United States Food and Drug Administration

Center for Drug Evaluation and Research

10903 New Hampshire Ave, Silver Spring, MD 20993, United States of America

CDERExports@fda.hhs.gov - Telephone (301) 796-4950

Certificate of a Pharmaceutical Product - Active Pharmaceutical Ingredient (API)

Certificate Number: **5W7X-8ANH** | Certificate Issued Date: **December 20, 2024** | Certificate Expiration Date: **December 20, 2026**

Importing Country: **GERMANY** | Exporting Country: **UNITED STATES of AMERICA**

1.1	Drug Trade Name, International or National non-proprietary name (as applicable) & dosage form: **TROMETAMOL**
1.2	Active Ingredient(s) and amount(s) per unit dose (complete quantitative composition is preferred): **See Attachments**
1.3	Is this product authorized by the certifying authority to be marketed in the certifying country or within the jurisdiction of the certifying regional authority? **No**
1.4	Is this product actually on the market in the certifying country or within the jurisdiction of the certifying regional authority? **Yes**
1.4.1	Are there restrictions of sale, distribution or administration of the product specified in the marketing authorization? **No**
2.B.1	Applicant for certificate name & address: **BioSpectra, 100 Majestic Way, Bangor, PA 18013 United States of America**
2.B.2	Status of Applicant: **Manufacturer**
2.B.3	Why is marketing authorization lacking? **Not Required**
Remarks:	**The firm proposes to export the active pharmaceutical ingredients (API) listed above, which when properly labeled with statement "Caution: For further manufacturing, processing or repacking", may be freely marketed in the United States of America at this time.**
3.1	Manufacturer name & address: **BioSpectra, 100 Majestic Way, Bangor, PA 18013 United States of America**
3.2	Does the certifying authority arrange for periodic inspection of the manufacturing plant in which the dosage form is produced? **Yes**
3.3	Periodicity of routine inspections (years): **Pursuant to section 510(h)(3) of the Federal Food, Drug & Cosmetic Act, Inspections will occur in accordance with a risk-based schedule**
3.4	Has the manufacture of this type of dosage form been inspected? **Yes**
3.5	Do the facilities and operations conform to GMPs as recommended by the WHO? (GMPs including 21 Code of Federal Regulations parts 210, 211, or ICH Q7A): **Yes, at time of inspection, site complies with FDA cGMP**
3.6	Does the information submitted by the applicant satisfy the certifying authority on all aspects of the manufacture of the product undertaken by another party? **Yes**

Carole Jones, Division Director

Exports Compliance Branch

Division of Global Drug Distribution and Policy

Office of Drug Security, Integrity & Response

To verify the authenticity of the information on this certificate, you may scan the QR code or visit www.access.fda.gov/fecv/searchCderCertificate to view a copy of the certificate as issued by FDA.
This certificate conforms to the format recommended by the World Health Organization format revised March 25, 2021. Website: www.who.int

5W7X-8ANH

BIOSPECTRA
Premium Pharmaceutical Ingredients

API
Product Code: TRIS-2257-25
Base Product Code: TRIS-1200

Tris/Tromethamine

EP, GMP, API Grade

Lot Number:	**TRIS-E04-1224-0000**
Retest Date:	**12/31/26**
Manufacture Date:	**12/01/24**
CAS Number:	**77-86-1**
EC Number:	**201-064-4**
NET Weight:	**25kg**
Molecular Weight:	**121.14 g/mol**
Molecular Formula:	$NH_2C(CH_2OH)_3$

Bio Active Grade Level
Caution: For manufacturing, processing, or repacking.
Caution: Rx Only
Intended Use Statement: Material in this package is suitable for use as a non-Sterile Active Pharmaceutical Ingredient manufactured in accordance with the ICH Q7 Good Manufacturing Practice Guide. The material in this package is not suitable to be used as a Sterile or Injectable Active Pharmaceutical Ingredient, Drug Product or Household Item.

Storage Conditions: 15-30°C Preserve in Tight Containers

Signal Word: Not Applicable
Hazard Statements: Not Applicable
Precautionary Statements: Not Applicable

Manufactured at: 100 Majestic Way, Bangor, PA 18013