



ANVISA GMP CERTIFICATION ACHIEVED

Milford, MA Site Recognized for
Pharmaceutical Manufacturing Excellence

Nitto AVecia's Milford site has received GMP Certification from ANVISA for the production of Eplontersen sodium, confirming compliance with Brazilian regulations and WHO standards.

VALID UNTIL: JULY 21, 2027



This GMP certification is a critical regulatory milestone that confirms full compliance with Brazil's GMP requirements as well as alignment with World Health Organization (WHO) standards. It reflects the consistent quality, safety, and operational excellence of our manufacturing operations – enabling trusted pharmaceutical production in one of the world's most stringent regulatory environments.

Impact of the Certification

- Regulatory Compliance: Demonstrates adherence to ANVISA's rigorous GMP framework.
- Quality Assurance: Affirms the robustness of our quality systems and manufacturing processes.
- Global Standards: Confirms alignment with both Brazilian regulations and WHO expectations.
- Operational Excellence: Highlights cross-department collaboration and preparation by our Quality and Regulatory teams.

Acknowledgements

We extend congratulations to our Quality and Regulatory Compliance Team for their meticulous preparation and to all departments whose ongoing collaboration made this achievement possible. This certification stands as a testament to our company's commitment to producing high-quality oligonucleotide therapeutics for customers worldwide.