Sugar Spheres

Sugar Spheres contain not less than 62.5 per cent and not more than 91.5 per cent of sucrose, $C_{12}H_{22}O_{11}$, calculated on the dried basis, the remainder consisting mainly of starch. They consist of approximately spherical particles of a labeled nominal size range. They may contain colour additives permitted for use in drugs.

Category. Pharmaceutical aid.

Description. Hard, brittle, free flowing, spherical masses ranging generally in size from 10 to 60 mesh. Usually white, but may be coloured.

Identification

A. A 10 per cent w/v solution produce a violet to deep blue colour on addition of *iodine*.

B. Specific optical rotation (see Test).

Tests

Particle size distribution estimation (2.5.7). Not less than 90 per cent of it passes the coarser sieve size stated in the labeling; all of it passes the next coarser sieve size listed in Table 1 of the chapter; and not more than 10 per cent passes the finer sieve size stated on the label.

Specific optical rotation (2.4.22). + 41.0° to + 61.0°, determined in a 10 per cent w/v solution prepared by dissolving 20 g in 160 ml of *water* and dilute to 200.0 ml with *water*. Pass the solubilised sucrose solution by vacuum filtration through fine filter paper.

Sulphated ash (2.3.18). Not more than 0.25 per cent, determined on 2.0 g at a temperature of about 700°.

Loss on drying (2.4.19). Not more than 4.0 per cent, determined on 1.0 g by drying in an oven at 105° for 4 hours.

Microbial contamination (2.2.9). Total aerobic viable count is not more than 100 CFU per g. 1 g is free from *Escherichia coli*, *Staphylococcus aureus* and *Pseudomonas aeruginosa*. 10 g is free from *Salmonella*.

Assay. Determine by liquid chromatography (2.4.14).

Test solution. Dissolve 1.0 g of Sugar Spheres in 20 ml of *water* and dilute to 50.0 ml with *water*.

Reference solution (a). A 2.0 per cent w/v solution of *sucrose IPRS* in *water*.

Reference solution (b). A solution containing 2.0 per cent w/v of *sucrose IPRS,* 0.1 per cent w/v of *dextrose IPRS,* 0.06 per cent w/v of *fructose IPRS,* 0.06 per cent w/v of *maltose monohydrate IPRS,* and 0.08 per cent w/v of *anhydrous lactose IPRS* in *water*.

Chromatographic system

- a stainless steel column 15 cm x 4.6 mm, packed with amino propylsilane bonded to porous silica (5 µm),
- column temperature:45°,
- mobile phase: a mixture of 80 volumes of *acetonitrile* and 20 volumes of *water,*
- flow rate: 2 ml per minute,
- refractive index detector at 40°,
- injection volume: 15 µl.

Name	Relative retention time
Fructose	0.5
Dextrose (glucose)	0.6
Sucrose	1.0
Maltose	1.3
Lactose	1.5

Inject reference solution (a) and (b). The test is not valid unless the resolution between all the adjacent peaks is not less than 1.3 in the chromatogram obtained with reference solution (b) and the relative standard deviation for replicate injections is not more than 2.0 per cent the chromatogram obtained with reference solution (a).

Inject reference solution (a) and the test solution.

Calculate the content of $C_{12}H_{22}O_{11}$.

Storage. Store protected from moisture, at a temperature not exceeding 30°.

Labelling. The label states the nominal particle size range. Label it to indicate the name and amount of any added color additives.

Solubility: Solubility in *water* varies according to the sugar-starch ratio.