Lindane Lotion

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Manufacturers, regulatory authorities, health authorities, researchers, and other stakeholders are invited to provide their feedback and comments on this draft proposal. Manufacturers are also invited to submit samples of their products to the IPC to ensure that the proposed monograph adequately controls the quality of the product(s) they manufacture. Comments and samples received after the last date will not be considered by the IPC before finalizing the monograph.

Please send any comments you may have on this draft document to lab.ipc@gov.in, with a copy to Dr. Gaurav Pratap Singh (email: gpsingh.ipc@gov.in) before the last date for comments.

Document History and Schedule for the Adoption Process

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Further follow-up action as required.	

Lindane Lotion

Gamma Benzene Hexachloride Lotion

Lindane Lotion is Lindane in a suitable aqueous vehicle.

It contains not less than 90.0 per cent and not more than 110.0 per cent of the stated amount of lindane (γ-$C_6H_6Cl_6$).

Usual strength. 1 per cent w/v.

Identification

Wind a strip of 20-mesh copper gauze 1.5 cm wide and 5 cm long around the end of a copper wire. Heat the gauze in the nonluminous flame of a Bunsen burner until it glows without coloring the flame green. Allow the gauze to cool, and repeat the heating and cooling step several times until a thorough coating of oxide is formed. Apply a small amount of lotion to the cooled gauze, ignite, and allow to burn freely in the air. Hold the gauze in the outer edge of the burner flame at a height of 4 cm. A bright green color is imparted to the flame.

Tests

pH (2.4.24).6.5 to 8.5.

Other tests. Comply with the tests stated under Lotion.

Assay. Determine by gas chromatography (2.4.13).

Mobile phase. A mixture of 6 volumes of *anhydrous ethyl ether* and 94 volumes of *hexane.*

Internal standard solution. A 0.1 per cent w/v solution of *n-docosane* in *methylene chloride*.

Solid support. 60 to100 mesh magnesium silicate that has been heated previously at 300° for 2 hours.

Test solution (a). Place a pledget of cotton on a removable porous plate at the base of a 2.5 cm × 20 cm chromatographic tube fitted with a polytef stopcock. Add 50 ml of solvent mixture and 10 g of solid support, and stir the mixture to expel air bubbles. Add 1.5 g of *anhydrous sodium sulphate* to the tube, and elute until the surface of the liquid is 4 cm above the solid support, discarding the eluate. Transfer a quantity of lotion contaninig 10 mg of Lindane to a 150-ml beaker, and add 10 g of solid support. Mix with a spatula, adding *hexane* as necessary to produce a homogeneous mixture, and continue stirring until a free-flowing powder is produced. Transfer this mixture to the chromatographic tube with the aid of three 5 ml portions of solvent mixture, and elute the tube with 225 ml of the solvent mixture at a flow rate of 2 to 3 ml per minutes, collecting the eluate in a 250-ml beaker. Remove the chromatographic tube, add 5.0 ml of internal standard solution to the eluate, and evaporate with the aid of gentle heat and a current of dry air to 5 ml.

Test solution (b). Transfer test solution (a) to a graduated centrifuge tube with the aid of 1 ml of *methylene chloride*, and evaporate with the aid of gentle heat and dry air to 3 ml. Avoid evaporating to dryness. If the mixture is inadvertently evaporated to dryness, discard it, and begin another test solution (b).

Reference solution (a). A 0.2 per cent w/v solution of *lindane IPRS* in *methylene chloride*.

Reference solution (b). Transfer 5.0 ml of reference solution (a) to a graduated centrifuge tube and add 5.0 ml of internal standard solution, evaporate with the aid of gentle heat and dry air to 3 ml. Avoid evaporating to dryness. If the mixture is inadvertently evaporated to dryness, discard it, and begin another reference solution (b).

Chromatographic system

– a glass or stainless steel column 1.8 m x 2 mm, packed with 3 per cent liquid phase (50 per cent of Phenyl- 50 per cent of methylpolysiloxane) on acid-washed, then water-washed until neutral, siliceous earth support (Such as OV-17),

– temperature:

column. 195°,

injection port and detector 250°,
– flame ionization detector,
– flow rate: 40 ml per minute, using nitrogen as the carrier gas,
– injection volume: 1 µl.

Inject reference solution (b). The test is not valid unless the resolution between the peaks due to lindane and n-docosane is not less than 5.0, the tailing factor is not more than 2.0 and the relative standard deviation for replicate injections is not more than 3.0.

Inject reference solution (b) and test solution (b).

Calculate the content of (γ-$C_6H_6Cl_6$) in the lotion.

Storage. Store protected from moisture.