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The Indian Pharma Industry: Present Scenario

VISION

To build a humane society through excellence in education and health care.

MISSION

To develop Nitte University as a centre of excellence, imparting quality education, generating competent, skilled manpower to face the scientific and social challenges with a high degree of credibility, integrity, ethical standards and social concern.

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'For Private Circulation Only'



From the Editor's desk

Research in the centers for higher education

In the recent years, lot of debate is going on related to research in the institutions offering higher education. In spite of a substantial amount of money being spent, the outcome still remains discouraging. The main reason for such a situation is “me-too” research. Most of the times, the researchers tend to take up the work with minor modification to the already reported outcomes.

However, there are other dimensions also. Lack of research facility is one among them. In many institutions the instrumentation available do not support the advanced techniques of research, hence the outcome reported remains ambiguous. Another reason is that all the teachers cannot be good researchers. The aptitude for research has to be developed over a period of time.

Providing the necessary infrastructure and rewarding the performance, may help in creating an environment to the promotion of research in institutions. Needless to say, the emphasis on research should not take the focus of teachers away from their primary objective of providing quality education to the students.

I take this opportunity to welcome the new batch of students of the year 2015-16 and wish them great success.

Dr. C.S. Shastry
Principal

NEWS FLASH - The FDA approves the first 3D printed drug product!

The Food and Drug Administration has given approval to the first 3D printed drug product in the history of mankind. Developed by Ohio-based pharmaceutical company Aprelia, ‘Spritam’ (levetiracetam) is a new drug that can control epileptic seizures. The ‘magic pill’ produced by 3D printing process allows layers of medication to be packaged more tightly in precise dosages and allows a high drug load — up to 1,000 mg — to be delivered in a single dose. An important advantage of this technology is that, 3D-printed pills could be custom-ordered, based on specific patient needs, rather than on a one-drug-fits-all approach. This means that tablets can be processed much closer to the patient. By making slight adjustments to the software before printing, hospitals could adjust doses for individual patients, a process of personalization that is otherwise very expensive. Moreover, Aprelia has utilized its trademark “ZipDose” technology, which uses 3D printing to create a more porous pill. Its structure causes the tablet to dissolve more quickly on contact with



liquid, making it much easier to swallow high doses than a conventional tablet. However, 3D printing technology itself is not new. It has been successfully used in several medical, dental and surgical applications such as 3D-printed surgical stents that improve blood flow, dental implants, prosthetics and even 3D-printed organs and bones.

PRESENT SCENARIO OF THE INDIAN PHARMACEUTICAL SECTOR

Mr. Sandeep DS
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Pharmaceuticals are medicinally effective chemicals, which are converted to dosage forms suitable for patients to imbibe in the basic chemical form. Pharmaceuticals are called bulk drugs and final dosage forms are known as formulations. Bulk drugs are derived from four types of intermediates i.e., raw materials viz., (i) plant derivatives or herbal products, (ii) animal derivatives e.g., insulin extracted from bovine pancreas, (iii) synthetic chemicals and (iv) biogenetic or human derivatives e.g., human insulin. These are substances known as medicines and used in preventing and curing illness and diseases. Usage of pharmaceutical is governed by underlying science of illness and disease.

World over the Pharmaceutical Industry is focused on Allopathy, the most modern medical science. Other modes of medical treatment such as homeopathy, Ayurveda and Unani are more prevalent in third world countries. Pharmaceutical Industry is driven by a global need to conquer disease. Medicines are developed to treat new diseases or improve upon the existing treatment. An in-depth understanding of human physiology and disease mechanism is a pre-requisite to pharma R&D.

The Indian pharmaceutical industry currently tops the chart amongst India's science-based industries with wide ranging capabilities in the complex field of drug manufacture and technology. A highly organized sector, the Indian pharmaceutical industry is estimated to be worth \$ 4.5 billion, growing at about 8 to 9 percent annually. Indian pharmaceutical industry is expected to grow at 19% in 2013. India is now among the top five pharmaceutical emerging markets. Further estimates the healthcare market in India to reach US\$ 31.59 billion by 2020.

