Benzyl Benzoate Application

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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

Description	Details
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Further follow-up action as required.	

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Change **to**: **Benzyl Benzoate Application**

Benzyl Benzoate Cutaneous Emulsion

Benzyl Benzoate Application contains 25 per cent w/v of Benzyl Benzoate in a suitable oil-in-water emulsified base.

Composition	
Benzyl Benzoate	250 g
Emulsifying Wax	20 g
Purified Water, freshly boiled and cooled sufficient to produce	1000 ml

Melt the Emulsifying Wax, add the Benzyl Benzoate and mix. Pour the mixture into sufficient warm Purified Water to produce 1000 ml and stir thoroughly until cold.

Benzyl Benzoate Application contains not less than 23.1 per cent and not more than 26.9 per cent w/v of benzyl benzoate, $C_{14}H_{12}O_2$.

Identification

In the Assay, the principal peak in the chromatogram obtained with the test solution corresponds to the peak in the chromatogram obtained with the reference solution.

Tests

Other tests. Comply with the tests stated under Lotions.

Assay. Determine by liquid chromatography (2.4.14).

Test solution. Weigh and transfer 1 g of the application to a 100-ml volumetric flask, add 50 ml of the mobile phase, shake and dilute to 100.0 ml with the mobile phase. Dilute 1.0 ml of the solution to 50.0 ml with the mobile phase.

Reference solution. A 0.005 per cent w/v solution of *benzyl benzoate IPRS* in the mobile phase.

Chromatographic system

- a stainless steel column 20 cm x 4.6 mm, packed with end-capped octadecylsilane bonded to porous silica (10 µm) (Such as Nucleosil C18),
- mobile phase: a mixture of 30 volumes of *water* and 70 volumes of *acetonitrile*,
- flow rate: 1.5 ml per minute,
- spectrophotometer set at 230 nm,
- injection volume: 20 µl.

Inject the reference solution. The test is not valid unless the relative standard deviation for replicate injection is not more than 2.0 per cent.

Inject the reference solution and the test solution.

Determine the weight per ml of the application (2.4.29) and calculate the content of $C_{14}H_{12}O_2$, weight in volume.

Labelling. The label states that the contents should be shaken before use.