

Nano-E™

Nanoemulsion Drug Delivery System for Highly Insoluble Drugs

LATITUDE Pharmaceuticals Inc.'s **Nanoemulsion Drug Delivery System (Nano-E[™])** is a versatile drug delivery platform for applications requiring a liquid formulation for highly insoluble small molecule, peptide, and protein drugs. Nano-E is being used in several NDA-stage and clinical-stage products.

The **Nano-E[™]** technology is the 505(b)(2)-enabling formulation behind two NDA-stage compounds that LATITUDE developed for its clients.

<u>Key Advantages and Properties of</u> <u>Nano-E™ Technology</u>

- Highly versatile drug delivery platform for insoluble or soluble compounds
- Small molecule and protein friendly
- pH neutral, non irritating, non-allergenic: clinically proven significant safety improvement for vein-irritating drugs
- For IV, IM, SC, IP, intrathecal, intra-articular, ophthalmic, oral routes of delivery
- IV bolus and infusion enabling
- Up to 5% drug loading by weight
- Tissue friendly and wound compatible
- Dilutable in standard IV diluents (e.g., D5W)
- All components are GRAS listed compendial grade (USP, NP, EP)
- Does not contain co-solvents (e.g., Cremophor) or detergents (e.g., polysorbate)
- PK profile bio-equivalent to solution formulations
- RT stability demonstrated for 1.5-2 years
- Filterable through 0.2 micron fiiters
- Lyophilizable as needed
- Simple and straightforward manufacturing
- Manufacturing feasibility demonstrated for two NDA-stage drugs
- Patent issued



