

reference substance separately in the minimum volume of methyl isobutyl ketone *R*, evaporate to dryness and record new spectra using the residues.

- B. Examine by thin-layer chromatography (2.2.27), using as the coating substance a suitable silica gel with a fluorescent indicator having an optimal intensity at 254 nm.

Test solution. Dissolve 30 mg of the substance to be examined in a mixture of 1 volume of acetone *R* and 9 volumes of methanol *R* and dilute to 10 ml with the same mixture of solvents.

Reference solution (a). Dissolve 30 mg of benperidol CRS in a mixture of 1 volume of acetone *R* and 9 volumes of methanol *R* and dilute to 10 ml with the same mixture of solvents.

Reference solution (b). Dissolve 30 mg of benperidol CRS and 30 mg of droperidol CRS in a mixture of 1 volume of acetone *R* and 9 volumes of methanol *R* and dilute to 10 ml with the same mixture of solvents.

Apply to the plate 10 µl of each solution. Develop over a path of 15 cm using a mixture of 1 volume of acetone *R* and 9 volumes of methanol *R*. Allow the plate to dry in air and examine in ultraviolet light at 254 nm. The principal spot in the chromatogram obtained with the test solution is similar in position and size to the principal spot in the chromatogram obtained with reference solution (a). The test is not valid unless the chromatogram obtained with reference solution (b) shows two clearly separated spots.

- C. Dissolve about 10 mg in 5 ml of ethanol *R*. Add 0.5 ml of dimrobenzene solution *R* and 0.5 ml of 2 *M* alcoholic potassium hydroxide *R*. A violet colour is produced which becomes brownish-red after 20 min.
- D. Mix about 5 mg with 45 mg of heavy magnesium oxide *R* and ignite in a crucible until an almost white residue is obtained (usually less than 5 min). Allow to cool, add 1 ml of water *R*, 0.05 ml of phenolphthalein solution *R1* and about 1 ml of dilute hydrochloric acid *R* to render the solution colourless. Filter. To a freshly prepared mixture of 0.1 ml of sodium *S* solution *R* and 0.1 ml of zincoyl nitrate solution *R*, add 1.0 ml of the filtrate. Mix, allow to stand for 5 min and compare the colour of the solution with that of a blank prepared in the same manner. The test solution is yellow and the blank is red.

TESTS

Related substances. Examine by liquid chromatography (2.2.29). Prepare the solutions immediately before use.

Test solution. Dissolve 0.10 g of the substance to be examined in dimethylformamide *R* and dilute to 10.0 ml with the same solvent.

Reference solution (a). Dissolve 2.5 mg of benperidol CRS and 2.5 mg of droperidol CRS in dimethylformamide *R* and dilute to 100.0 ml with the same solvent.

Reference solution (b). Dilute 1.0 ml of the test solution to 100.0 ml with dimethylformamide *R*. Dilute 5.0 ml of this solution to 20.0 ml with dimethylformamide *R*.

The chromatographic procedure may be carried out using:

- a stainless steel column 0.1 m long and 4.6 mm in internal diameter packed with base-deactivated octadecylsilyl silica gel for chromatography *R* (3 µm);
- as mobile phase at a flow rate of 1.5 ml/min:
 - Mobile phase A.** A 10 g/l solution of tetrabutylammonium hydrogen sulphate *R*.
 - Mobile phase B.** Acetonitrile *R*.

Time (min)	Mobile phase A (per cent v/v)	Mobile phase B (per cent v/v)	Comment
0 - 15	100 → 60	0 → 40	linear gradient
15 - 20	60	40	isocratic elution
20 - 25	100	0	switch to initial eluent composition
25 - 0	100	0	restart gradient

— as detector a spectrophotometer set at 275 nm.

Equilibrate the column for at least 30 min with acetonitrile *R* and then equilibrate with the initial eluent composition for at least 5 min.

Adjust the sensitivity of the system so that the height of the principal peak in the chromatogram obtained with 10 µl of reference solution (b) is at least 50 per cent of the full scale of the recorder.

Inject 10 µl of reference solution (a). When the chromatogram is recorded in the prescribed conditions, the retention times are: benperidol about 6.5 min and droperidol about 7 min. The test is not valid unless the resolution between the peaks corresponding to benperidol and droperidol is at least 2.0. If necessary, adjust the concentration of acetonitrile in the mobile phase or adjust the time programme for the linear gradient.

Inject 10 µl of dimethylformamide *R* as a blank, 10 µl of the test solution and 10 µl of reference solution (b). In the chromatogram obtained with the test solution: the area of any peak, apart from the principal peak, is not greater than the area of the principal peak in the chromatogram obtained with reference solution (b) (0.25 per cent); the sum of the areas of all the peaks, apart from the principal peak, is not greater than twice the area of the principal peak in the chromatogram obtained with reference solution (b) (0.5 per cent). Disregard any peak obtained with the blank and any peak with an area less than 0.2 times the area of the principal peak in the chromatogram obtained with reference solution (b).

Loss on drying (2.2.32). Not more than 0.5 per cent, determined on 1.000 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 in a platinum crucible.

ASSAY

Dissolve 0.300 g in 50 ml of a mixture of 1 volume of oxidrous acetic acid *R* and 7 volumes of methyl ethyl ketone *R* and titrate with 0.1 *M* perchloric acid, using 0.2 ml of naphthoquinone solution *R* as indicator.

1 ml of 0.1 *M* perchloric acid is equivalent to 38.14 mg of C₁₇H₂₃FN₂O₂.

STORAGE

Store protected from light.

IMPURITIES



A. 1-(4-piperidin-4-yl)-1,3-dihydro-2*H*-benzimidazol-2-one.

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