



ARTSS™ Aqueous Room Temperature Stable Solution

LATITUDE Pharmaceuticals Inc.'s **Aqueous Room Temperature Stable Solution (ARTSS™)** platform reformulates lyophilized drug preparations into stable liquid formulations. The ARTSS™ platform substitutes the costly and time-consuming lyophilization process, allowing for convenient, ready-to-use liquid drug formulations.

Example of the ARTSS platform: OraVerse®

Phentolamine mesylate is an alpha-adrenergic blocker, originally approved as an antihypertensive drug and provided in a lyophilized form for intravenous and intramuscular administration. Phentolamine mesylate can also be used to counteract the effect of local dental anesthesia. However, the lyophilized form is not readily accepted for use in dental practices. LATITUDE scientist applied the ARTSS platform and developed a ready-to-use, aqueous liquid formulation for phentolamine mesylate with more than 2-year shelf life at room temperature. This new formulation has been approved by the FDA for marketing under the name OraVerse®.

OraVerse® represents a first-in-class therapeutic which was made possible by a new ARTSS™ formulation for an old drug, and was approved in a relatively short time by FDA under the 505(b)(2) regulatory path.



Key Advantages of ARTSS™ Technology

- Transforms lyophilized powder to liquid
 - Enables new indications by providing the ready-to-use feature
 - Meets the urgent-use needs for rescue drugs
 - Decreases cost and complexity in manufacturing and use
 - Resurrects or extends patent status for existing drugs
- Converts refrigeration to room temperature storage
 - Eliminates cold-chain requirements in manufacturing, shipping & storage
 - Provides convenience for patient use
- Applicable to small molecules, peptides and proteins
- Demonstrated also for:
 - Vancomycin (lyo to liquid)
 - Glucagon (lyo to liquid)
 - Proton pump inhibitors (lyo to liquid)
 - Human insulin (refrigerated to room temperature stored)
 - And others