Cranberry Liquid Preparation

Cranberry Liquid Preparation is a bright red juice derived from the fruits of Vaccinium macrocarpon Ait. or Vaccinium oxycoccos Linné (Fam. Ericaceae). It contains no added substances.

Packaging and storage— Preserve in well-closed containers, and store in a refrigerator.

Labeling— The label states the Latin binomial name and, following the official name, the parts of the plant source from which the article was derived. The label also states that it is for manufacturing purposes only.

Identification—

A: The retention times of the quinic acid, malic acid, and citric acid peaks in the chromatogram of the Test preparation correspond to those in the chromatogram of the Standard preparation, as obtained in the test for Content of organic acids.

B: Absence of adulterants—

Standard solution— Dissolve accurately weighed quantities of tartaric acid and fumaric acid in water to obtain a solution having concentrations of about 1.0 and 0.1 mg per mL, respectively.

Test solution— Use the Liquid Preparation.

Mobile phase and Chromatographic system— Proceed as directed for Content of organic acids.

Procedure— Separately inject equal volumes (about 20 µL) of the Standard solution and the Test solution into the chromatograph, and record the chromatograms. The retention times of the tartaric acid and fumaric acid peaks in the chromatogram of the Standard solution do not correspond to any of the retention times for peaks observed in the chromatogram of the Test solution.

Refractive index 831 : between 1.3435 and 1.3445.

pH 791 : 2.5 ±0.1.

Limit of sorbitol and sucrose—

Mobile phase and Test preparation— Prepare as directed for Content of dextrose and fructose.

Standard preparation— Dissolve accurately weighed quantities of USP Sorbitol RS and USP Sucrose RS in water to obtain a solution having known concentrations of about 0.5 mg of each USP Reference Standard per mL.

Chromatographic system— Proceed as directed for Content of dextrose and fructose. Chromatograph the Standard preparation, and record the peak responses as directed for Procedure: the relative retention times are about 0.4 for sucrose and 1.0 for sorbitol; the resolution, R, between sucrose and sorbitol peaks is not less than 1.8; and the relative standard deviation for replicate injections is not more than 2.0%.

Procedure— Separately inject equal volumes (about 20 µL) of the Standard preparation and the Test preparation into the chromatograph, record the chromatograms, and measure the areas of the peaks. Calculate the percentages of sucrose and sorbitol in the volume of Liquid Preparation taken by the formula:

$$0.5(C/V)(rU / rS)$$

in which C is the concentration, in mg per mL, of the appropriate USP Reference Standard in the Standard preparation; V is the volume, in mL, of Liquid Preparation taken for the Test preparation; and rU and rS are the peak responses of the appropriate analyte obtained from the Test preparation and the Standard preparation, respectively: not more than 0.05% each of sorbitol and sucrose is found.

Content of dextrose and fructose—

Mobile phase— Use filtered and degassed water.

Standard preparation— Dissolve accurately weighed quantities of USP Dextrose RS and USP Fructose RS in water to obtain a solution having known concentrations of about 6.0 and 2.0 mg per mL, respectively.

Test preparation— Transfer about 1.0 g of sodium carboxylate cation-exchange resin, accurately weighed, to a 50-mL beaker, add 5 mL of water to make a slurry, and transfer the slurry to a polypropylene automatic pipet fitted with a small plug of silanized glass wool. Quantitatively transfer the slurry to a small chromatographic tube, rinsing the beaker with water and packing the column evenly. Keep the column wet until ready for use. Using a volumetric pipet, transfer 1.0 mL of Liquid Preparation to the column, collect the eluate, and discard it. Pipet 4.0 mL of water onto the top of the column, collect the eluate in a clean vial, and filter if necessary.

Chromatographic system— The liquid chromatograph is equipped with a refractive index detector and a 7.8-mm × 30-cm analytical column that contains packing L19 and is fitted with a

guard column that contains packing L19. The analytical column temperature is maintained at 85 ,
and the flow rate is about 0.6 mL per minute. Chromatograph the Standard preparation, and record the peak responses as directed for Procedure: the relative retention times are about 0.8 for dextrose and 1.0 for fructose; the resolution, R, between the dextrose and fructose peaks is not less than 1.8; and the relative standard deviation for replicate injections is not more than 2.0%.

Procedure— Separately inject equal volumes (about 20 µL) of the Standard preparation and the Test preparation into the chromatograph, record the chromatograms, and measure the areas of all the peaks. Calculate the percentages of dextrose and fructose in the volume of Liquid Preparation taken by the formula:

$$0.5(C/V)(rU / rS)$$

in which C is the concentration, in mg per mL, of the appropriate USP Reference Standard in the Standard preparation; V is the volume, in mL, of Liquid Preparation taken for the Test preparation; and rU and rS are the peak area responses of the appropriate analyte obtained from the Test preparation and the Standard preparation, respectively: not less than 2.4% dextrose and not less than 0.7% of fructose are found.

Content of organic acids—

Mobile phase— Transfer about 27.2 g of monobasic potassium phosphate, accurately weighed, to a 1000-mL volumetric flask, and dissolve in 950 mL of water. Adjust with phosphoric acid to a pH of 2.4, dilute with water to volume, mix, and filter.

Standard preparation— Dissolve accurately weighed quantities of USP Citric Acid RS, USP Malic Acid RS, and USP Quinic Acid RS in water to obtain a solution having known concentrations of about 1.0 mg of each USP Reference Standard per mL.

Test preparation— Use the filtered Liquid Preparation.

Chromatographic system— The liquid chromatograph is equipped with a 214-nm detector, a 4.6-mm × 25-cm analytical column containing packing L1, and a guard column containing 5-µm packing L1. The flow rate is about 0.6 mL per minute. Prior to use, condition the column with methanol, with water, and finally with Mobile phase. Chromatograph the Standard preparation, and record the peak responses as directed for Procedure: the relative retention times are about 0.4 for quinic acid, 0.5 for malic acid, and 1.0 for citric acid; the resolution, R, between quinic acid

and malic acid is not less than 2.5; and the relative standard deviation for replicate injections is not more than 2.0%.

Procedure— Separately inject equal volumes (about 20 µL) of the Standard preparation and the Test preparation into the chromatograph, record the chromatograms, and measure the peak area responses. Calculate the percentages of quinic acid, malic acid, and citric acid in the Liquid Preparation by the formula:

$$0.1C(rU / rS)$$

in which C is the concentration, in mg per mL, of the appropriate USP Reference Standard in the Standard preparation; and rU and rS are the peak area responses of the appropriate analyte obtained from the Test preparation and the Standard preparation, respectively: not less than 0.9% each of quinic acid and citric acid is found; not less than 0.7% of malic acid is found; and the ratio of quinic acid to malic acid is not less than 1.0.