Piramal
Pharma Solutions

LIPOSOME DRUG DELIVERY

ABSTRACT

The global market for NDDS in cancer therapy was valued at USD 3,655.3 million in 2013 and is expected to reach USD 15,984.2 million in 2020, growing at a CAGR of 23.7% during the forecast period from 2014 to 2020.

The world is witnessing a continuous rise in the incidence of various types of cancer. Clinical benefits of embolic agents and nanoparticles over other therapy and drug delivery systems; technological advances leading to the development of new and innovative therapy; and expanding therapeutic indications of existing NDDS are some of the major factors expected to drive growth of global NDDS in cancer therapy market during the forecast period from 2014 to 2020.

On the other hand, factors such as high treatment cost associated with NDDS, strict regulatory pathways and cost associated with new product development may restrict market growth to some extent. One of the major opportunities in this market is nano-enabled drug delivery systems, as this segment has been anticipated to grow at the highest CAGR of 24.7% during the forecast period.

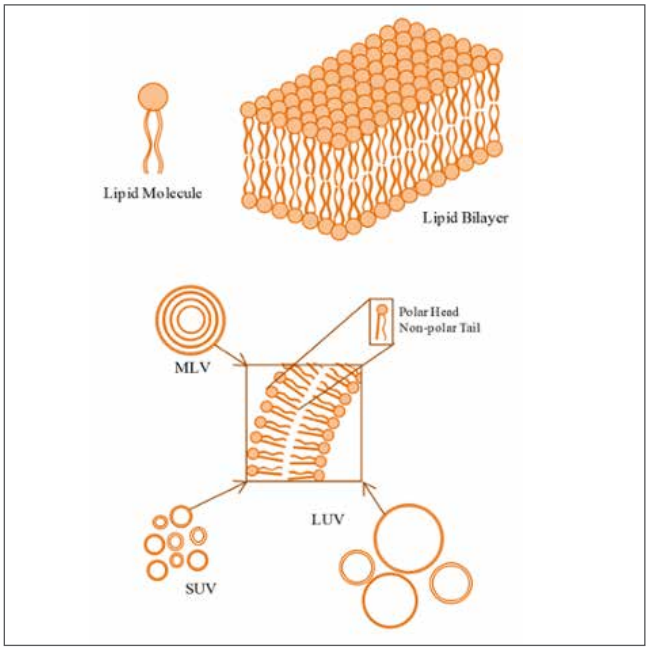
Nanoparticles in novel drug delivery systems have emerged as a promising technology to treat patients suffering from various types of cancer. The market for nanoparticles segment was valued at USD 3,307.7 million in 2013 with the largest revenue share in the overall NDDS in cancer therapy market.

Liposomes are microvesicles composed of a bilayer and/or a concentric series of multiple bilayers separated by aqueous compartments formed by amphipathic molecules such as phospholipids that enclose a central aqueous compartment. In a liposome drug product, the drug substance is contained in liposomes. Typically, water soluble drugs are contained in the aqueous compartment and hydrophobic drugs are contained in the lipid layer of the liposomes. Release of drugs from liposome formulations can be modified by the presence of polyethylene glycol and/or cholesterol or other potential additives in the liposome.

The evolution of the science and technology of liposomes has been used in the development of the drug carrier concept as a promising drug delivery system. The liposome was adopted as a promising delivery system because of its organized structure which could hold drugs depending on their solubility characteristics, in both aqueous and lipid compartments.

Complexity of these products can be projected by the fact that FDA issued guidance for development of liposomal drug products with separate guidance for development of generic drug product like doxorubicin liposomes, amphotericinB liposomes, protein bound paclitaxel, etc. The manufacturing process of these products is complex and detailed characterization is imperative.

Complex Injectables present various challenges that demand detailed characterization to successfully develop a product. The manufacturing of complex injectables is a multiple step, product specific process involving formation of a drug-lipid complex, hydration, drug loading using different methods, particle size reduction, homogenization, extrusion, lyophilization, etc. Processing of complex injectable sterile liquid or lyophilized product requires careful evaluation and strict control of critical process parameters to manufacture a product with a target profile that meets quality requirements.



PIRAMAL COMPLEX FORMULATION DEVELOPMENT CAPABILITIES

- All types of liposomes and other lipid-based drug delivery systems for both NCE and generic molecules
- Solubility enhancement using liposomes and lipid-based systems
- Pre-formulation, formulation feasibility and prototype development
- Product specific high-end manufacturing technique for different liposomal products (spray drying, high speed and high pressure homogenization, extrusion, thin film formation, sonication and lyophilization/freeze drying)
- QbD approach for liposomal product development, scale-up and process optimization
- Microbiological method development

PIRAMAL COMPLEX FORMULATION CHARACTERIZATION CAPABILITIES

- Particle size and particle size distribution
- Zeta potential
- Drug loading and encapsulation efficiency
- Microscopic characteristics using inverted microscope, TEM and cryo-TEM
- Phase transition of liposome
- In vitro drug release
- HPLC method development and validation
- HPLC measurement of drug potency and impurities
- HPLC measurement of lipid content and impurities
- Residual solvent determination by GC
- DOE with minitab software
- Freeze drying microscope and differential scanning calorimetry (DSC) for development of lyophilized cycle

Piramal R&D, Mumbai has the capability and extensive experience in complex injection development including liposome drug product development for both NCE and generic molecules. Our customer base includes top ten global pharma companies through leading generics, speciality pharma and biotech companies from North and South America, Europe, Asia and Australia.

Piramal Pharma Solutions is a contract development and manufacturing organization (CDMO), offering end-to-end development and manufacturing solutions across the drug life cycle. We serve our clients through a globally integrated network of facilities in North America, Europe and Asia. This enables us to offer a comprehensive range of services including Drug Discovery Solutions, Process & Pharmaceutical Development services, Clinical Trial Supplies and Commercial supply of APIs and Finished dosage forms. We also offer specialized services like development and manufacture of Highly Potent APIs, Antibody Drug Conjugation and are well versed in technologies such as Bio-catalysis, Route Scouting etc. Our capability as an integrated service provider & experience with various technologies enables us to serve Innovator and Generic companies worldwide.

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