

DEFINITION

Magnesium sulphate heptahydrate contains not less than 99.0 per cent and not more than the equivalent of 100.5 per cent of MgSO_4 , calculated with reference to the dried substance.

CHARACTERS

A white, crystalline powder or brilliant, colourless crystals, freely soluble in water, very soluble in boiling water, practically insoluble in alcohol.

IDENTIFICATION

- A. It gives the reactions of sulphates (2.3.1).
B. It gives the reaction of magnesium (2.3.1).

TESTS

Solution S. Dissolve 5.0 g in *water R* and dilute to 50 ml with the same solvent.

Appearance of solution. Solution S is clear (2.2.1) and colourless (2.2.2, *Method II*).

Acidity or alkalinity. To 10 ml of solution S add 0.05 ml of *phenol red solution R*. Not more than 0.2 ml of 0.01 M *hydrochloric acid* or 0.01 M *sodium hydroxide* is required to change the colour of the indicator.

Chlorides (2.4.4). 1.7 ml of solution S diluted to 15 ml with *water R* complies with the limit test for chlorides (300 ppm).

Arsenic (2.4.2). 0.5 g complies with limit test A for arsenic (2 ppm).

Iron (2.4.9). 5 ml of solution S diluted to 10 ml with *water R* complies with the limit test for iron (20 ppm).

Heavy metals (2.4.8). 12 ml of solution S complies with limit test A for heavy metals (10 ppm). Prepare the standard using *lead standard solution (1 ppm Pb) R*.

Loss on drying (2.2.32). 48.0 per cent to 52.0 per cent, determined on 0.500 g by drying in an oven at 110 °C to 120 °C for 1 h and then at 400 °C to constant mass.

ASSAY

Dissolve 0.450 g in 100 ml of *water R* and carry out the complexometric titration of magnesium (2.5.11).

1 ml of 0.1 M *sodium edetate* is equivalent to 12.04 mg of MgSO_4 .

01/2005:0403

MAGNESIUM TRISILICATE

Magnesii trisilicas

DEFINITION

Magnesium trisilicate has a variable composition corresponding approximately to $\text{Mg}_2\text{Si}_3\text{O}_8 \cdot x\text{H}_2\text{O}$ and contains not less than the equivalent of 29.0 per cent of magnesium oxide (MgO ; M_r 40.30) and not less than the equivalent of 65.0 per cent of silicon dioxide (SiO_2 ; M_r 60.1), both calculated with reference to the ignited substance.

CHARACTERS

A white powder, practically insoluble in water and in alcohol.

IDENTIFICATION

- A. 0.25 g gives the reaction of silicates (2.3.1).
B. 1 ml of solution S (see Tests) neutralised with *dilute sodium hydroxide solution R* gives the reaction of magnesium (2.3.1).

TESTS

Solution S. To 2.0 g add a mixture of 4 ml of *nitric acid R* and 4 ml of *distilled water R*. Heat to boiling with frequent shaking. Add 12 ml of *distilled water R* and allow to cool. Filter or centrifuge to obtain a clear solution and dilute to 20 ml with *distilled water R*.

Alkalinity. To 10.0 g in a 200 ml conical flask, add 100.0 g of *water R* and heat on a water-bath for 30 min. Allow to cool and make up to the initial mass with *water R*. Allow to stand and filter or centrifuge until a clear liquid is obtained. To 10 ml of the liquid add 0.1 ml of *phenolphthalein solution R*. Not more than 1.0 ml of 0.1 M *hydrochloric acid* is required to change the colour of the indicator.

Water-soluble salts. In a platinum dish, evaporate to dryness on a water-bath 20.0 ml of the liquid obtained in the test for alkalinity. The residue, ignited to constant mass at 900 °C, weighs not more than 30 mg (1.5 per cent).

