CATEGORY IV MONOGRAPH

Athlete's Foot Treatments

I) Description:

This monograph applies to products in cream, ointment, lotion, gel, powder, spray powder, aerosol liquid, solution, foam, or soap form intended to treat athlete's foot by killing or inhibiting the growth and reproduction of the fungus tinea pedis. The medicinal ingredients and their concentrations in Category IV products are restricted to those specified in this monograph. The medicinal ingredients must be identified on product labelling by the names given in this monograph.

II) Pharmaceutical Quality:

a) All ingredient (medicinal and nonmedicinal) and finished product specifications should, as a minimum, meet the standards described in the publications referred to in Schedule B to the Food and Drugs Act, 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 product's 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(s) 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. It is recommended that antimicrobial preservative effectiveness be determined in order to establish that the product is capable of resisting microbial contamination.

III) Ingredients:

a) **Single Medicinal ingredients:**

i)	Chlorphenesin	0.5 - 1 %
ii)	Clioquinol (Iodochlorhydroxyquin)	3 %
iii)	Haloprogin	1 %
iv)	Povidone-Iodine	10 %
v)	Tolnaftate	1 %
vi)	Undecylenic acid	10 - 25 %
vii)	Calcium undecylenate	10 - 25 %
viii)	Copper undecylenate	10 - 25 %
ix)	Zinc undecylenate	10 - 25 %

b) **Combinations of Medicinal Ingredients:**

Two or more of the following may be combined provided that the combined ingredients provide a total undecylenate concentration of 10-25 %:

i) undecylenic acid
ii) calcium undecylenate
iii) copper undecylenate
iv) zinc undecylenate

c) **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.

Ingredients of botanical origin added as non-medicinal ingredients must comply with the Drugs Directorate Policy, Herbs used as Non-medicinal Ingredients in Nonprescription Drugs for Human Use.

Herbal ingredients are not permitted except as fragrance components.

IV) **Labelling:**

a) This monograph describes those requirements that are specific to this class of drugs. Other requirements described in the *Regulations to the Food and Drugs Act* and in the *Guide for the Labelling of Drugs for Human Use* must also be met.

b) **Directions for Use:**

i) **Indications**

1) for the treatment of athlete's foot (tinea pedis)

The following statements are also acceptable:

2) cures athlete's foot (acceptable provided a direction "use daily for the full treatment period" is specified);

3) kills athlete's foot fungus;

4) relieves (itching, scaling, burning, cracking, redness, soreness, irritation) of athlete's foot.

5) For Tolnaftate: with daily use, for the prevention of athlete's foot, for individuals with recurring problems.

ii) **Unacceptable Claims**

1) kills athlete's foot fungus **on contact**;

2) any reference to treatment of fungal nail infections.

iii) **Dosage Directions**

1) cleanse skin with soap and water and dry thoroughly;

2) For treatment: apply (spray) a thin layer over affected area morning and night for full treatment period (4 weeks);

3) For prevention: apply (spray) thin layer to feet once or twice daily;

4) (in applying medication) pay special attention to spaces between toes;

5) wear well-fitting, ventilated shoes and cotton socks.

iv) **Warnings**

1) For external use only;

2) Avoid contact with eyes; if this happens, rinse thoroughly with water;

3) Do not use for infections of the nails;

4) Do not use in children under 2 years of age, except on the advice of a doctor (or a direction that the product should be used by adults and children over 2 years);

5) If irritation occurs or if there is no improvement following the full treatment period of 4 weeks, discontinue use and consult a doctor.

V) **References:**

1) **United States Federal Register** Vol. 47, No. 56 March, 1982 pp 12480-12566. Topical Antifungal Drug Products for Over-the-Counter Human Use; Establishment of a Monograph.

2) **United States Federal Register** Vol. 54, No. 237 December, 1989 pp 51136-51160. Topical Antifungal Drug Products for Over-the-Counter Human Use; Tentative Final Monograph.

3) **Self-Medication. A Reference for Health Professionals,** 3rd Edition, 1988, Canadian Pharmaceutical Association.

4) **American Handbook of Nonprescription Drugs,** 9th Edition, 1990, American Pharmaceutical Association.

5) **Canadian Drug Identification Code Book,** 18th Edition, 1992, Health and Welfare Canada.

6) **Compendium of Pharmaceuticals and Specialties,** 27th Edition, 1992, Canadian Pharmaceutical Association.

7) **Drugdex**, Vol. 73, 1974-1992, Micromedex Inc.

8) **Remington's Pharmaceutical Science,** 18th Edition, 1990, Philadelphia College of Pharmaceutical Sciences.

9) **Martindale, The Extra Pharmacopoeia,** 29th Edition, 1989, The Pharmaceutical Press, London.

10) **Goodman and Gilman's The Pharmacological Basis of Therapeutics,** 8th Edition, 1990. Gilman, A.G., Rall, T.W., Nies, A.S. and Taylor, P. (Eds), Pergamon Press, Inc., NY.

11) **Drug Facts and Comparisons,** 1989. J.B. Lippincott Company, Facts and Comparisons Division, St. Louis, Missouri.

12) **Drug Information for the Health Care Professional,** 12th Edition, 1992, The United States Pharmacopoeial Convention, Inc., Rockville, MD.

13) Wong, E. and Grant, D. 1984 Antifungal agents - use in athlete's foot. **On Continuing Practice** 11:2-6.

14) **AMA Drug Evaluations Annual,** 1992, American Medical Association.

15) **F. D. C. Reports,** December 18, 1989. pp. 17-18.

Appendix I

Formulated Preparations

Proper Name	USP 1995	BP 1993	BPC 1976
chlorphenesin			X
clioquinol	X		X
clioquinol cream	X	X	
clioquinol ointment	X		
compound clioquinol topical powder	X		
haloprogin	X		
haloprogin cream	X		
haloprogin topical solution	X		
povidone-iodine	X		
povidone-iodine ointment	X		
povidone-iodine solution		X	
povidine-Iodine Cleansing Solution	X		
povidone-iodine topical solution	X		
tolnaftate	X		X
tolnaftate topical aerosol powder	X		
tolnaftate cream	X		
tolnaftate gel	X		
tolnaftate topical powder	X		
tolnaftate topical solution	X		
undecylenic acid	X		X
compound undecylenic acid ointment	X		
calcium undecylenate	X		
zinc undecylenate	X		X