with the reference solution, the resolution between the peaks corresponding to methyl stearate and methyl palmitate is at least 5.0.

Inject 1 μl of the test solution. Calculate the percentage content of stearic acid and palmitic acid from the areas of the peaks in the chromatogram obtained with the test solution by the normalisation procedure, disregarding the peak due to the solvent.

FUNCTIONALITY-RELATED CHARACTERISTICS

This section provides information on characteristics that are recognised as being relevant control parameters for one or more functions of the substance when used as an excipient. This section is a non-mandatory part of the monograph and it is not necessary to verify the characteristics to demonstrate compliance. Control of these characteristics can however contribute to the quality of a medicinal product by improving the consistency of the manufacturing process and the performance of the medicinal product during use. Where control methods are cited, they are recognised as being suitable for the purpose, but other methods can also be used. Wherever results for a particular characteristic are reported, the control method must be indicated.

The following characteristic may be relevant for magnesium stearate used as a lubricant in solid dosage forms (compressed and powder).

Specific surface area (*2.9.26, Method I*). Determine the specific surface area in the P/P_0 range of 0.05 to 0.15.

Sample outgassing: 2 h at 40 °C.

01/2008:0044
corrected 6.0

MAGNESIUM SULPHATE HEPTAHYDRATE

Magnesii sulfas heptahydricus

$MgSO_4,7H_2O$ M_r 246.5
[10034-99-8]

DEFINITION

Content: 99.0 per cent to 100.5 per cent (dried substance).

CHARACTERS

Appearance: white or almost white, crystalline powder or brilliant, colourless crystals.

Solubility: freely soluble in water, very soluble in boiling water, practically insoluble in ethanol (96 per cent).

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*): maximum 300 ppm.

Dilute 1.7 ml of solution S to 15 ml with *water R*.

Arsenic (*2.4.2, Method A*): maximum 2 ppm, determined on 0.5 g.

Iron (*2.4.9*): maximum 20 ppm.

Dilute 5 ml of solution S to 10 ml with *water R*.

Heavy metals (*2.4.8*): maximum 10 ppm.

12 ml of solution S complies with test A. Prepare the reference solution 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 110-120 °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 $MgSO_4$.

01/2008:0403
corrected 6.0

MAGNESIUM TRISILICATE

Magnesii trisilicas

DEFINITION

It has a variable composition corresponding approximately to $Mg_2Si_3O_8,xH_2O$.

Content:

- *magnesium oxide* (MgO; M_r 40.30): minimum 29.0 per cent (ignited substance),
- *silicon dioxide* (SiO_2; M_r 60.1): minimum 65.0 per cent (ignited substance).

CHARACTERS

Appearance: white or almost white powder.

Solubility: practically insoluble in water and in ethanol (96 per cent).

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 this 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: maximum 1.5 per cent.

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 ± 50 °C, weighs a maximum of 30 mg.

Chlorides (*2.4.4*): maximum 500 ppm.

Dilute 0.5 ml of solution S to 15 ml with *water R*. 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*): maximum 0.5 per cent.

Dilute 0.3 ml of solution S to 15 ml with *distilled water R*.

Arsenic (*2.4.2, method A*): maximum 4 ppm, determined on 2.5 ml of solution S.

Heavy metals (*2.4.8*): maximum 40 ppm.

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 this solution complies with test A. Prepare the reference solution using *lead standard solution (2 ppm Pb) R*.

Loss on ignition: 17 per cent to 34 per cent, determined on 0.5 g by ignition to constant mass at 900 ± 50 °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 3 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 R1*. Incinerate the filter and its contents in a platinum crucible, then ignite the residue (SiO_2) at 900 ± 50 °C to constant mass.

01/2008:1342

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 C_{16}*: 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.

01/2008:0344

MAIZE STARCH

Maydis amylum

DEFINITION

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