Chlorides (2.4.4). 0.5 ml of solution S diluted to 15 ml with *water R* complies with the limit test for chlorides (500 ppm). Prepare the standard using a mixture of 5 ml of *chloride standard solution (5 ppm Cl) R* and 10 ml of *water R*.

Sulphates (2.4.13). 0.3 ml of solution S diluted to 15 ml with *distilled water R* complies with the limit test for sulphates (0.5 per cent).

Arsenic (2.4.2). 2.5 ml of solution S complies with limit test A for arsenic (4 ppm).

Heavy metals (2.4.8). Neutralise 10 ml of solution S with *dilute ammonia R1*, using *metanil yellow solution R* as an external indicator. Dilute to 20 ml with *water R* and filter if necessary. 12 ml of the solution complies with limit test A for heavy metals (40 ppm). Prepare the standard using *lead standard solution (2 ppm Pb) R*.

Loss on ignition: 17 per cent to 34 per cent, determined on 0.5 g ignited to constant mass at 900 °C in a platinum crucible.

Acid-absorbing capacity. Suspend 0.25 g in 0.1 M *hydrochloric acid*, dilute to 100.0 ml with the same acid and allow to stand for 2 h in a water-bath at 37 ± 0.5 °C, with frequent shaking. Allow to cool. To 20.0 ml of the supernatant solution add 0.1 ml of *bromophenol blue solution R* and titrate with 0.1 M *sodium hydroxide* until a blue colour is obtained. The acid-absorbing capacity is not less than 100.0 ml of 0.1 M *hydrochloric acid* per gram.

ASSAY

Magnesium oxide. To 1.000 g in a 200 ml conical flask, add 35 ml of *hydrochloric acid R* and 60 ml of *water R* and heat in a water-bath for 15 min. Allow to cool, filter, wash the conical flask and the residue with *water R* and dilute the combined filtrate and washings to 250.0 ml with *water R*. Neutralise 50.0 ml of the solution with *strong sodium hydroxide solution R* (about 8 ml). Carry out the complexometric titration of magnesium (2.5.11).

1 ml of 0.1 M *sodium edetate* is equivalent to 4.030 mg of MgO .

Silicon dioxide. To 0.700 g add 10 ml of *dilute sulphuric acid R* and 10 ml of *water R*. Heat for 90 min on a water-bath with frequent shaking, replacing the evaporated water. Allow to cool and decant onto an ashless filter paper (diameter 7 cm). Wash the precipitate by decantation with three quantities, each of 5 ml, of hot *water R*, transfer it to the filter and wash it with hot *water R* until 1 ml of the filtrate remains clear after the addition of 0.05 ml of *dilute hydrochloric*

acid R and 2 ml of *barium chloride solution RI*. Incinerate the filter and its contents in a platinum crucible, then ignite the residue (SiO_2) at 900 °C to constant mass.

01/2005:1342

MAIZE OIL, REFINED

Maydis oleum raffinatum

DEFINITION

Refined maize oil is the fatty oil obtained from the seeds of *Zea mays* L. by expression or by extraction, then refined.

CHARACTERS

A clear, light yellow or yellow oil, practically insoluble in water and in alcohol, miscible with light petroleum (bp: 40 °C to 60 °C) and with methylene chloride.

It has a relative density of about 0.920 and a refractive index of about 1.474.

IDENTIFICATION

- A. Carry out the identification of fatty oils by thin-layer chromatography (2.3.2). The chromatogram obtained with the test solution is similar to that obtained with the reference solution.
- B. It complies with the test for composition of fatty acids (see Tests).

TESTS

Acid value (2.5.1). Not more than 0.5, determined on 10.0 g. If intended for use in the manufacture of parenteral dosage forms, not more than 0.3.

Peroxide value (2.5.5). Not more than 10.0. If intended for use in the manufacture of parenteral dosage forms, not more than 5.0.

Unsaponifiable matter (2.5.7). Not more than 2.8 per cent, determined on 5.0 g.