According to the estimates, the Indian diagnostics and labs test services, in view of its growth potential, is expected to reach Rs159.89 billion by 2013. The Indian market for both therapeutic and diagnostic antibodies is expected to grow exponentially in the coming years. Findings from the report suggest that more than 60% of the total antibodies market is currently dominated by diagnostic antibodies.

Growth of Import-Export

Imports- As per the Directorate General of Commercial Intelligence and Statistics (D.G.C.I.S.) Kolkata, the value of imports of "Medicinal and Pharmaceuticals Products" for the latest period 2007-08 to 2010-11 is as under:

Year	Value of import of "Medicinal and pharmaceuticals products"	Growth%
2007-08	293.54	14.37
2008-09	398.21	35.66
2009-10	424.56	6.62
2010-11*	475.51	12.00

Exports - As Per DGCIS, Kolkata Exports of "Drugs and Pharmaceuticals and Fine Chemicals" for the period 2007-08 to 2010-11 are below:-

Year	Value of import of "Medicinal and pharmaceuticals products"	Growth%
2007-08	67.34	14.79
2008-09	86.49	28.43
2009-10	99.59	15.15
2010-11*	109.37	9.82

Some of the major Indian pharmaceutical firms, including Sun Pharma, Cadila Healthcare and Piramal Life Sciences, had applied for conducting clinical trials on at least 12 new drugs in 2010, indicating a growing interest in new drug discovery research.

Some of the leading Indian players by sales (INR Billion)

Company name	Sales in INR billion
Cipla	69.77
Ranbaxy Lab	76.86
Dr Reddy's Labs	66.86
Sun Pharma	40.15
LupinLtd	53.64
AurobindoPharma	42.84
Jubilant Life	26.41
Cadila Health	31.52
Ipca Labs	23.52
Wockhardt	26.50

Challenges and future growth

Current global financial conditions and the threat of a broad recession accelerated the timetable for implementing transformational changes in global organizations, as the industry confronts lower corporate stock prices and an increasingly cost-averse customer. The Indian stock market may be dreading a possible recession but Indian pharma

companies seem unfazed by slowdown fears. Riding on better sales in the domestic and export markets, Indian pharmaceutical industry is being expected to continue with its good performance. Today Indian pharmaceutical Industry can look forward to the years to come, with great expectations.

India will see the largest number of merger and acquisitions (M&A) in the pharmaceutical and healthcare sector, according to consulting firm Grant Thornton. A survey conducted across 100 companies has revealed that one-fourth of the respondents were optimistic about acquisitions in the pharmaceutical sector.

In addition, the pharmaceutical companies such as Cipla, Ranbaxy, Dr Reddy's Labs and Lupin might soon be part of the government's ambitious 'Jan Aushadhi' project. In

an attempt to commercialize the project, the Government is likely to rope in the private sector to bulk-procure generic drugs from them. There are 117 Jan Aushadhi stores across the country and the plan is to expand to at least 600 in the next two years and 3,000 by 2016.

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2. A brief report on pharmaceutical industry in india. www.cci.in, 2014:1-10.
3. Based on Survey of Report by Elysium Pharmaceutical Ltd. page 1-16

DEPARTMENT ACTIVITIES

DEPARTMENT OF PHARMACEUTICAL CHEMISTRY

RESEARCH PUBLICATIONS

DR. B C REVANASIDDAPPA, Asst. Professor

1. Antiepileptic Activity of Some Novel Substituted Fluorid Benzothiazole Derivatives. *International Journal of Pharmacy and Pharmaceutical Sciences* July 2015, 7(7) : 157-159
2. Synthesis of certain 1,3,4-Oxadiazoles as Antimicrobial Agents. *Indian Journal of Pharmaceutical Science and Research* 2015; 5(3): 151-153
3. Synthesis and Biological Evaluation of N-(Substituted Phenyl)-2-(5H-[1,2,4] triazino [5,6-b] indol-3-ylsulfanyl) acetamides as Antimicrobial, Antidepressant, and Anticonvulsant Agents. *Russian Journal of Bioorganic Chemistry* 2015; 41(2): 223-230

