

**Government of Nepal
Ministry of Health and Population
Department of Drug Administration
National Medicines Laboratory
Quality and Method Validation Section**

Analytical profile of Calcium Polystyrene Sulphonate Oral Powder

Analytical Profile No.: CALP 075/076/AP050

Calcium Polystyrene Sulphonate Oral Powder contains not less than 90.0% and not more than 110.0% of the stated amount of Calcium Polystyrene Sulphonate.

1. Identification:

Positive for calcium

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

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

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

3. Assay

For calcium

Carefully heat 1g of sample in a platinum crucible until a white ash is obtained and dissolve in 10ml of 2M hydrochloride acid with the aid of heat. Transfer the resulting solution to a conical flask using 20ml of water. Add 50ml of 0.05M disodium edetate VS, 20ml of ammonia buffer pH 10.9 and titrate the excess of disodium edetate with 0.05M 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 2.004mg of Ca.

Calculation:-

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

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Where,

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

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

N = Normality of VS of edetate disodium

Wt. = Weight of sample in mg

LC = Label claim in gm/sachet

AW = Average fill weight of sachet in gm

Calcium content: 1.080gm to 1.320 gm

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

$$\frac{100 \times \text{calcium content}}{8} = \dots\dots\dots\text{gm/sachet}$$

4.Other tests: As per pharmacopoeial requirement.