

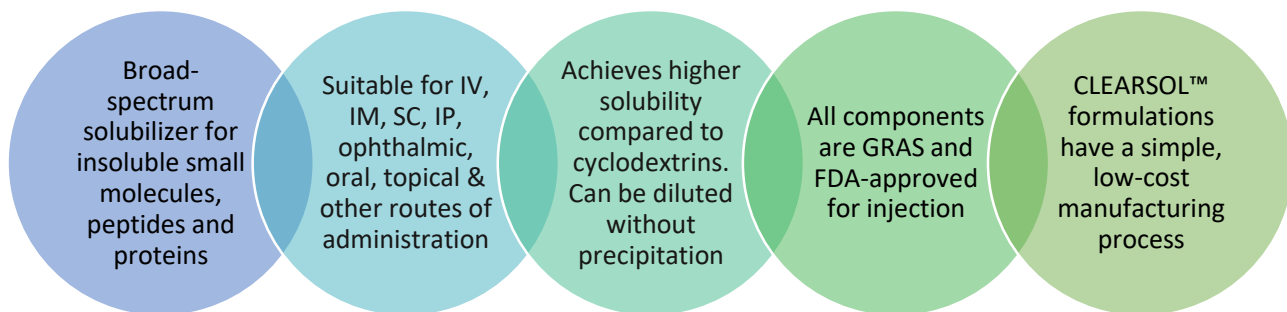
CLEAR SOL™

Improved Solubility for Your Insoluble API

CLEAR SOL™ is a novel, clinically-tested vehicle for solubilizing the most difficult APIs

- Forms stable, ready-to-administer one-phase aqueous solutions with insoluble APIs
- Achieves greater API solubility than cyclodextrins, polysorbates, and organic solvents
- Proven safe for use in animals and humans
- Suitable for multiple routes of administration
- Reduces formulation development time and risk
- Developed by LATITUDE Pharmaceuticals, a premier developer of drug delivery systems

CLEAR SOL™ Is Versatile, Effective & Safe



CLEAR SOL™ Advantages

- ✓ Simple to use: just add API to CLEAR SOL™ and mix
- ✓ CLEAR SOL™ formulations can be diluted in common infusion diluents without precipitation of the API
- ✓ Clinical safety established for human use
- ✓ Non-allergenic, non-hemolytic, non-irritating and well-tolerated
- ✓ Well characterized biocompatibility, metabolism & safe use history
- ✓ Patents pending



CLEAR SOL™ with Your API

Evaluate CLEAR SOL™ in your own lab

- ✓ Request your free CLEAR SOL™ evaluation sample
- ✓ Test solubility of your API by simply mixing with CLEAR SOL™

LATITUDE can evaluate, optimize and/or provide development support for your API in CLEAR SOL™

- ✓ Proof-of-concept, optimization, toxicology, and clinical formulation development
- ✓ R&D and CMC support for regulatory filings

Contact Us for More Information or for Your CLEAR SOL™ Free Sample



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CLEAR SOL™ Dissolves Insoluble APIs Better Than Cyclodextrins

Drug	Structure	Function	Reported solubility in water (mg/mL)	Measured Solubility in SBE-β-CD (mg/ml)	Measured Solubility in ClearSol (mg/ml)	Fold-difference, ClearSol vs. SBE-β-CD
Amiodarone	Small molecule	Anti-arrhythmic	0.7	9.28	118	13
Amphotericin	Small molecule	Antifungal	<0.0001	<0.1	2.4	24
Aprepitant	Small molecule	Antiemetic	< 0.0001	<0.1	12.7	127
Camptothecin	Small molecule	Anticancer	< 0.0001	<0.1	0.75	8
Celecoxib	Small molecule	Anti-inflammatory	0.001-0.0001	0.22	7.3	33
Clarithromycin	Small molecule	Antibiotic	< 0.0001	<0.1	9.1	91
Ibuprofen	Small molecule	Anti-inflammatory	0.021	2.82	53.1	19
Irinotecan HCl	Small molecule	Anticancer	< 0.0001	0.18	20.4	113
Itraconazole	Small molecule	Antifungal	< 0.0001	<0.1	0.75	8
Levodopa	Small molecule	Anti-Parkinson's	5	1.49	10	7
Paclitaxel	Small molecule	Anticancer	< 0.0001	<0.1	1	10
Phytonadione	Small molecule	Vitamin K	< 0.0001	0.178	28.2	158
Posaconazole	Small molecule	Antifungal	< 0.0001	0.18	0.5	3
Prednisolone	Small molecule	Steroid	< 0.0001	1.4	1	1
Progesterone	Small molecule	Steroid	0.017	2.91	12	4
Propofol	Small molecule	Anesthetic	< 0.0001	14.03	50.8	4
Tyrosine	Small molecule	Amino acid	0.45	<0.1	1	10
Voriconazole	Small molecule	Antifungal	< 0.0001	7.95	20	3
Casein	Protein	Nutritional supplement	0.001-0.0001	<0.1	1	10
Cyclosporine	Peptide	Immune suppressant	0.001-0.0001	0.045	8.1	180

* SBE-β-CD concentration: 157.8 mg/ml

CLEAR SOL™ Is Safe in Multiple Preclinical Studies

Species	Route of Administration	Dose (mL)	N	Maximum Nonlethal Dose (mL)	Noteworthy Findings
Single-Dose Toxicity					
SD Rat	Subcutaneous	0.93 (M) 0.69 (F)	15M 15F	≥0.93 (M) ≥0.69 (F)	Transient, non-adverse, minimal to mild injection site irritation
NZW Rabbit	Subcutaneous	0.57	6M	≥0.57	Transient, non-adverse, slight dermal irritation
Repeat Dose Toxicity for 28 days					
Beagle Dog	Intravenous	22.8 (M) 20.8 (F)	2M 2F	≥22.8 (M) ≥20.8 (F)	No adverse systemic effects

CLEAR SOL™ Is Safe in Human Studies

The safety and tolerability of subcutaneous injection of CLEAR SOL™ was assessed in 35 healthy adults under an FDA-approved IND. CLEAR SOL™ was well-tolerated both systemically and locally with no adverse events reported.

CLEAR SOL™ for the Creation of Bioequivalent Formulations

Bioequivalent PK profiles

△ : CLEAR SOL™-formulated IV drug

vs

○ : Branded comparator product