MR. ABHISHEK KUMAR, Asst. Professor

Synthesis, Antioxidant and Cytotoxicity Studies of Some Novel Carboxamide Derivatives of 2-Quinolones. *Indian Journal of Heterocyclic Chemistry* 2015; 24: 333-336

DEPARTMENT OF PHARMACEUTICS

RESEARCH PUBLICATIONS

DR. R. NARAYANA CHARYULU, Professor

1. Formulation and in vitro Comparative Evaluation of Orodispersible Tablets of Esomeprazole. *World Journal of Pharmaceutical Research* May 2015; 4(5): 2173-2181
2. Formulation and in vitro Comparative Evaluation of Orodispersible Tablets of Pantoprazole. *International Journal of Chemical Science and Technology* April 2015; 5(2): 399-404
3. Pharmacokinetic Evaluation of Bilayered Buccoadhesive Compacts Containing Enalapril

Maleate Using Rabbits. *International Journal of Pharmacy and Pharmaceutical Research* March 2015; 2(4): 66-75

4. *Liquid Crystals as Novel Drug Carrier: A Review Trends in Drug Delivery* 2015; 2(1): 1-9

MR. AMIT PATIL, Asst. Professor

1. Simultaneous Estimation of Baclofen and Nimesulide: Method Development and Validation by UV-Spectrophotometric Method. *Research Reviews: A Journal of Drug Formulations, Development and Production*, 2015; 2(2): 6-11
2. Formulation and Characterization of Liquisolid Tablet of Skeletal Muscle Relaxants and Anti-Inflammatory Drugs. *Research Reviews: A Journal of Drug Formulations, Development and Production*, 2015; 2(2): 6-14
3. Formulation Development of Antihypertensive Buccal Patches and Characterisation. *Research Reviews: A Journal of Drug Formulations, Development and Production*, 2015; 2(2): 15-27
4. Formulation and Evaluation of an Antifungal Emulgel Containing Carbopol 940 as Gelling Agent. *Trends in Drug Delivery*, 2015; 2(1): 28-37
5. Simultaneous Estimation of Atenolol and Nifedipine to be incorporated in Buccal Patch: Method Development and Validation by UV-Spectrophotometric Approach. *Research and Reviews: A Journal of Pharmacognosy*, 2015; 2(1): 28-32

MR. JOBIN JOSE, Asst. Professor

1. Solubility Enhancement of an Antifungal agent by association with dendrimers. *Indian Journal of Research in Pharmacy and Biotechnology*, Mar-April 2015; 3(2): 171-175
2. Evaluation of the efficacy of 20% Ocimum sanctum gel in the Treatment of Experimental Periodontitis.

International Journal of Pharmaceutical Investigation, 2015; 5(1): 35-42

MR. PRASHANT NAYAK, Asst. Professor

Comparative Evaluation of In Vitro Antioxidant Activity of Bark, Flowers and Fruit Extracts of *Pongamia Pinnata*. *Research Reviews: A Journal of Pharmacognosy*, 2015; 2, (2): 14-21

WORKSHOPS/SEMINARS ATTENDED

Dr. R. Narayana Charyulu and Dr. Marina Koland attended a two day awareness program on “Current Regulatory Requirements for members of Institutional Ethics Committee”, May 19 & 20, 2015 at Father Muller Medical College, Mangalore. This workshop was organized by the Clinical Development Services Agency (CDSA), an extramural unit of Translational Health Science & Technology Institute (THSTI), Dept. of Biotechnology (DBT), Ministry of Science and Technology, Govt. of India.

