DEPARTMENT OF DRUG ADMINISTRATION

NATIONAL MEDICINES LABORATORY

QUALITY AND METHOD VALIDATION SECTION

Analytical profile of Diaveridine and Sulphaquinoxaline Powder [Veterinary]

Analytical Profile No.: Diave Sulpha 080/81/AP 137

Diaveridine and Sulphaquinoxaline oral powder contains contains not less than 90.0% and not more than 110.0% of the stated amount of Diaveridine and Sulphaquinoxaline.

Usual Strength: Each gram contains

Sulphaquinoxaline BP (vet) 187 mg

Diaveridine Base 33 mg

1. Identification:

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

2. Assay: *Determine by liquid chromatography*

2.1 Test solution: Weigh about 1 g of the sample (i.e. equivalent to 33 mg of Diaveridine) in a 100 ml volumetric flask .Add about 70 ml of 30% of dimethylsulfoxide in acetonitrile sonicate for 15 minutes. Cool and volume make up to mark with same solvent. Filter the sample through what man filter paper. Dilute 5ml of resulting solution to 50 ml with 30% acetonitrile solution. Mix and filter the final solution through 0.2µm filter paper.

2.2 Reference solution:

2.2.1 Diaveridine standard solution:

Weigh accurately about 33 mg of Diaveridine working standard ,transfer to 100 ml volumetric flask, add about 70 ml of 30%v/v of Dimethylsulfoxide in acetonitrile for 15 minutes, cool and make up the volume with the same diluent.(Solution A)

2.2.2 Sulphaquinoxaline Standard Solution:

Weigh accurately about 47 mg of sulphaquinoxaline working standard ,transfer to 25 ml volumetric flask, add about 15 ml of 30%v/v of Dimethylsulfoxide in acetonitrile for 15 minutes ,cool and make up the volume with same diluent.(Solution B)

2.2.3. Composite Standard:

Mix 5 ml of solution A and solution B in a 50 ml volumetric flask, volume make up to mark with 30% acetonitrile solution. Filter the final solution 0.2 µm filter paper.

2.3 Chromatographic system:

Column: C18 (4.6mmX 250-mm, 5µ)

Flow rate: 1.0 ml/min

Detector: 280 nm

Injection volume: 10µL

Column temperature: 30 °C

Mobile phase: 2 g/L of monobasic Ammonium phosphate in a mixture of Acetonitrile, Acetic acid, Tetrahydrofuran, Ammonium hydroxide and water (400:10:5:2:583).Filter through a filter of 0.5µm nylon membrane filter.

Diluent: 30%v/v of Dimethylsulfoxide in acetonitrile and 30% acetonitrile.

2.4 Procedure: Inject the reference solution five times and sample solutions. The test is not valid unless the column efficiency is not less than 2000 theoretical plates, tailing factor is not more than 2.0, and the relative standard deviation for replicate injections is not more than 2.0%. Measure the peak responses.

5. Other tests: As per pharmacopoeial requirements.