DEPARTMENT OF DRUG ADMINISTRATION National Medicines Laboratory

ANALYTICAL METHOD VALIDATION COMMITTEE

Metronidazole and Furazolidone Bolus

Analytical Profile No.: Metr Fur 076/077/AP078

Metronidazole and Furazolidone Bolus contains not less than 90 per cent and not more than 110

per cent of the stated amount of Metronidazole and Furazolidone.

1. Identification:

1.1 Metronidazole: The final solution prepared for the assay shows maximum absorption at about

276 nm in UV/VIS spectrophotometer and its absorption spectrum shows concordance with that

of metronidazole reference solution.

1.2 Furazolidone: Dissolve a quantity of sample equivalent to 10 mg of Furazolidone in 10 ml of

dimethylformamide and add 0.5 ml of 1 M ethanolic potassium hydroxide. A deep blue color is

produced.

Tests:

2. Assay:

2.1 Metronidazole: *Determine by UV-VIS Spectroscopy*

2.1.1 Test solution: Weigh individually 20 tablets and crush them into fine powder. Weigh a

quantity of sample equivalent to 50 mg of Metronidazole and dissolve it into 100 ml volumetric

flask with 0.1 M HCl, make up the volume to 100 ml with the same solvent. Pipette out 2 ml of

the resulting solution into 100 ml volumetric flask and make up the volume with 0.1 M HCl.

2.1.2 Reference solution: Weigh accurately about 50 mg of Metronidazole RS in 100 ml

volumetric flask, add about 70 ml of 0.1 M HCl, mix well by sonicating and make up the volume

using the same solvent. Transfer 1 ml of the resulting solution in 100 ml volumetric flask and make

up the volume using same solvent.

2.1.3 Procedure: Measure the absorbance of test solution and reference solution at the maximum

at 276 nm and calculate the content of metronidazole by comparision.

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2.2 Furazolidone: Color Development

2.2.1 Test Solution: Weigh individually 20 tablets and crush them into fine powder. Weigh a

quantity of sample equivalent to 50 mg of Furazolidone and transfer into 50 ml volumetric flask.

Add 25 ml of dimethylformamide, heat on water bath for 30 minutes, cool to room temperature

and make up the volume to 50 ml with dimethylformamide. Dilute 1 ml of the resulting solution

to 25 ml with dimethylformamide.

2.2.2 Reference Solution: Weigh accurately about 50 mg of Furazolidone RS in 50 ml volumetric

flask, add about 25 ml of dimethylformamide, heat on water bath for 30 minutes, cool to room

temperature and make up the volume to 50 ml with the same solvent. Dilute 1 ml of the resulting

solution to 25 ml with dimethylformamide.

2.2.3 Procedure: To 1 ml each of test and reference solution add 5 ml of dimethylformamide and

0.2 ml of 0.1 M methanolic potassium hydroxide. Immediately measure the absorbance of both

the solutions at 550 nm against the solvent blank. Calculate the content of Furazolidone by

comparision.

3. Other Tests: As per pharmacopoeial requirements.