DEPARTMENT OF PHARMACY PRACTICE RESEARCH PUBLICATIONS

DR. D.S. PURANIK, Assoc. Professor

1. Anti-Stress Activity of *Euphorbia Thymifolia* L Aqueous Root Extract in Female Rats. *International Journal of Pharma Sciences and Research*, April 2015; 6(4):640-644
2. Role of *Euphorbia Thymifolia* L Ethanolic Root Extract in Treating Female Reproductive Dysfunction in Rats. *International Journal of Pharmacological Research*, April. 2015; 5(4): 75-79
3. Protective Effect of *Euphorbia Thymifolia* L Root on Reproductive Dysfunction in Female Rats. *Asian Journal of Pharmacology and Toxicology*, 2015; 3(8): 8-11

AMNIOTIC FLUID EMBOLISM

Dr. Prerana Shetty

Assoc. Professor

Dept. of Pharmaceutical Chemistry

Amniotic Fluid Embolism acronymically known as ‘AFE’ is a rare and inchoately understood obstetric emergency in which amniotic fluid which is construed to mean the liquor amni. The albuminous transparent fluid in the amnion protects the foetus from injury, helps in the maintenance of the even temperature and prevent development of any adhesions between the amnion (which is construed to mean the innermost of the membranes that envelop the embryo in uterus and filled with amniotic fluid and the foetus, foetal cells hair or other debris enter the blood stream of the mother via the placental bed of the uterus and trigger an allergic reaction which will culminate in cardio respiratory heart and lung) collapse as also results in coagulopathy (which is construed to mean a disorder affecting blood coagulation).

The syndrome resulting from a traumatic delivery and injection of amniotic fluid into the maternal circulation was first characterized in the year 1941. This obstetric emergency has been estimated to be the fifth most common cause of maternal mortality in the world. There has been a marked discrepancy in regard to the incidence as well as mortality of amniotic fluid embolism. An apposite explanation that can be offered for this inconsistency being the dearth of sensitive and specific diagnostic studies to positively and definitely identify the cases of AFE leading to over and under reporting.

A profound respiratory failure with deep cyanosis (which is construed to mean a bluish discoloration of the skin and mucous membranes owing to the presence of excessive amounts of reduced haemoglobin in the arterial blood. Cyanosis becomes visible when the amount of reduced haemoglobin exceeds 5 g/dl.) accompanied by cardio vascular shock following convulsions and profound coma, will be occasioned once the fluid and fetal

cells find an access into the maternal pulmonary circulation.

AFE is occasioned in a phasic manner. Under the first phase, the patient experiences acute paucity of breath as also hypotension {which is construed to mean an abnormally low blood pressure that reduces blood flow to the brain causing dizziness and fainting which drastically progresses to cardiac arrest leading to a reduction of perfusion the term is construed to mean the passage of fluid through a vascular bed of an organ or tissue to the heart and lungs} which results in the patient slipping into coma. Formerly, the maternal mortality rate was 60-80%, of late, the mortality rate has been reported at 26.4% the II Phase is known as the hemorrhagic phase and the same could be accompanied by host of complications like severe shivering, coughing, vomiting and the sensation of a bad taste in the mouth. This is also accompanied by excessive bleeding and collapse of the cardiovascular system which leads to fetal distress as also death unless the child is delivered safely.

Causes of AFE could be owing to the ruptured membranes (1) Rupture of the uterine or cervical veins.(2) a pressure gradient from uterus to vein.

