

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

Analytical profile of Clotrimazole and Lignocaine Hydrochloride Ear drops

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 (3 X 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 indicator. (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.