IDENTIFICATION

It complies with the identification test for fatty oils by thin-layer chromatography (*2.3.2*). The chromatogram obtained is similar to the typical chromatogram for arachis oil.

TESTS

Acid value (*2.5.1*): maximum 0.5, determined on 10.0 g.

Peroxide value (*2.5.5*): maximum 5.0.

Unsaponifiable matter (*2.5.7*): maximum 1.0 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. Gas chromatography (*2.4.22, Method A*). Use the mixture of calibrating substances in Table 2.4.22.-3.

Composition of the fatty acid fraction of the oil:

- *saturated fatty acids of chain length less than* C_{16}: maximum 0.4 per cent,
- *palmitic acid*: 7.0 per cent to 16.0 per cent,
- *stearic acid*: 1.3 per cent to 6.5 per cent,
- *oleic acid* (equivalent chain length on polyethyleneglycol adipate 18.3): 35.0 per cent to 72.0 per cent,
- *linoleic acid* (equivalent chain length on polyethyleneglycol adipate 18.9): 13.0 per cent to 43.0 per cent,
- *linolenic acid* (equivalent chain length on polyethyleneglycol adipate 19.7): maximum 0.6 per cent,
- *arachidic acid*: 0.5 per cent to 3.0 per cent,
- *eicosenoic acid* (equivalent chain length on polyethyleneglycol adipate 20.3): 0.5 per cent to 2.1 per cent,
- *behenic acid*: 1.0 per cent to 5.0 per cent,
- *erucic acid* (equivalent chain length on polyethyleneglycol adipate 22.3): maximum 0.5 per cent,
- *lignoceric acid*: 0.5 per cent to 3.0 per cent.

Water (*2.5.12*): maximum 0.3 per cent, determined on 3.00 g, if intended for use in the manufacture of parenteral dosage forms.

STORAGE

In a well-filled container, protected from light.

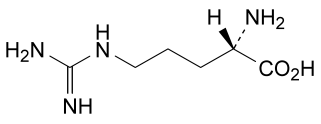
LABELLING

The label states, where applicable, that the substance is suitable for use in the manufacture of parenteral dosage forms.

01/2008:0806
corrected 6.0

ARGININE

Argininum



$C_6H_{14}N_4O_2$ M_r 174.2
[74-79-3]

DEFINITION

Arginine contains not less than 98.5 per cent and not more than the equivalent of 101.0 per cent of (*S*)-2-amino-5-guanidinopentanoic acid, calculated with reference to the dried substance.

CHARACTERS

A white or almost white, crystalline powder or colourless crystals, freely soluble in water, very slightly soluble in alcohol.

IDENTIFICATION

First identification: A, C.

Second identification: A, B, D, E.

A. It complies with the test for specific optical rotation (see Tests).

B. Solution S (see Tests) is strongly alkaline (*2.2.4*).

C. Examine by infrared absorption spectrophotometry (*2.2.24*), comparing with the spectrum obtained with *arginine CRS*. Examine the substances prepared as discs.

D. Examine the chromatograms obtained in the test for ninhydrin-positive substances. The principal spot in the chromatogram obtained with test solution (b) is similar in position, colour and size to the principal spot in the chromatogram obtained with reference solution (a).

E. Dissolve about 25 mg in 2 ml of *water R*. Add 1 ml of *α-naphthol solution R* and 2 ml of a mixture of equal volumes of *strong sodium hypochlorite solution R* and water. A red colour develops.

TESTS

Solution S. Dissolve 2.5 g in *distilled water R* and dilute to 50 ml with the same solvent.

Appearance of solution. Solution S is clear (*2.2.1*) and not more intensely coloured than reference solution BY_6 (*2.2.2, Method II*).

Specific optical rotation (*2.2.7*). Dissolve 2.00 g in *hydrochloric acid R1* and dilute to 25.0 ml with the same acid. The specific optical rotation is + 25.5 to + 28.5, calculated with reference to the dried substance.

Ninhydrin-positive substances. Examine by thin-layer chromatography (*2.2.27*), using a *TLC silica gel plate R*.

Test solution (a). Dissolve 0.10 g of the substance to be examined in *dilute hydrochloric acid R* and dilute to 10 ml with the same acid.

Test solution (b). Dilute 1 ml of test solution (a) to 50 ml with *water R*.

Reference solution (a). Dissolve 10 mg of *arginine CRS* in *0.1 M hydrochloric acid* and dilute to 50 ml with the same acid.

Reference solution (b). Dilute 5 ml of test solution (b) to 20 ml with *water R*.

Reference solution (c). Dissolve 10 mg of *arginine CRS* and 10 mg of *lysine hydrochloride CRS* in *0.1 M hydrochloric acid* and dilute to 25 ml with the same acid.

Apply to the plate 5 µl of each solution. Allow the plate to dry in air. Develop over a path of 15 cm using a mixture of 30 volumes of *concentrated ammonia R* and 70 volumes of *2-propanol R*. Dry the plate at 100 °C to 105 °C until the ammonia disappears completely. Spray with *ninhydrin solution R* and heat at 100 °C to 105 °C for 15 min. Any spot in the chromatogram obtained with test solution (a), apart from the principal spot, is not more intense than the spot in the chromatogram obtained with reference solution (b)

(0.5 per cent). The test is not valid unless the chromatogram obtained with reference solution (c) shows two clearly separated spots.

