United States Food and Drug Administration

Center for Drug Evaluation and Research

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

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

Certificate Number: **2Q62-2YU9** Certificate Issued Date: **May 23, 2025** Certificate Expiration Date: **May 23, 2027**

Importing Country: **FRANCE** Exporting Country: **UNITED STATES of AMERICA**

1.1	Drug Trade Name, International or National non-proprietary name (as applicable) & dosage form: **POTASSIUM BROMIDE**
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? (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.