

LABELLING STANDARD

Valerian

I) Category:

Sleep aid or sedative

II) Description:

This labelling standard (LS) applies to products containing Valerian as a single medicinal ingredient in the form of crude dried root in tablet, capsule, powder, extract, tinctures, drops or tea bags intended to be used as a sleeping aid/sedative. The medicinal ingredient must be identified on product labelling by the name given in this monograph.

III) 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:

- i) *Pharmacopoeial standards for formulated and non-formulated single herbal ingredient preparations that are contained in Schedule B publications are shown in Appendix I. Note that this list is intended as a guide only and is not necessarily current or all inclusive.*
- ii) *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 eg., 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.*

IV) Ingredients:

a) Single Medicinal Ingredient:

Valerian (Valerian officinalis) root.

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.

V) **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:**i) **Indications**

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

- **As a sleep aid:**

- 1) For relief of occasional sleeplessness (insomnia) (due to overwork, tiredness or fatigue).
- 2) To help reduce difficulty falling asleep.

- **As a daytime sedative:**

- 3) For the relief of nervousness, edginess, jitteriness, and restlessness due to the feeling of fatigue.

Note: Use of the term "mild sedative" is acceptable.

Unacceptable indications/claims:

Any reference to anxiety state, apprehension, worry, concern, fear, tension and /or quality or type of sleep (eg. restful, better sleep, etc.).

ii) **Dosages:**

The dosage should be specified as being for adults.

- **As a daytime sedative:**

Liquid extract: 1:1 in 60% alcohol, 0.3-1.0 ml three times daily

Tincture: 1:8 in 65% alcohol, 4-8 ml three times daily

Concentrated Infusion: 1:5 in 25% alcohol, 2-4 ml three times daily

Other dosage forms: the equivalent of 0.3-1 g crude dried root three times daily

- **As a sleep aid:**

Any one of the above dosages may be stated as a single dose at bedtime.

iii) **Warnings:****For all indications:**

- 1) For occasional use only (when this not stated elsewhere).
- 2) Do not exceed recommended dose except on the advice of a doctor.
- 3) Avoid alcoholic beverages while taking this product.

Additional warnings for use as a sleep aid:

- 4) If sleeplessness persists continuously for more than two weeks, consult your physician. Insomnia may be a symptom of serious underlying medical illness.

Additional warnings for use as a daytime sedative:

- 5) May cause drowsiness.
- 6) Do not use while driving a motor vehicle or operating machinery because these activities require alertness.

created: 17 May 1996

References:

1. **British Herbal Pharmacopoeia, Vols 1-3.** Produced by the British Herbal Medicine Association Scientific Committee, 1980/81.
2. **CRC Handbook of Medicinal Herbs**, edited by James A. Duke. Boca Raton, Florida : CRC Press, 1985

3. Grieve, M. **A Modern Herbal**. New York : Dover Publications, Inc., 1971
4. **Lawrence Review of Natural Products**, edited by Lawrence Liberti. October 1991.
5. Spoerke, David G. **Herbal Medications** . Santa Barbara, California : Woodridge Press Pub. Co., 1980.
6. Tyler, Varro E. **The New Honest Herbal**. Philadelphia : George F. Strickley Company, 1987.
7. Wren, R.C. **Potter's New Cyclopedia of Botanical Drugs & Preparations** . Saffron Waldon, England : C.W.Daniel Co. Ltd., 1989.
8. **Sleeping Aid Labelling Standard**. Drugs Directorate, Electronic Bulletin Board System (BBS). July, 1993.
9. **Traditional Herbal Medicines (Revised)** Drugs Directorate Guideline, Electronic Bulletin Board System (BBS). October, 1995.
10. Witchel, Max. **Herbal Drugs and Phytopharmaceuticals**. CRC Press. 1994

APPENDIX I: FORMULATED PREPARATIONS

FORMULATED PREPARATIONS	U.S.P. XXIII (1995)	B.P. (1993)	(B)P.C. (1994)
Valerian Root		X	
Valerian Powder		X	