DEPARTMENT OF DRUG ADMINISTRATION
National Medicines Laboratory
ANALYTICAL METHOD VALIDATION COMMITTEE

Calcium Polystyrene Sulphonate Oral Powder

Analytical Profile No.: CALP 075/076/AP050

Calcium Polystyrene Sulphonate Oral Powder contains not less than 90 per cent and not more than 110 per cent of the stated amount of calcium polystyrene sulfonate.

1. Identification:

A. To 0.2 ml of a neutral solution containing a quantity of the substance to be examined equivalent to about 0.2 mg of calcium (Ca^{++}) per milliliter, add 0.5 ml of a 2 g/l solution of glyoxal-hydroxyanil R in ethanol (96 percent) R, 0.2 ml of dilute sodium hydroxide solution R and 0.2 ml of sodium carbonate solution R. Shake with 1 ml to 2 ml of chloroform R and add 1 ml to 2 ml of water R. The chloroform layer is colored red.

B. Dissolve about 20 mg of the substance to be examined in 5 ml of acetic acid R, add 0.5 ml of potassium ferrocyanide solution R. The solution remains clear. Add about 50 mg of ammonium chloride R. A white crystalline precipitate is formed.

Tests:

2. Assay

For calcium

Carefully heat 1 g of sample in a platinum crucible until a white ash is obtained and dissolve in 10 ml of 2 M hydrochloride acid with the aid of heat. Transfer the resulting solution to a conical flask using 20 ml of water. Add 50 ml of 0.05 M disodium edetate VS, 20 ml of ammonia buffer pH 10.9 and titrate the excess of disodium edetate with 0.05 M zinc sulphate VS, using a 0.5 % w/v solution of mordant black T in ethanol (96%) as indicator to a red purple end point.

Each ml of 0.05M disodium edetate VS is equivalent to 2.004 mg of Ca.

Calculation:-

$$\frac{\mathbf{V \times 2.004(factor) \times N(VS) \times AW \times 100}}{\mathbf{0.05 \times wt.(mg) \times LC}}$$

Where,

V = Volume consumed {Blank titration volume consumed (Vo)-Sample titration (V1)}

2.004 = 0.05 M edetate disodium is equivalent to 2.004 mg of calcium

N = Normality of VS of edetate disodium

Wt = Weight of sample in mg

LC = Label claim in g/sachet

AW = Average fill weight of sachet in g

Calcium content: 1.080 g to 1.320 g

Calcium Polystyrene Sulphonate (100 mg Calcium Polystyrene Sulphonate contain 8 mg Calcium):

$$\frac{100 \text{ x calcium content}}{8} = \text{……..g/sachet}$$

Weigh ointment equivalent to 50 mg of Moxifloxacin in a separating flask, add about 40 ml of cyclohexane and extract with 4 x 20 ml of mobile phase, collect the mobile phase in a 100 ml volumetric flask. Dilute up to the mark to 100 ml with mobile phase. Further dilute 1 ml of this solution to 10 ml with mobile phase.

3. Microbial Limit Test: As per IP (latest edition)

Limit:

Total bile tolerant gram –ve bacteria: NMT 100 cfu per g

Pseudomonas aeruginosa	Should be Absent per g
Escherichia coli	Should be Absent per g
Salmonella	Should be Absent per g

4. Other tests: As per pharmacopoeial requirement