the test solution and reference solution (a) and the declared content of human insulin plus A21 desamido human insulin in human insulin CRS.

STORAGE
In an airtight container, protected from light, at –18 °C or below, until released by the manufacturer. When thawed, insulin is stored at 5 ± 3 °C and used for manufacturing preparations within a short period of time. To avoid absorption of humidity from the air during weighing, the insulin must be at room temperature.

LABELLING
The label states whether the substance is produced by enzymatic modification of porcine insulin or by rDNA technology.

INSULIN INJECTION, BIPHASIC
Insulinum biphasicum injectabile

Biphasic insulin injection complies with the monograph on Insulin preparations, injectable (0854) with the amendments prescribed below.

DEFINITION
Biphasic insulin injection is a sterile suspension of crystals containing bovine insulin in a solution of porcine insulin.

CHARACTERS
A white or almost white suspension. When examined under a microscope, the majority of the particles are seen to be rhombohedral crystals, with a maximum dimension measured from corner to corner through the crystal greater than 10 µm but rarely exceeding 40 µm.

IDENTIFICATION
Examine the chromatograms obtained in the assay. The position of the peaks due to the two insulins in the chromatogram obtained with the test solution correspond to those of the principal peaks in the chromatogram obtained with the appropriate reference solution.

TESTS
pH (2.2.3). The pH of the suspension to be examined is 6.6 to 7.2.

Insulin in the supernatant: 22.0 per cent to 28.0 per cent of insulin in solution. Determine by the method described in the test for insulin in the supernatant in the monograph on Insulin preparations, injectable (0854).

Total zinc: 26.0 µg to 37.5 µg per 100 IU of insulin. Determine by the method described in the monograph on Insulin preparations, injectable (0854).

INSULIN INJECTION, BIPHASIC ISOPHANE
Insulinum isophanum biphasicum injectabile

Biphasic isophane insulin injection complies with the monograph on Insulin preparations, injectable (0854) with the exception of the test for Insulin in the supernatant and with the amendments prescribed below for the other tests.

DEFINITION
Biphasic isophane insulin injection is a sterile buffered suspension of either porcine or human insulin, complexed with protamine sulphate or another suitable protamine, in a solution of insulin of the same species.

PRODUCTION
Biphasic isophane insulin injection is prepared by carrying out the procedures described in the monograph on Insulin preparations, injectable (0854).

Biphasic isophane insulin injection is produced by mixing, in defined ratios, soluble insulin injection and isophane insulin injection. The defined ratios shall be demonstrated by a test method which has been approved by the competent authority to comply with the label claim.

CHARACTERS
A white or almost white suspension which on standing deposits a white or almost white sediment and leaves a colourless or almost colourless supernatant liquid; the sediment is readily resuspended by gently shaking. When examined under a microscope, the particles are seen to be rod-shaped crystals, the majority with a maximum dimension greater than 1 µm but rarely exceeding 60 µm, free from large aggregates.

IDENTIFICATION
Examine the chromatograms obtained in the Assay. The position of the peak due to insulin in the chromatogram obtained with the test solution corresponds to that of the principal peak obtained with the appropriate reference solution.

TESTS
Total zinc. Not more than 40.0 µg per 100 IU of insulin, determined as described in the monograph on Insulin preparations, injectable (0854).

LABELLING
The label states in addition to the indications mentioned in the monograph on Insulin preparations, injectable (0854) the ratio of soluble insulin injection to isophane insulin injection used in the manufacturing process of biphasic isophane insulin injection.