Calcium Carbonate Oral Suspension

NOTE: This monograph was developed to cover unlicensed formulations.

Details for the public consultation of this monograph are as follows:

<table>
<thead>
<tr>
<th>Expert Advisory Group</th>
<th>ULM: Unlicensed Medicines</th>
</tr>
</thead>
<tbody>
<tr>
<td>Contact Details</td>
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<td>Deadline for Comment</td>
<td>31st March 2019</td>
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<td>BP 2020</td>
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<td>Notes:</td>
<td>New monograph</td>
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Action and use

Antacid.

DEFINITION

Calcium Carbonate Oral Suspension is a suspension of Calcium Carbonate in a suitable vehicle.

The oral suspension complies with the requirements stated under Oral Liquids and with the following requirements. Where appropriate, the oral suspension also complies with the requirements stated under Unlicensed Medicines.

Content of calcium carbonate, CaCO₃

90.0 to 110.0% of the stated amount.

IDENTIFICATION

A. To a volume of the oral suspension add 1 drop of a suitable antifoaming agent and dilute to 5 volumes with 2M hydrochloric acid. The solution, when introduced on a platinum wire into a flame, imparts a yellow-red colour to the flame.

B. Add 1 drop of a suitable antifoaming agent to a volume of the oral suspension containing 0.6 g of Calcium Carbonate in a flask and dilute to 2 volumes with 2M hydrochloric acid. Trap the gas produced by the effervescent mixture and bubble through 0.1M barium hydroxide. A white precipitate is formed.

TESTS

ACIDITY OR ALKALINITY

pH 7.0 to 8.7, Appendix V L.

Dissolution
Complies with the requirements stated under Unlicensed Medicines, Oral Suspensions. Use a volume of the oral suspension containing one dose.

**ASSAY**

To a quantity of the oral suspension containing 1.2 g of Calcium Carbonate add 2 drops of a suitable antifoaming agent and 50 mL of 1M hydrochloric acid; boil for 2 minutes and allow to cool. Titrate the excess hydrochloric acid with 1M sodium hydroxide, using 1 mL of phenolphthalein solution as indicator. Each mL of 1M hydrochloric acid consumed is equivalent to 50.05 mg of CaCO₃.