

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

Analytical profile of Solution of Glycerin and Sodium Chloride

Analytical Profile No.: Gly Sod 080/81/AP 140

Solution of Glycerin and Sodium Chloride contains not less than 90.0% and not more than 110.0% of the stated amount of both Glycerin and Sodium Chloride.

Usual Strength: 15% w/v (Both Glycerin and Sodium Chloride)

1. Identification:

1.1 For Glycerin: Mix 1 ml of solution with 0.5 ml of nitric acid and superimpose 0.5 ml of potassium dichromate solution; a blue ring develops at the interface of two liquids. Allow standing for 10 minutes; the blue color does not diffuse into the lower layer.

1.2 For Sodium Chloride: Acidify 1 ml of the solution with dilute nitric acid and add 0.4 ml of silver nitrate solution. Shake and allow to standing. A curdled, white precipitate is formed. Centrifuge and wash the precipitate with three quantities, each of 1 ml, of water. Carry out this operation rapidly in subdued light, disregarding the supernatant solution may not become perfectly clear. Suspend the precipitate in 2 ml of water and add 2.5 ml of 25% ammonia solution. The precipitate dissolves easily with the possible exception of few large particles which dissolve slowly.

2. Assay: *Determine by Titrimetry*

2.1 For Glycerin: Dilute 11 gm. of the solution with sufficient water to produce 100 ml. Pipette 5 ml of this solution and transfer to a 250 ml conical flask add 15 ml of water and neutralize with 0.1M sodium hydroxide using bromocresol purple solution as indicator. Add 1.6 gm. of sodium periodate and then add 3 ml of ethylene Glycol, mix, and titrate with 0.1 M sodium hydroxide. Calculate the percentage of Glycerin.

Each ml of 0.1M sodium hydroxide is equivalent to 0.0091 gm. of Glycerin.

2.2 For Sodium Chloride: Dilute 11 gm. of the solution with sufficient water to produce 100 ml. Pipette 5 ml of this solution, transfer to a 25 ml conical flask, add 5 ml of glacial acetic acid and 50 ml of methanol; mix. Titrate with 0.1M silver nitrate using Eosin solution as indicator. Calculate the percentage of sodium chloride.

Each ml of 0.1M silver nitrate is equivalent to 0.005844 gm. of sodium chloride.

Note: Prepare the required solutions and standardize them as per IP.

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3. Other tests: As per pharmacopoeial requirements.

Subject to approval from DAC