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Alginate Raft-forming Oral Suspension

General Notices

DEFINITION

Alginate Raft-forming Oral Suspension is a suspension containing Sodium Alginate, Sodium Bicarbonate and Calcium Carbonate in a suitable flavoured vehicle. It may be coloured. The suspension forms a raft.

The oral suspension complies with the requirements stated under Oral Liquids and with the following requirements.

Content of active constituents

90.0 to 110.0 % of the stated amount of sodium alginate.

PRODUCTION

The content of the active constituents in the oral suspension is measured using suitably validated methods.

IDENTIFICATION

A. Dilute a quantity of the oral suspension containing 0.25 g of Sodium Alginate, accurately weighed, in sufficient *water* to produce 200 mL. Filter and dilute a portion of this solution with sufficient *water* to produce a solution containing 0.0125% w/v of Sodium Alginate. To 1 mL of this solution, add 1 mL of a freshly prepared 4% w/v solution of *resorcinol* and 6 mL of *sulfuric acid*. An orange-pink colour is produced.
B. Evaporate to dryness a quantity of the oral suspension containing 1 g of Sodium Alginate on a water bath. Shake 0.2 g of the residue with 20 mL of *water*. To 5 mL of this solution add 1 mL of *calcium chloride solution*. A voluminous gelatinous mass is formed.
C. Evaporate to dryness a quantity of the oral suspension containing 1 g of Sodium Alginate on a water bath. The residue yields the reactions characteristic of *sodium*, Appendix VI.

TESTS

Alkalinity

pH, 7.0 to 9.5, Appendix V L.

Relative density

1.03 to 1.07 g/mL, Appendix V G.

Raft strength

The mean raft strength is not less than 7.5 g, determined by the following method. Carry out the method for *texture analysis of semi-solids or gels*, Appendix XVII F. Introduce 150 mL of *0.1M hydrochloric acid* into a 250 mL beaker having an internal diameter of 60 to 70 mm. Place in a water bath such that the volume of water in the bath is level with the top of the acid in the beaker and allow to equilibrate to 36.5° to 37.5°. Suspend an L-shaped probe comprising 1 mm diameter 316 gauge stainless steel having a 90 mm vertical arm with a hook at the top and a 20 mm horizontal arm such that the vertical arm of the probe hangs down the centre axis of the beaker and the horizontal arm is in the lower third of the acid.

Using a syringe (without needle), remove a quantity of suspension, previously shaken, equivalent to one dose. Where a dosage range is specified, use the maximum dose. Wipe the outside of the syringe and add the suspension evenly into the medium (the time taken to add the entire dose is approximately 5 seconds).

After 30 minutes, remove the beaker from the water bath, dry the outside of the beaker and transfer to a suitable texture analyser. Attach the probe to the arm of the texture analyser, and lift the arm so that the probe is lifted through the raft at a speed of 5 mm/sec. Record the peak raft strength in g.

LABELLING

The label states the sodium content of the suspension.