BIOSPECTRA
Premium Pharmaceutical Ingredients

Dear Sir or Madam,

BioSpectra certifies that the methods used in, and the facilities and controls used for the manufacture, processing, packaging, and holding of the Tromethamine, Active Pharmaceutical Ingredient, comply with current good manufacturing practices in accordance with the International Council on Harmonization Guidance for Industry, ICH Q7 Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients.

We commit to register our facility with the US FDA annually and will be open to FDA inspection for compliance with cGMP.

U.S. FOOD & DRUG ADMINISTRATION
DRUG ESTABLISHMENTS CURRENT REGISTRATION SITE

Firm Name	FDA Establishment Identifier	DUNS	Business Operations	Address	Expiration Date
BioSpectra Inc.	3010476065	042724830	ANALYSIS; API MANUFACTURE;	100 Majestic Way, Bangor, Pennsylvania (PA) 18013, United States (USA)	12/31/2024

https://www.accessdata.fda.gov/scripts/cder/drls/getdrls.cfm

Sincerely,

Dora Meissner
Executive Vice President of Quality Systems
610-599-3441
Dora.Meissner@BioSpectra.us
100 Majestic Way
Bangor, PA 18013