Chlorides (*2.4.4*). To 5 ml of solution S add 0.5 ml of *dilute nitric acid R* and dilute to 15 ml with *water R*. The solution complies with the limit test for chlorides (200 ppm).

Sulphates (*2.4.13*). To 10 ml of solution S, add 1.7 ml of *dilute hydrochloric acid R* and dilute to 15 ml with *distilled water R*. The solution complies with the limit test for sulphates (300 ppm).

Ammonium (*2.4.1*). 50 mg complies with limit test B for ammonium (200 ppm). Prepare the standard using 0.1 ml of *ammonium standard solution (100 ppm NH_4) R*.

Iron (*2.4.9*). In a separating funnel, dissolve 1.0 g in 10 ml of *dilute hydrochloric acid R*. Shake with three quantities, each of 10 ml, of *methyl isobutyl ketone R1*, shaking for 3 min each time. To the combined organic layers add 10 ml of *water R* and shake for 3 min. The aqueous layer complies with the limit test for iron (10 ppm).

Heavy metals (*2.4.8*). Dissolve 2.0 g in *water R* and dilute to 20 ml with the same solvent. 12 ml of the solution 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*). Not more than 0.5 per cent, determined on 1.000 g by drying in an oven at 105 °C.

Sulphated ash (*2.4.14*). Not more than 0.1 per cent, determined on 1.0 g.

ASSAY

Dissolve 0.150 g in 50 ml of *water R*. Using 0.2 ml of *methyl red mixed solution R* as indicator, titrate with *0.1 M hydrochloric acid* until the colour changes from green to violet-red.

1 ml of *0.1 M hydrochloric acid* is equivalent to 17.42 mg of $C_6H_{14}N_4O_2$.

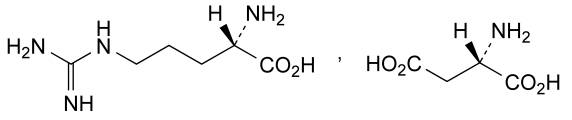
STORAGE

Store protected from light.

01/2008:2096
corrected 6.0

ARGININE ASPARTATE

Arginini aspartas



$C_{10}H_{21}N_5O_6$ M_r 307.3
[7675-83-4]

DEFINITION

(2*S*)-2-Amino-5-guanidinopentanoic acid (2*S*)-2-aminobutanedioate.

Content: 99.0 per cent to 101.0 per cent (dried substance).

CHARACTERS

Appearance: white or almost white granules or powder.

Solubility: very soluble in water, practically insoluble in alcohol and in methylene chloride.

IDENTIFICATION

A. It complies with the test for specific optical rotation (see Tests).

B. Infrared absorption spectrophotometry (*2.2.24*).

Comparison: *arginine aspartate CRS*.

C. Examine the chromatograms obtained in the test for ninhydrin-positive substances.

Results: the 2 principal spots in the chromatogram obtained with test solution (b) are similar in position, colour and size to the 2 principal spots in the chromatogram obtained with reference solution (a).

TESTS

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

Appearance of solution. Solution S is clear (*2.2.1*) and not more intensely coloured than reference solution Y_7 (*2.2.2, Method II*).

pH (*2.2.3*): 6.0 to 7.0 for solution S.

Specific optical rotation (*2.2.7*): + 25 to + 27 (dried substance).

Dissolve 2.50 g in *dilute hydrochloric acid R* and dilute to 25.0 ml with the same acid.

Ninhydrin-positive substances. Thin-layer chromatography (*2.2.27*).

Test solution (a). Dissolve 0.20 g of the substance to be examined in *water R* and dilute to 10 ml with the same solvent.

Test solution (b). Dilute 1 ml of test solution (a) to 10 ml with *water R*.

Reference solution (a). Dissolve 25 mg of *arginine R* and 25 mg of *aspartic acid R* in *water R* and dilute to 25 ml with the same solvent.

Reference solution (b). Dilute 2 ml of reference solution (a) to 50 ml with *water R*.

Plate: *TLC silica gel G plate R*.

Mobile phase: *ammonia R, propanol R* (36:64 *V/V*).

Application: 5 µl.

Development: over 2/3 of the plate.

Drying: at 100-105 °C for 10 min.

Detection: spray with *ninhydrin solution R* and heat at 100-105 °C for 10 min.

System suitability: reference solution (b):

– the chromatogram shows 2 clearly separated principal spots.

Limit: test solution (a):

– *any impurity*: any spots, apart from the 2 principal spots, are not more intense than each of the 2 principal spots in the chromatogram obtained with reference solution (b) (0.2 per cent).

Chlorides (*2.4.4*): maximum 200 ppm.

Dilute 2.5 ml of solution S to 15 ml with *water R*.

Sulphates (*2.4.13*): maximum 300 ppm.

To 0.5 g add 2.5 ml of *dilute hydrochloric acid R* and dilute to 15 ml with *distilled water R*. Examine after 30 min.

Ammonium (*2.4.1*): maximum 100 ppm, determined on 100 mg.

Heavy metals (*2.4.8*): maximum 20 ppm.

12 ml of solution S complies with limit test A. Prepare the standard using *lead standard solution (2 ppm Pb) R*.

Loss on drying (*2.2.32*): maximum 0.5 per cent, determined on 1.000 g by drying in an oven at 60 °C for 24 h.

Sulphated ash (*2.4.14*): maximum 0.1 per cent, determined on 1.0 g.