Government of Nepal
Ministry of Health and Population
Department of Drug Administration
National Medicines Laboratory
Quality and Method Validation Section

Analytical profile of Carboxymethylcellulose Eye Drops

Analytical Profile No.: Carboxy 080/081/AP 134

Carboxymethylcellulose Sodium Eye Drop contains not less than 90.0% and not more than 110.0% of the stated amount of Carboxymethylcellulose Sodium.

Usual Strength: 10 mg/ml

1. Identification:

The light absorption of Standard Solution and Sample Solution will be identical.

2. pH: As per manufacturer's specification

3. Assay: *Determine by UV Spectrometry*

3.1 Preparation of Solution A: Weigh accurately and transfer about 1.25 gm of Diphenylamine into a clean & dried 100 ml volumetric flask. Add about 50 ml of Glacial acetic acid and sonicate with intermittent shaking for about 2 minutes to dissolve and cool the solution to room temperature. Add 30 ml of concentrated Hydrochloric acid and mix well.

3.2 Test solution: Transfer about 2 ml of Sample solution equivalent to 20 mg of Carboxymethylcellulose Sodium into a 200 ml clean and dried volumetric flask. Add about 120 ml of purified water and sonicate with intermittent shaking for about 5 minutes to dissolve and cool the solution to room temperature. Make volume up to the mark with the same, and mix well.

3.3 Reference solution: Weigh accurately and transfer about 20 mg of Carboxymethylcellulose Sodium WS to 200 ml clean and dried volumetric flask and add 120 ml of purified and sonicate with intermittent shaking for about 5 minutes to dissolve and cool the solution to room temperature. Make volume up to mark with the same and mix well.

3.4 Preparation of Blank: Purified water.

3.5 Treatment of Standard, Sample and Blank: Pipette 2 ml of each Standard, Sample and blank solution to different screw cap dried test tube and add 5 ml of solution A and mix well. Immerse the test tube in oil bath at 105˚ to 108˚ C for 30 minutes, the bath temperature being kept uniform within 0.1˚ C

during this time. After 30 minutes remove the test tube from the oil bath and immediately insert into ice bath to cool down. Measure the absorbance of these solution as soon as possible.

3.6 Procedure: Measure the absorbance at the maximum absorbance at about 635 nm using 1-cm glass cell.

4. Other tests: As per Pharmacopoeial requirements.