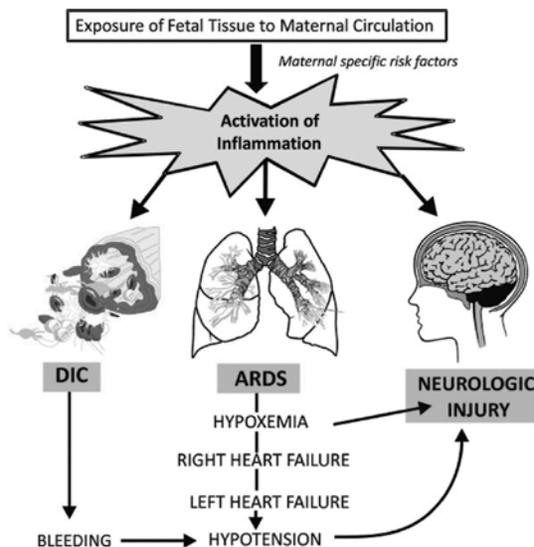
Treatment in the year 1941 Steiner and Luschbaugh described AFE for the first time after they found fetal debris in the pulmonary circulation of women who died during labour. The current data obtained from the National Amniotic fluid Embolus Registry divulged that the process is more similar to anaphylaxis (the term is construed to mean a hyper sensitivity reaction that occurs upon exposure to an antigen to which the body has previously formed on IGE antibody immunoglobulin E) than to Embolism and the epithet anahylactoid syndrome of pregnancy has been suggested because fetal tissue or amniotic fluid components are not ubiquitously found in women

who present with signs as well as symptoms ascribable to AFE.

The confirmed and positive diagnosis of AFE has been made during the autopsy owing to the presence of fetal squamous cells which are found in the maternal pulmonary circulation, however fetal squamous cells are commonly found in the circulation of laboring patients who do not develop the syndrome.

The pathophysiology (the term is construed to mean the physiology of disordered function) of AFE is poorly understood based on the original description, it was theorized that Amniotic fluid and fetal cells enter the maternal circulation possibly triggering an anaphylactic reaction to fetal antigens.

Two hypotheses concerning the pathophysiology of AFE has been tested by Benson (1) clinical symptoms result from Mast cell degranulation (the term is construed to mean the loss of granules) with the release of histamine and tryptase or (2) clinical symptoms result from activation of the complement pathway. Autopsy could even divulge fetal squames and fibrin thrombi in the pulmonary tree. Blood drawn 2 hours subsequent to the onset of symptoms could reveal a serum tryptase level of 4.7 mg/ml (as against the normal level < 1mg/ml). the development of AFE could also present classic symptoms such as the spontaneous rupture of membranes demonstrated no increase in mast cells or degranulation in lung tissue as shown by Giemsa staining initiating event is poorly understood. However usually during labour or other procedure amniotic fluid and debris or some as yet unidentified substance, enters the maternal pulmonary circulation which could trigger a colossal anaphylactic reaction, an abrupt activation of the complement cascade or both the progression usually occurs in a phasic manner in the first phase. Pulmonary Artery Vasospasm (which is construed to mean: spasm of the blood vessels causing a decrease in their caliber) with pulmonary hypertension and elevated right ventricular pressure cause hypoxia (the term is construed to mean an inadequate level of oxygen in the tissues blood or air) which causes myocardial (the term is construed to mean pertaining to the myocardium the middle and thickest layer of the heart wall composed of cardiac muscle or disease affecting the myocardium) Capillary damage and pulmonary capillary damage, left heart failure and acute respiratory distress syndrome. Women who survive these events may enter the phase II. This is a hemorrhagic phase characterized by massive haemorrhage with uterine atony: (the term atony is construed to mean lack of tone or strength) and disseminated intravascular coagulation or DIC, however fatal consumptive coagulopathy: (the term is construed to mean any disorder affecting blood coagulation) may be the initial presentation AFE occurs when the barrier between amniotic fluid and



maternal circulation is broken and possibly under a pressure gradient fluid abnormally enters the maternal venous system via endo cervical veins the placental site (i.e placenta is separated) or a uterine trauma site. Early recognition of amniotic fluid embolism is critical to a successful outcome. The diagnosis can be confirmed by the identification of lanugo (the term is construed to mean hair, fine soft downy hair that covers a foetus and is shed before birth) fetal hair and fetal squamous cells squames in blood aspirated from the right ventricle. The cornerstone of management is a multidisciplinary approach

with supportive treatment of failing organ systems. Despite improved modalities for diagnosing AFE and better intensive care support facilities the mortality is still high.

