CHARACTERS
A yellow, crystalline powder or yellow crystals, odourless or almost odourless, very slightly soluble in water and in alcohol, soluble in dimethylformamide.

IDENTIFICATION
A. Carry out the test protected from bright light. Use the solution prepared for the assay. Examine between 220 nm and 400 nm (2.2.25), the solution shows two absorption maxima, at 266 nm and 367 nm. The ratio of the absorbance at the maximum at 367 nm to that at the maximum at 266 nm is 1.36 to 1.42.

B. Dissolve about 10 mg in 10 ml of dimethylformamide R.

To 1 ml of the solution add 0.1 ml of 0.5 M alcoholic potassium hydroxide. A brown colour develops.

TESTS
Related substances. Examine by thin-layer chromatography (2.2.27), using silica gel HF254 as the coating substance.

Test solution. Dissolve 0.25 g of the substance to be examined in a minimum of dimethylformamide R and dilute to 10 ml with acetone R.

Reference solution. Dilute 1 ml of the test solution to 100 ml with acetone R.

Apply separately to the plate 10 µl of each solution. Develop over a path of 15 cm using a mixture of 10 volumes of methanol R and 90 volumes of nitromethane R. Allow the plate to dry in air and heat at 100 °C to 105 °C for 5 min. Examine in ultraviolet light at 254 nm. Spray with phenylhydrazine hydrochloride solution R. Heat the plate at 100 °C to 105 °C for a further 10 min. When examined in ultraviolet light and after spraying, any spot in the chromatogram obtained with the test solution, apart from the principal spot, is not more intense than the spot in the chromatogram obtained with the reference solution (1.0 per cent).

Loss on drying (2.2.32). Not more than 1.0 per cent, determined on 1.00 g by drying in an oven at 100 °C to 105 °C.

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

ASSAY
Carry out the assay protected from bright light. Dissolve 0.120 g in 50 ml of dimethylformamide R and dilute to 1000.0 ml with water R. Dilute 5.0 ml of the solution to 100.0 ml with a solution containing 18 g/l of sodium acetate R and 0.14 per cent V/V of glacial acetic acid R. Measure the absorbance (2.2.25) at the absorption maximum at 367 nm, using the sodium acetate solution described above as compensation liquid.

Calculate the content of $\text{C}_3\text{H}_4\text{N}_2\text{O}_3$, taking the specific absorbance to be 765.

STORAGE
Store protected from light, at a temperature below 25 °C.

NITROGEN
Nitrogenium

$\text{N}_2$

$M$, 28.01

01/2005:1247

See the information section on general monographs (cover pages)
gas is at least 35 per cent of the full scale of the recorder. The assay is not valid unless the chromatograms obtained show a clear separation of oxygen and nitrogen. Inject the gas to be examined and reference gas (b). Calculate the content of N₂ in the gas to be examined.

IDENTIFICATION
First identification: A.
Second identification: B, C.
A. Examine the chromatograms obtained in the Assay. The retention time of the principal peak in the chromatogram obtained with the substance to be examined is approximately the same as that of the principal peak in the chromatogram obtained with reference gas (b).
B. In a 250 ml conical flask replace the air by the substance to be examined. Place a burning or glowing splinter of wood in the flask. The splinter is extinguished.
C. In a suitable test tube, place 0.1 g of magnesium R in turnings. Close the test tube with a two-hole stopper fitted with a glass tube reaching about 1 cm above the turnings. Pass the substance to be examined through the glass tube for 1 min without heating, then for 15 min while heating the test tube to a red glow. After cooling, add 5 ml of dilute sodium hydroxide solution R. The evolving vapours change the colour of moistened red litmus paper R blue.

TESTS
Carbon dioxide. Not more than 300 ppm V/V, determined using a carbon dioxide detector tube (2.1.6).
Carbon monoxide. Not more than 5 ppm V/V, determined using a carbon monoxide detector tube (2.1.6).
Water vapour. Not more than 67 ppm V/V, determined using a water vapour detector tube (2.1.6).

STORAGE
Store as a compressed gas or a liquid in appropriate containers complying with the legal regulations.

IMPURITIES
A. carbon dioxide,
B. carbon monoxide,
C. oxygen,
D. water.

NITROGEN, LOW-OXYGEN
Nitrogenium oxygenio depletum

N₂

DEFINITION
This monograph applies to nitrogen which is used for inerting finished medicinal products which are particularly sensitive to degradation by oxygen. It does not necessarily apply to nitrogen used in earlier production steps.

Content: minimum 99.5 per cent V/V of N₂, calculated by deduction of the sum of impurities found when performing the test for impurities.

CHARACTERS
Colourless and odourless gas.

Solubility: at 20 °C and at a pressure of 101 kPa, 1 volume dissolves in about 62 volumes of water and about 10 volumes of alcohol.

PRODUCTION
Oxygen: maximum 5 ppm V/V, determined using an oxygen analyser with a detector scale ranging from 0 ppm V/V to 100 ppm V/V and equipped with an electrochemical cell. The gas to be examined passes through a detection cell containing an aqueous solution of an electrolyte, generally potassium hydroxide. The presence of oxygen in the gas to be examined produces variation in the electric signal recorded at the outlet of the cell that is proportional to the oxygen content.
Calibrate the analyser according to the manufacturer’s instructions. Pass the gas to be examined through the analyser using a suitable pressure regulator and airtight metal tubes and operating at the prescribed flow rates until constant readings are obtained.

Impurities. Gas chromatography (2.2.28).
Gas to be examined. The substance to be examined.
Reference gas (a). Use ambient air.
Column:
– material: stainless steel,
– size: l = 2 m, Ø = 2 mm,
– stationary phase: appropriate molecular sieve for chromatography (0.5 nm).
Carrier gas: helium for chromatography R.
Flow rate: 40 ml/min.
Temperature:
– column: 50 °C,
– detector: 130 °C.
Detection: thermal conductivity.
System suitability: reference gas (a): adjust the injected volumes and operating conditions so that the height of the peak due to nitrogen in the chromatogram obtained is at least 35 per cent of the full scale of the recorder:
– the chromatogram obtained shows a clear separation of oxygen and nitrogen.
Limit:
– total: not more than 0.5 per cent of the sum of the areas of all the peaks (0.5 per cent V/V).

IDENTIFICATION
First identification: A.
Second identification: B, C.
A. Examine the chromatograms obtained in the test for impurities (see Production).
Results: the principal peak in the chromatogram obtained with the gas to be examined is similar in retention time to the principal peak in the chromatogram obtained with reference gas (b).
B. In a 250 ml conical flask replace the air by the gas to be examined. Place a burning or glowing splinter of wood in the flask. The splinter is extinguished.
C. In a suitable test tube, place 0.1 g of magnesium R in turnings. Close the test tube with a two-hole stopper fitted with a glass tube reaching about 1 cm above the turnings. Pass the gas to be examined through the glass tube for 1 min without heating, then for 15 min while heating the test tube to a red glow. After cooling, add 5 ml of dilute sodium hydroxide solution R. The evolving vapours turn the colour of moistened red litmus paper R blue.