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 Clotrimazole and Lignocaine Hydrochloride Ear drop

Analytical Profile No.: Clotri Ligno 080/81/AP 145

Clotrimazole and Lignocaine Hydrochloride Ear drop contains not less than 90.0% and not more than 110.0% of the stated amount of both Clotrimazole and Lignocaine Hydrochloride.

Usual Strength: Clotrimazole 1.0% w/v

Lignocaine Hydrochloride 2.0% w/v

1. Identification:

1.1 Lignocaine Hydrochloride: Take sample volume equivalent to 0.2 gm. Of Lignocaine Hydrochloride add sufficient Sodium Hydroxide solution to make alkaline, filter , wash the residue with water, dissolve half of the residue in 1 ml of ethanol(95%) and 0.5 ml of 10% w/v solution of cobalt chloride; a bluish-green precipitate is formed.

1.2 Clotrimazole: By titration method it gives emerald green color change during assay procedure

2. Assay: *Determine by Extraction and Titrimetry*

2.1 For Clotrimazole: Take 10 ml of Ear Drop sample i.e equivalent to 100 mg of Clotrimazole to a separating funnel containing about 20 ml water. Extract with solvent ether (3X 40 ml). Wash the combined ether layer with 20 ml of water and pass through anhydrous sodium sulphate (**preserve the combined aqueous layer for estimation of Lignocaine Hydrochloride**). Evaporate ether layer on water bath, cool and add 15 ml of acetic acid and 15-20 ml of 1-4 Dioxane. Carry out the non-aqueous titration using crystal violet solution as indicator (end point, violet to emerald green color)

Each ml of 0.02 N Perchloric acid is equivalent to 6.896 gm. of Clotrimazole

2.2 For Lignocaine Hydrochloride: Titrate the entire aqueous layer preserved during estimation of Clotrimazole with 0.1 N Silver nitrate using potassium chromate as indication (end point: Light yellow to reddish brown).

Each ml of 0.1N Silver nitrate is equivalent to 28.88 gm. Of Lignocaine Hydrochloride.

Note: For preparation and standardization of the reagents refer to Indian Pharmacopoeia

3. Other tests: As per pharmacopoeial requirements.