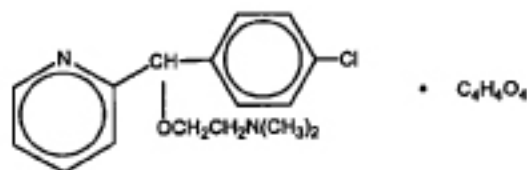
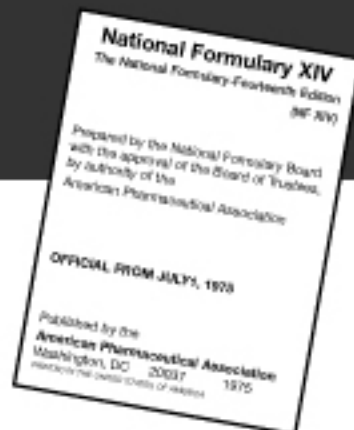


# MONOGRAPH

## Carbinoxamine Maleate Elixir



$C_{16}H_{19}ClN_2O_4$  406.87

Ethanamine, 2-[(4-chlorophenyl)-2-pyridinylmethoxy]-N, N-dimethyl-, (Z)-2-butenedioate (1:1)

2-[p-Chloro- x-[2-(dimethylamino) ethoxy]benzyl]pyridine maleate (1:1) [3505-38-2]

Category—Antihistaminic.

Usual Dose—4 mg three or four times daily.

Usual Dose Range—4 to 8 mg.

Description—Carbinoxamine Maleate occurs as a white, odorless, crystalline powder.

Solubility—Carbinoxamine Maleate is very soluble in water, is freely soluble in alcohol and in chloroform, and is very slightly soluble in ether.

Elixir Available—Carbinoxamine Maleate Elixir usually available contains the following amount of carbinoxamine maleate: 4 mg in 5 ml.

Carbinoxamine Maleate Elixir contains not less than 95.0 percent and not more than 105.0 percent of the labeled amount of  $C_{16}H_{19}ClN_2O_4$ .

**Packaging and storage**—Preserve Carbinoxamine Maleate Elixir in tight, light-resistant containers.

**Reference standards**—*NF Carbinoxamine Maleate Reference Standard*—Dry at 105° for 2 hours before using.

**Identification**—A 1 in 50,000 solution of carbinoxamine maleate in dilute sulfuric acid (1 in 70) prepared from Carbinoxamine Maleate Elixir as directed under *Salts of Organic Nitrogenous Bases*, exhibits an absorbance maximum at  $263 \pm 2$  nm. The absorptivity at 263 nm is within 7.0% of that of a 1 in 50,000 solution of *NF Carbinoxamine Maleate Reference Standard* in dilute sulfuric acid (1 in 70), similarly measured.

**pH**—The pH of Carbinoxamine Maleate Elixir is between 5.0 and 6.7.

**Assay**—Transfer an accurately measured volume of Carbinoxamine Maleate Elixir, equivalent to about 80 mg of carbinoxamine maleate, to a 250-ml separator, add 4 g of sodium bicarbonate, and mix. Extract with five 20-ml portions of chloroform, and filter the extracts into a beaker through a small pledget of cotton. Evaporate the combined chloroform extracts to about 50 ml on a steam bath, and add 50 ml of glacial acetic acid. Add 1 drop of crystal violet TS, and titrate with 0.05 N perchloric acid to a blue-green end-point. Perform a blank determination, and make any necessary correction. Each ml of 0.05 N perchloric acid is equivalent to 10.17 mg of  $C_{16}H_{19}ClN_2O_4$ .

**Alcohol content, Method I**—The content of  $C_2H_5OH$  is between 6.5 and 8.0%.