LABELLING STANDARD

ECHINACEA ROOT

Description:

This labelling standard (LS) applies to products containing Echinacea (*Echinacea angustifolia, E. pallida* and/or *E. purpurea*) as a single medicinal ingredient in the form of fresh or dried root or rhizome in tablet, capsule, powder, extract, tincture, drops or tea intended to be used **for the relief of sore throat due to colds or for the symptomatic relief of mild skin conditions and eruptions**. The medicinal ingredient must be identified on product labelling by the name given in this monograph.

I. Pharmaceutical Quality:

A. All ingredients (medicinal and nonmedicinal) and finished product specifications should, as a minimum, meet Schedule B or equivalent standards. Where no Schedule B monograph exists for the dosage form, specifications should be similar to those of a comparable compendial dosage form. In the absence of a Schedule B standard for any dosage form, testing must be adequate to demonstrate the products' identity, potency, purity and quality.

B. **Special Notes:**

Finished product specifications should include tests for identification and an assay with suitable limits for the medicinal ingredient including its components. The specifications for all dosage forms should include a description of the dosage form including organoleptic properties as well as physico-chemical testing e.g., pH, specific gravity, viscosity, appropriate to the dosage form. Where antimicrobial preservatives are added, an assay with suitable limits should be included. Antimicrobial preservative effectiveness should be determined in order to establish that the product is capable of resisting microbial contamination.

II. Ingredients:

A. **Single Medicinal Ingredient:**

Root or rhizome of *E. angustifolia* D.C. var. *angustifolia, E. pallida* (Nutt.) Nutt. and/or *E. purpurea* (L.) Moench).

B. **Declaration:**

Refer to the Drugs Directorate Guideline: Traditional Herbal

Medicines (Revised) October 1995.

C. **Combinations**:

None accepted in this LS.

D. **Nonmedicinal Ingredients**:

Nonmedicinal ingredients must be restricted to those substances, necessary for the formulation of the dosage form. Their concentration must not exceed the minimum required to provide their intended effect. They must be harmless in the amounts used, their presence must not affect the bioavailability, therapeutic efficacy or safety of the medicinal ingredients and they must not interfere with assays and tests for the medicinal ingredients and, if present, antimicrobial preservatives, prescribed in Schedule B publications.

Ingredients of botanical origin added as nonmedicinal ingredients must comply with the Drugs Directorate Policy, Herbs used as Nonmedicinal Ingredients in Nonprescription Drugs for Human Use.

III. Labelling:

A. This LS describes those requirements that are specific to this class of drugs. Other requirements described in the *Regulations to the Food and Drugs Act*, in the *Guide for the Labelling of Drugs for Human Use* and in *Traditional Herbal Medicines (Revised)* October 1995 must also be met.

B. **Directions for Use:**

1. **Indications**:

a) The product must be identified as a **Traditional Herbal Medicine...** and one of the following would be considered acceptable:

i) for the relief of sore throat due to colds

ii) for the symptomatic relief of mild skin conditions and eruptions (Note: no specific skin conditions may be mentioned)

b) Unacceptable indications/claims:

i) prevents colds/flu

ii) reduces the severity of colds/flu

2. **Dosages**:

The dosage should be specified as being for adults:

dried root and rhizome: 1 g or by infusion or decoction, three times daily

liquid extract (1:1 in 45% alcohol): 0.25 - 1.0 mL, three times daily

tincture (1:5 in 45% alcohol): 1-2 mL, three times daily

3. **Warnings:**

a) When recommended for sore throat due to colds:

i) If symptoms are severe or persist for more than 2 days consult a doctor.

REFERENCES:

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6. R. C. Wren, Potter's New Cyclopaedia of Botanical Drug and Preparations, The C.W. Daniel Company Limited, Saffron Walden, England, 1988.

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8. Grieve, M., A Modern Herbal, Dover Publications, New York, NY, 1971.

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