Alkaline impurities (2.4.19). It complies with the test for alkaline impurities in fatty oils.

Composition of fatty acids (2.4.22, Method A). The fatty-acid fraction of the oil has the following composition:

- *fatty acids of chain length less than C₁₆*: not more than 0.6 per cent,
- *palmitic acid*: 8.6 per cent to 16.5 per cent,
- *stearic acid*: not more than 3.3 per cent,
- *oleic acid*: 20.0 per cent to 42.2 per cent (equivalent chain length on polyethyleneglycol adipate 18.3),
- *linoleic acid*: 39.4 per cent to 65.6 per cent (equivalent chain length on polyethyleneglycol adipate 18.9),
- *linolenic acid*: 0.5 per cent to 1.5 per cent (equivalent chain length on polyethyleneglycol adipate 19.7),
- *arachidic acid*: not more than 0.8 per cent,
- *eicosenoic acid*: not more than 0.5 per cent (equivalent chain length on polyethyleneglycol adipate 20.3),
- *behenic acid*: not more than 0.5 per cent,
- *other fatty acids*: not more than 0.5 per cent.

Sterols. Determined by gas chromatography (2.4.23), the sterol fraction of the oil contains not more than 0.3 per cent of brassicasterol.

Water (2.5.32). If intended for use in the manufacture of parenteral dosage forms, not more than 0.1 per cent, determined on 5.00 g by the micro-determination of water. Use a mixture of equal volumes of *decanol R* and *anhydrous methanol R* as the solvent.

STORAGE

Store protected from light, at a temperature not exceeding 25 °C.

LABELLING

The label states:

- where applicable, that the substance is suitable for use in the manufacture of parenteral dosage forms,
- whether the oil is obtained by mechanical expression or by extraction.

01/2005:0344

MAIZE STARCH

Maydis amyllum

DEFINITION

Maize starch is obtained from the caryopsis of *Zea mays* L.

CHARACTERS

Appearance: matt, white to slightly yellowish, very fine powder which creaks when pressed between the fingers.

Solubility: practically insoluble in cold water and in alcohol.

The presence of granules with cracks or irregularities on the edge is exceptional.

It is tasteless.

IDENTIFICATION

- A. Examined under a microscope, using not less than 20 × magnification and using equal volumes of *glycerol R* and *water R*, it appears as either angular polyhedral granules of irregular sizes with diameters ranging from about 2 µm to about 23 µm or as rounded or spheroidal granules of irregular sizes with diameters ranging from about 25 µm to about 35 µm. The central hilum consists of a distinct cavity or two-to five-rayed cleft and there are no concentric striations. Between crossed nicol prisms, the starch granules show a distinct black cross intersecting at the hilum.
- B. Suspend 1 g in 50 ml of *water R*, boil for 1 min and cool. A thin, cloudy mucilage is formed.
- C. To 10 ml of the mucilage obtained in identification test B add 0.04 ml of *iodine solution RI*. An orange-red to dark blue colour is produced which disappears on heating.

TESTS

pH (2.2.3): 4.0 to 7.0.

Shake 5.0 g with 25.0 ml of *carbon dioxide-free water R* for 60 s. Allow to stand for 15 min.

Foreign matter. Examined under a microscope using a mixture of equal volumes of *glycerol R* and *water R*, not more than traces of matter other than starch granules are present. No starch grains of any other origin are present.

Oxidising substances (2.5.30): maximum 20 ppm, calculated as H_2O_2 .

Sulphur dioxide (2.5.29): maximum 50 ppm.

Iron (2.4.9): maximum 10 ppm.

Shake 1.5 g with 15 ml of *dilute hydrochloric acid R*. Filter. The filtrate complies with the limit test for iron.

Loss on drying (2.2.32): maximum 15.0 per cent, determined on 1.000 g by drying in an oven at 130 °C for 90 min.

Sulphated ash (2.4.14): maximum 0.6 per cent, determined on 1.0 g.