Wheat Starch

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Manufacturers, regulatory authorities, health authorities, researchers, and other stakeholders are invited to provide their feedback and comments on this draft proposal. Comments and samples received after the last date will not be considered by the IPC before finalizing the monograph.

Please send any comments you may have on this draft document to arnd-ipc@gov.in , with a copy to Dr. Gaurav Pratap Singh (email: gpsingh.ipc@gov.in) before the last date for comments.

Document History and Schedule for the Adoption Process

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Wheat Starch

This Monograph has been harmonized with corresponding texts of the European Pharmacopoeia, the Japanese Pharmacopoeia and the United States Pharmacopoeia. Portion of the IP text that are not part of the PDG harmonized text, are marked with symbols (♦ ♦).

Wheat starch is obtained from the caryopsis of *Triticum aestivum* Linn. (*T. vulgare* Vill.). The glute content is monitored and stated on the label.

♦**Category**. Pharmaceutical aid. ♦

Description. A very fine, white or almost white powder, which creaks when pressed between the fingers.

Wheat starch does not contain starch granules of any other origin. It may contain a minute quantity, if any, of tissue fragments of the original plant.

Identification

A. On microscopic examination (2.5.8), using a mixture of equal volume of *glycerin* and *water* as a mounting agent. It shows large and small granules, and, very rarely, intermediate sizes. The large granules, 10 µm to 60 µm in diameter, are discoid or, more rarely, reniform in surface view. The central hilum and striations are invisible or barely visible and the granules sometimes show cracks on the edges. In side view, the granules are elliptical and fusiform and the hilum appears as a slit along the main axis. The small granules, rounded or polyhedral, are 2 µm to 10 µm in diameter. Between orthogonally orientated polarising plates or prisms, the granules show a distinct black cross intersecting at the hilum.

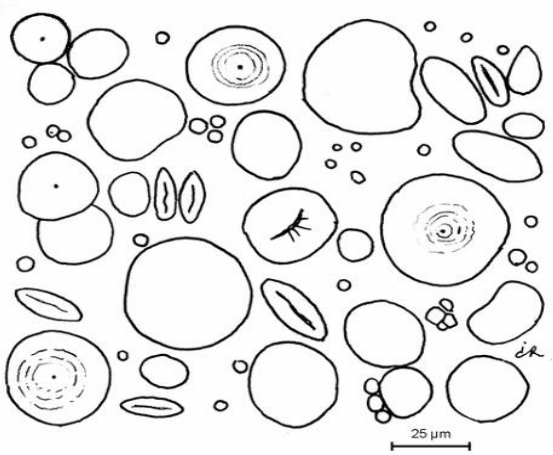

Fig. – Illustration for identification test A of wheat starch.

B. Suspend 1 g in 50 ml of *water* and boil for 1 minute and cool; a thin and cloudy mucilage is formed.

C. To 1 ml of the mucilage obtained in identification test B add 0.05 ml of *iodine and potassium iodide solution.* A dark blue colour is produced, which disappears on heating.

Tests

pH (2.4.24). 4.5 to 7.0, determined in a slurry prepared by shaking 5.0 g of substance under examination with 25.0 ml of *carbon dioxide-free water* for 1 minute and allow to stand for 15 minutes.

Iron (2.3.14). Shake 1.5 g of the substance under examination with 15 ml of *2 M hydrochloric acid*, and filter. 10 ml of the filtrate complies with the limit test for iron (10 ppm), using 1.0 ml of iron standard solution (10 ppm).

Total protein. Not more than 0.3 per cent (corresponding to 0.048 per cent of nitrogen).

Determine the nitrogen content by using following method and calculate the quantity of protein by multiplying by 6.25.

Weigh 3.0 g of substance and transfer to a combustion flask add 4 g of a powdered mixture of 100 g of *dipotassium sulphate*, 3 g of *copper sulphate pentahydrate* and 3 g of *titanium dioxide*, and add three glass beads. Wash any adhering particles from the neck of the flask with a fine jet of *water.* Add 25 ml of *sulphuric acid,* allowing it to run down the sides

of the flask, and swirl to mix the contents. Close the mouth of the flask loosely, for example by means of a glass bulb with a short stem, to avoid excessive loss of *sulphuric acid*. Heat gradually at first, then increase the temperature until there is vigorous boiling with condensation of *sulphuric acid* in the neck of the flask, take precautions to prevent the upper part of the flask from becoming overheated. Continue heating until a clear solution is obtained and the inside wall of the flask is free from carbonaceous material. Cool, dissolve the solid material by cautiously adding 25 ml of *water* to the mixture, cool again and place in a steam-distillation apparatus. Add a suitable volume of strong *sodium hydroxide solution* to change the colour of the solution from bluish-green to brown or black, and distil immediately by-passing steam through the mixture. Collect about 40 ml of distillate in 50.0 ml of *0.01 M hydrochloric acid*, adding enough *water* if necessary to cover the tip of the condenser. Towards the end of the distillation, lower the receiver so that the tip of the condenser is above the surface of the acid and rinse the end of the condensing tube with a small quantity of *water.* Take precautions to prevent any *water* on the outer surface of the condenser from reaching the contents of the receiver. Titrate the distillate with *0.025 M sodium hydroxide*, using *methyl red mixed solution* as indicator. Carry out a blank determination in the same manner.

Calculate the percentage content of nitrogen using the following expression

$$\text{Content of nitrogen} = [0.03503 \times (n_2 - n_1)]/w$$

Where,

n_2= volume of *0.025 M sodium hydroxide* used in the blank determination (ml)

n_1 = volume of *0.025 M sodium hydroxide* used in the test solution (ml)

w = weight of the substance (g).

Sulphur dioxide (2.3.40). Not more than 50 ppm.

Oxidising substances. Transfer 4.0 g to a glass-stoppered, 125-ml conical flask and add 50.0 ml of *water*. Insert the stopper, and swirl for 5 minutes. Transfer to a glass-stoppered, 50-ml centrifuge tube, and centrifuge to clarify. Transfer 30.0 ml of the clear supernatant liquid to a glass-stoppered, 125-ml conical flask. Add 1 ml of *glacial acetic acid* and 0.5 g to 1.0 g of *potassium iodide*. Insert the stopper, swirl, and allow to stand for 25 minutes to 30 minutes in the dark. Add 1 ml of *starch solution* prepared by mixing 1 g of *soluble starch* with 10 mg of *red mercuric iodide* and add sufficient cold *water* to make a thin a paste. Add 200 ml of boiling *water* and boil for 1 minute with continuous stirring. Cool and use only the clear solution. Titrate with *0.002 M sodium thiosulphate* to the disappearance of the starch-iodine colour. Carry out a blank titration.

Each ml of *0.002 M sodium thiosulphate* is equivalent to 34 µg of oxidant, calculated as *hydrogen peroxide*.

Not more than 1.4 ml of *0.002 M sodium thiosulphate* is required (20 ppm, calculated as H_2O_2).

Microbial contamination (2.2.9). The total aerobic viable count is not more than 10^3 CFU per g; the total combined molds and yeasts count is not more than 10^2 CFU per g; 1 g is free from *Escherichia coli* and 10 g is free from *Salmonella species.*

Sulphated ash (2.3.18). Not more than 0.6 per cent.

Loss on drying (2.4.19). Not more than 15.0 per cent, determined on 1.0 g by drying in an oven at 130º for 90 minutes.

♦**Storage**. Store protected from moisture.

Labelling. The label states the gluten content. ♦

Solubility. Practically insoluble in cold *water* and in *ethanol (96 per cent).*