics (Loss on drying*, Particle size distribution and Powder flow)	Definition (after partial hydrolysis as occasion demands), Identification (2) – dispersion test, Heavy metals	None

* Loss on drying is a harmonized attribute. It is also included in the Functionality-Related Characteristics section of the EP monograph.

YG
KM PD

Reagents and reference materials

Each pharmacopoeia will adapt the text to take account of local reference materials and reagent specifications.

European Pharmacopoeia

Signature	Name	Date
P. Dörr	Petra Doerr	28/10/2021

Japanese Pharmacopoeia

Signature	Name	Date
Y. Goda for Y. Yoshida	Yukihiro Goda	15 Nov, 2021

United States Pharmacopeia

Signature	Name	Date
K T. M	Kevin Moore	9-Nov-2021

Powdered Cellulose

»Powdered Cellulose is purified, mechanically disintegrated cellulose prepared by processing alpha cellulose obtained as a pulp from fibrous plant materials.

Identification—

A: Prepare iodinated zinc chloride solution by dissolving 20 g of zinc chloride and 6.5 g of potassium iodide in 10.5 mL of water. Add 0.5 g of iodine, and shake for 15 minutes. Place about 10 mg of Powdered Cellulose on watch glass, and disperse in 2 mL of iodinated zinc chloride solution: the substance takes on a violet-blue color.

B: Transfer 0.25 g of Powdered Cellulose, accurately weighed to 0.1 mg, to a 125-mL conical flask. . Add 25.0 mL of water and 25.0 mL of 1.0 *M* cupriethylenediamine hydroxide solution. Immediately purge the solution with nitrogen, insert the stopper, and shake on a wrist action shaker or other suitable mechanical shaker until completely dissolved. Transfer an appropriate volume of the solution to a calibrated number 150 Cannon-Fenske or equivalent viscosimeter. Allow the solution to equilibrate at 25 ± 0.1° for not less than 5 minutes. Time the flow between the 2 marks on the viscosimeter, and record the flow time, t_1, in seconds. Calculate the kinematic viscosity, $(KV)_1$, of the Powdered Cellulose taken by the formula:

$t_1 (k_1)$,

in which k_1 is the viscosimeter constant. Obtain the flow time, t_2, for a 0.5 *M* cupriethylenediamine hydroxide solution using a number 100 Cannon-Fenske or equivalent viscosimeter. Calculate the kinematic viscosity, $(KV)_2$, of the solvent by the formula:

$t_2 (k_2)$,

in which k_2 is the viscosimeter constant. Determine the relative viscosity, η_{rel}, of the Powdered Cellulose specimen taken by the formula:

$(KV)_1/(KV)_2$.

Determine the intrinsic viscosity, [η]*c*, by interpolation, using the *Intrinsic Viscosity Table* in the *Reference Tables* section. Calculate the degree of polymerization, *P*, by the formula:

(95)[η]*c* / W_S[(100 - %*LOD*)/100],

in which W_S is the weight, in g, of the Powdered Cellulose taken, and %*LOD* is the value obtained from the test for *Loss on drying*. The degree of polymerization is greater than 440.

pH —Mix 10 g with 90 mL of water, and allow to stand with occasional stirring for 1 hour: the pH of the supernatant liquid is between 5.0 and 7.5.

Loss on drying —Dry 1.0 g at 105° for 3 hours: it loses not more than 6.5% of its weight.

Residue on ignition: not more than 0.3%, calculated on the dried basis, determined on 1.0 g.

Water-soluble substances—Mix 6.0 g with 90 mL of recently boiled and cooled water, and allow to stand with occasional stirring for 10 minutes. Filter, with the aid of vacuum, discard the first 10 mL of the filtrate, and pass the filtrate through the same filter a second time, if necessary, to obtain a clear filtrate. Evaporate a 15.0-mL portion of the filtrate in a tared evaporating dish to dryness without charring, dry at 105° for 1 hour, cool in a desiccator, and weigh: the difference between the weight of the residue and the weight obtained from a blank determination does not exceed 15.0 mg (1.5%).

Ether-soluble substances—Place 10.0 g in a chromatography column having an internal diameter of about 20 mm, and pass 50 mL of peroxide-free ether through the column. Evaporate the eluate to dryness in a previously dried and tared evaporating dish with the aid of a current of air in a fume hood. After all the ether has evaporated, dry the residue at 105° for 30 minutes, cool in a desiccator, and weigh: the difference between the weight of the residue and the weight obtained from a blank determination does not exceed 15.0 mg (0.15%).