

## 1. Drugs (including Drug Delivery)

Stage	Technology Readiness Level	Definition
Ideation	TRL-1	Need identified, Basic principles observed and reported (Scientific research begins to be translated into applied research and development )
Proof of Principle	TRL-2	Research ideas developed, hypothesis formulated and protocols developed (Idea proven on initial level by <i>In-vitro studies</i> i.e. biochemical studies etc)
Proof of Concept demonstrated	TRL-3	Hypothesis testing and initial proof of concept (PoC) is demonstrated in a limited number of in vitro models and limited in-vivo efficacy studies (Studies proven by <i>In-vitro</i> model studies i.e. relevant Cell based models, ex-vivo, organoid cell model and In-vivo efficacy in minimum number of animals).
Proof of concept established	TRL-4	Efficacy, & safety of candidate drug formulation is demonstrated in a defined animal model (Results of formulation studies, pharmacokinetic studies & ADME , PD , safety of candidate formulations at preliminary level and efficacy in <i>in-vivo</i> disease model)
Early stage validation	TRL-5	Pre-clinical studies, including GLP efficacy, acute and chronic toxicity in animal model producing sufficient data for DCGI application for clinical trials. DCGI approval for Phase-1 trial
	TRL-6	Material produced in GLP facility for clinical trials. Phase-1 Clinical trials done and results submitted to DCGI. Investigative new drug application reviewed by DCGI for approving Phase-II Clinical trials
Late stage Validation	TRL-7	Phase-II Clinical trials completed and data reviewed by DCGI and Phase-III Clinical trial plan approved
Pre-commercialization	TRL-8	Phase-III Clinical trials completed successfully. DCGI approves the New Drug Application and provides commercial manufacturing license for market introduction
Commercialization and post market studies	TRL-9	Commercial launch of the new drug, Post marketing studies and surveillance