Understanding biological & biosimilar medicines

Frequently Asked Questions

Q. What is a biological medicine?

A. Biological modicines, including biosimilars, are directed or monufactured from a living biological system. They include burntones (e.g. inculin), enzymes (to speed up chemical tractions), blood factors (to regulate clotting), antibodies (to support the immune system), voccines and advanced therapies (each accell, gene and tissue therapy products).

Histogical medicines are among many of today's most important medicines. By acct, it is predicted that seven of the top ten medicines worldwide will be biologica."

Q. What is a biosimilar medicine?

A. A bioximillar in a biological medicine that in developed to be similar to an approved biological medicine (the 'originator' biological medicine) and can only be marketed after the patent and data endianterity period has expired. As its more suggests, a bioximilar is not an exact regy of its originator biological medicine due to its complex molecular structure and unique manufacturing process. Manufacturers of bioximilars are required to demonstrate that there are no-clinically meaningful differences between the bioximilar and originator biological medicine in scena of safety, quality and efficient, "

Q. What is a small molecule medicine?

A. Small molecule medicines are made by combining certain obsessions in a defined series of chemical reactions. Because these molecules are smaller and involve fewer process steps thus biological medicines, they are easier to displacate. This kind of medicine is often taken smally, most often as a pill. Generic medicine: A medicine that contains an exact copy of the active pharmaceutical impredicat of the small molecule originator medicine.

Biological sordicioe: Biological medicines, including bioximitars, that bave been developed in living organisms.

Originator modicine: The original medicine on which a bioximilar or generic drug bases its application for marketing authorisation.

Q. How are biological medicines different?

A. There are several key differences between biological and small malerale medicines:

- Molecular structure biological medicines are much larger and more complex than small molecule medicines.
- Development and manufacture biological medicines have complex manufacturing processes that must be tightly controlled to provide a consistent product.
- Immunigation due to their size and complexity, biological medicines have the potential to induce surrounted or unexpected immune reactions.
- Administration most biological medicines, including bioximilars, must be administered by injection or infection.
- Transport and storage biological medicines generally degrade quickly if subject to high temperatures.
 Therefore, biological modicines, including biosimilars, meanly need to be stored in a refrigerator.





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need for policy and law makers to think and act in a systemic manner and to be more reflective and responsive in finding new solutions within and outside the patent system to the long standing problems as well as emerging challenges of Biologics & Biosimilars in Dermatology Shekhar Neema, Manas Chatterjee, 2024-02-21 A drug is typically manufactured through chemical synthesis which means that it is made by combining specific chemical ingredients in an ordered process Biologics are medicines made from living cells through highly complex manufacturing processes and must be handled and administered under carefully monitored conditions Biologics are used to prevent treat diagnose or cure a variety of diseases including cancer chronic kidney disease autoimmune disorders and infectious diseases A biosimilar is a biologic that is similar to another biologic drug already that has already been approved This book is a complete guide to the use of biologics and biosimilars in the treatment of dermatologic disorders Beginning with an overview of the history and classification of biologics and the concept of biosimilars the following chapters explain their therapeutic use for different skin conditions The final sections cover related topics such as cost effectiveness and quality of life with biologic therapy and the book concludes with discussion on future developments and the use of small molecule treatment This second edition has been fully updated to provide clinicians with the latest advances in the field Previous edition 9789352703647 published in 2018 **Biosimilar Drug Product Development** Laszlo Endrenyi, Dr. Paul Declerck, Shein-Chung Chow, 2017-02-24 When a biological drug patent expires alternative biosimilar products are developed. The development of biosimilar products is complicated and involves numerous considerations and steps The assessment of biosimilarity and interchangeability is also complicated and difficult Biosimilar Drug Product Development presents current issues for the development of biosimilars and gives detailed reviews of its various stages and contributing factors as well as relevant regulatory pathways and pre and post approval Regulatory Toxicology in the European Union Tim Marrs, Kevin Woodward, 2018-02-21 Consumer and issues environmental protection depend on the careful regulation of all classes of chemicals Toxicology is the key science used to evaluate safety and so underpins regulatory decisions on chemicals With the growing body of EU legislation involved in chemical regulation there is a concomitant need to understand the toxicological principles underlying safety assessments Regulatory Toxicology in the European Union is the first book to cover regulatory toxicology specifically in Europe It addresses the need for a wider understanding of the principles of regulatory toxicology and their application and presents the relationship between toxicology and legislative processes in regulating chemical commodities across Europe This title has a broad scope covering historical and current chemical regulation in Europe the role of European agencies and institutions and also the use of toxicology data for important classes of chemicals including human and veterinary medicines animal feed and food additives biocides pesticides and nanomaterials This book is therefore extremely pertinent and timely in the toxicology field at present This book is an essential reference for regulatory authorities industrialists academics undergraduates and postgraduates working within safety and hazards toxicology the biological sciences and the medicinal

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Advances in Novel Formulations for Drug Delivery Raj K. Keservani, Rajesh Kumar Kesharwani, Anil K. Sharma, 2023-03-14 ADVANCES in NOVEL FORMULATIONS for DRUG DELIVERY The 27 chapters describe novel strategies for drug nutraceutical delivery and embrace the development of formulations with herbal ingredients while also highlighting disease therapeutics Drug delivery technology has witnessed many advancements purported to cater to the customized needs of its ultimate beneficiaries the patients Today dosage forms are not confined to conventional tablets capsules or injectables but have evolved to cover novel drug carriers such as particulates vesicles and many others Nanotechnological advancements have played a major role in this paradigm shift in ways of delivering active pharmaceutical ingredients A new dimension in the use of food as medicine has also gained prominence in recent years A portmanteau of nutrition and pharmaceuticals is nutraceuticals also known as functional foods and dietary supplements. The technologies which were earlier included in drug delivery have been attempted for the delivery of nutraceuticals as well Herbal actives have received increased attention due to their low risk to benefit ratio. The field of drug delivery is guite dynamic in nature as witnessed by its evolution from conventional dosage forms to nanotechnology assisted drug products A variety of formulations via different drug delivery routes have been developed to treat cure mitigate diseases or disorders. This book comprising of 27 chapters is a thorough compilation of information relevant to drug delivery systems with an emphasis on products based on nanotechnology Audience Researchers scientists industry professionals formulators and product developers regulatory agencies in a variety of settings including novel drug delivery research laboratories pharmaceutical and pharmacy industries biomedical sciences food and nutraceuticals manufacturers and nanotechnology Pharmaceutical Medicine and Translational Clinical Research Divya Vohora, Gursharan Singh, 2017-11-14 Pharmaceutical Medicine and Translational Clinical Research covers clinical testing of medicines and the translation of pharmaceutical drug research into new medicines also focusing on the need to understand the safety profile of medicine and the benefit risk balance Pharmacoeconomics and the social impact of healthcare on patients and public health are also featured It is written in a clear and straightforward manner to enable rapid review and assimilation of complex information and contains reader friendly features As a greater understanding of these aspects is critical for students in the areas of pharmaceutical medicine clinical research pharmacology and pharmacy as well as professionals working in the pharmaceutical industry this book is an ideal resource Includes detailed coverage of current trends and key topics in pharmaceutical medicine including biosimilars biobetters super generics and Provides a comprehensive look at current and important aspects of the science and regulation

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