

Complex Injectable: A Challenging Opportunity

Article Courtesy of Piramal Pharma Solutions Inc.

Complex injectables include lyophilized products, highly potent drugs, long-acting suspensions, and liposomes which require complex manufacturing capabilities or use of new drug delivery systems (NDDS). For injectables, NDDS includes drug delivery systems like self-injection devices, such as auto and pen injectors, which improve patient compliance and enable differentiation.

Market Scenario

The injectable drug delivery market is \$326.1 billion and expected a CAGR of 12 percent. North America is estimated to command the largest share and is expected to grow at a CAGR of 11.2 percent to reach \$247.1 billion by 2020.

The global market for complex injectables, PEGylated, Depot and Lipo-

somes, has especially grown steadily at a CAGR (2010-2015) of 6 percent and is expected to perform well in the near future. The growth is further strengthened due to existence of a strong pipeline – 40 PEGylated drugs, 12 depot injections and seven liposomal drug formulations. The U.S. generic injectable market is also expected to grow at a CAGR (2015-2020) of 10 percent since injectable drugs worth \$16 billion are expected to go off patent in the period between 2015-2019 in the U.S. alone.

Other part of complexity is lyophilization of injectables. The market for cytotoxic lyophilized vials has grown at a CAGR (2010-2015) of 7 percent while the noncytotoxic lyophilized market grew at 4 percent, reaching an overall value of \$23.4 billion in 2015. The growth can be said to have been driven by the varied applications of this technique in areas like anti-bacterial, anti-he-



mophilic, CVS and hormonal.

Varied Applications

- The 505 (b)(2) market has also been growing due to more and more successful applications of these complex injectables.
- Biologics form a part of complex formulations catered by PEGylation techniques.
- Bioavailability is proven better by complex injectables as compared to conventional drugs. e.g. liposomal formulations.
- Sustained release injectable that creates a depot of drug has an added advantage of reduced dosing frequency and ease of use in psychotic patients.

Challenges — Complex Injectables

- Improving safety efficacy ratio of “old” drugs by formulating individual drug therapy, dose titration and therapeutic drug monitoring.
- Extensive rheological studies for appropriate administration and delivery.
- Need of appropriate container/closure system.
- Reconstitution must result in a biocompatible solution suitable for IV infusion, IM injection or SC injection.
- High capital investments and operational costs.
- Ensuring sterility and stability of the product.
- Comparability and control strategy concerns facilities.
- Specialized skill, equipment and resource are necessary.
- Maintaining USFDA-compliant manufacturing.

Piramal Capabilities (Booth #1703)

We offer complex injectable development services from our facility located in Mumbai, India, which is forward integrated with our FDA inspected manufacturing site lo-

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PIRAMAL PHARMA SOLUTIONS *(continued from page 8)*

cated in Lexington, Kentucky. We have the technical know-how and expertise to handle complex sterile formulations.

Services Offered

- Preformulation and formulations services for sterile injectable:
 - o Sterile solutions and depot injections.
 - o Nanoparticles and liposomes.
 - o Pegylated and lyophilized products.
 - o In-situ salt formations.
- Clinical Scale and scale up development of lyophilized formulations.
- Development and manufacture of potent drug products.

- Full-service microbiology laboratory testing of drug substances and drug products.

Salient Features

- Specializes in freeze drying technology in the injectable
- GLP analytical development laboratory is registered with USFDA and have received DUNS NO.
- Mobile isolator technology with ISO class 5 environment.

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.