Additional diagnostic tools for confirmation of the amniotic fluid embolism suspected clinically include (1) chest x-ray (2) lung scan (3) central venous pressure (4) coagulation profile. The key factors in the management of AFE are early recognition, prompt resuscitation and delivery of the fetus. The inputs of consultants (anesthesiologist) obstetricians hematologist, intensivists) must be enlisted early.

Monitoring of the patient suspected fluid embolism includes continuous cardiac and respiratory monitoring with pulse oximetry or with an end tidal CO₂ monitor.

The management of AFE is supportive and focuses initially or rapid maternal cardiopulmonary stabilization and adequate oxygenation to the vital organs transthoracic transesophageal echo cardiography may guide fluid therapy with evaluation of ventricular filling. An arterial line and pulmonary catheter may also help to guide the therapy. Dopamine or noradrenaline may be the ideal agents because of the additional B- adrenergic effects which improve cardiac function in addition to a adrenergic vasoconstrictor effects. In atrophic support with Dobutamine or Milrinone may be needed specific coagulation laboratory abnormalities are treated with fresh frozen plasma. Cryoprecipitate fibrinogen profound fetal acidemia often develops with maternal collapse and early delivery may improve the fetal outcome. Uterine tone should be maintained in the usual way using oxytocin, ergometrin and prostaglandins such as carboprost and misoprost indicated bimanual uterine massage and uterine packing may help to reduce blood loss.

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INJECTABLE INSITU IMPLANTS: A NOVEL DRUG DELIVERY SYSTEM

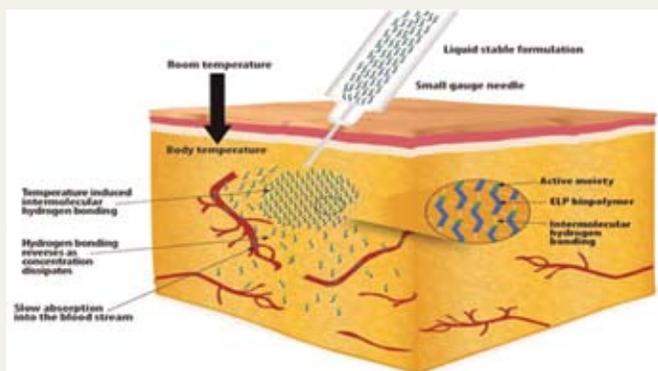
Ms. Vineetha K

II Year M.Pharm

Department of Pharmaceutics

The current trend towards developing sustained release injectable formulations such as microspheres, solid implants, or gel systems has been increased due to several advantages of these systems such as site-specific action, reduced side effects, and improved patient compliance. Some of the limitations of microspheres are low drug loadings and difficulty in particle size control, while the solid implants may require surgery for insertion or removal from body. In situ implants (ISI) systems have been introduced to overcome these limitations in addition to their various biomedical applications.

In situ implants are capable of releasing drug in a sustained manner maintaining relatively constant plasma profiles. They are designed such that they are fluid prior to injection. Once injected, the formulation responds to change in the environment to give high viscosity or depot at the injection site. Several mechanisms such as solvent exchange, pH change, UV irradiation, ionic cross-linking, temperature transition, and chemical reactions may lead to the in situ implant formation.



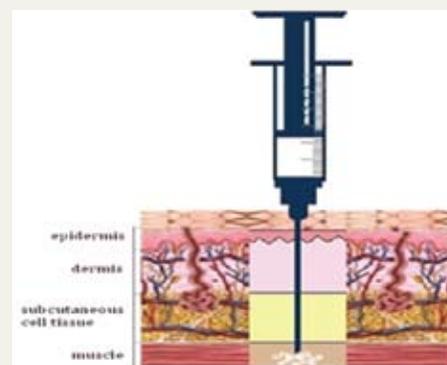
Compared to conventional controlled release formulations, in situ forming drug delivery systems possess potential advantages like simple manufacturing process, ease of administration, and reduced frequency of administration, improved patient compliance and comfort, use of non-toxic carriers, prolonged residence time and controlled drug release. Moreover these systems avoid painful surgical procedures to insert solid implants. These systems combine the advantages of an injectable solution with respect to ease of manufacture and administration and that of a solid implant with respect to localization at the site of administration and sustained release arising from slow absorption in surrounding tissues. They help in achieving higher drug concentrations at the desired site of action to minimize systemic side effects, since they are made of biodegradable polymers and biocompatible solvents, they do not require removal.

In the ISI system, a biodegradable polymer is dissolved in a biocompatible solvent. The drug may be dissolved or suspended in the polymer solution (polymer phase). Solvents such as 2-N-methyl pyrrolidone (NMP), dimethyl sulfoxide (DMSO), and 2-pyrrolidone can be used to get highly concentrated polymer solution. After injection in the body, the polymer forms in situ implants and sustains the release of the entrapped drug. The type of polymer used plays an important role in the formulation of these long acting drug delivery systems and can significantly affect the release rate of drugs. Among those,

biodegradable polymers are preferred as surgical removal of the implant is not required. Some of the biodegradable polymers that may be used for in situ implants are carbopol 934, HPMC, poly-lactic acid, poly-lactic-co-glycolic acid (PLGA), poly-e-caprolactone, alginate, chitosan derivatives, poly-vinyl alcohol, poly-vinyl derivatives, and pectin.

Injectable in situ forming implants are classified into five categories, according to their mechanism of depot formation: (1) thermoplastic pastes, (2) in situ cross linked systems, (3) in situ polymer precipitation, (4) thermally induced gelling systems, (5) in situ solidifying organ gels. Of these, in situ polymer precipitation systems have become commercially available so far.

Currently, there are two injectable in situ forming depots on the market: Atridox® and Eligard®. Both products were developed based on the Atrigel technology of Dunn et al. This technology employs PLGA



dissolved in N-methyl-2-pyrrolidone (NMP), which is a water miscible solvent, and a drug powder suspended in this solution prior to application. Injectable in situ setting semi-solid drug depots are being developed as alternative delivery system. These implants are made of biodegradable products, which can be injected via a syringe into the body and once injected, solidify to form a semi-solid depot.

As evident by the growing number of sustained-release injectable pharmaceutical products on the market, injectable depot systems are becoming one of the most effective systems for long term drug delivery. Owing to the enhanced quality of life and the cost of therapy supported by the advances in drug formulation and polymer science, more sophisticated injectable depot systems will be developed and commercialized in the near future. Moreover, the introduction of more potent drugs and protein/ peptide drugs have many advantages such as protection of sensitive proteins from degradation, prolonged or modified release, pulsatile release patterns, and enhancement of patient compliance. These important and unique advantages offer potential commercial success of the future sustained-release injectable pharmaceutical products that have novel active pharmaceutical ingredients, including therapeutic proteins and peptides.

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- Ghadge A T et al. A review on parenteral implants. International Journal of Research and Reviews in Pharmacy and Applied Sciences. 2014; 4(2):1056-1072.

TOPPERS OF THE YEAR 2014-15



MS. VINEETHA K
I M.Pharm (Pharmaceutics)



MS. BEEBI SHAMA C
I M.Pharm (Pharmacology)



MS. ANISTY MARIA JOY
I M.Pharm (Pharmacy Practice)



MR. S. TUSHAR KESHAV
II M.Pharm (Pharmaceutics)



MS. SHERIN THOMAS
II M.Pharm (DRA)



MS. SMITHA JOSEPH
II M.Pharm (Pharmacy Practice)



MR. AVINASH T.S.
II M.Pharm (Pharmacology)



MS. BINDHU V
II M.Pharm (Pharmacology)



MS. LIMRA B. H
I B.Pharm



MS. RISHAL RELITA M.
II B.Pharm



MS. RUKYA
II B.Pharm



MS. SREELAXMI SHENOY K
III B.Pharm



MS. DEEKSHA SUVARNA
IV B.Pharm



MS. SHEBIN P. KURIAN
I Pharm D



MS. ANJOL KURIAN
II Pharm D



MS. GAYATHRI BABURAJ
III Pharm D