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DEVELOPMENT AND VALIDATION OF A REVERSED-PHASE HPLC METHOD FOR SIMULTANEOUS DETERMINATION OF IRBESARTAN AND HYDROCHLOROTHIAZIDE IN PHARMACEUTICAL DOSAGE FORMS.

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Article Received: January 2024 Accepted: February 2024 Published: March 2024

Abstract:
A rapid and precise reverse phase high performance liquid chromatographic method has been developed for the validated of Irbesartan and Hydrochlorothiazide, in its pure form as well as in tablet dosage form. Chromatography was carried out on a Symmetry C18 (4.6 x 150mm, 5µm) column using a mixture of Methanol: Phosphate Buffer pH 3.5 (65:35) as the mobile phase at a flow rate of 1.0ml/min, the detection was carried out at 270 nm. The retention time of the Irbesartan and Hydrochlorothiazide was 2.456, 4.312±0.02min respectively. The method produce linear responses in the concentration range of 5-25mg/ml of Irbesartanand 2.5-12.5mg/ml of Hydrochlorothiazide. The method precision for the determination of assay was below 2.0%RSD. The method is useful in the quality control of bulk and pharmaceutical formulations.

Keywords: *Irbesartan, Hydrochlorothiazide, RP-HPLC, validation.*

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CURRENT APPROVAL PROCEDURE FOR NEW REGULATIONS, STANDARDS, POLICIES & GUIDANCE ISSUED BY REGULATORY AUTHORITIES

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Article Received: January 2024 Accepted: February 2024 Published: March 2024

Abstract:
MHRA (Medicines And Health Products Regulatory Agency) is the regulatory authority body for pharmaceuticals approval in the UK union. MHRA is formed by the merging of two separate agencies in 2003 i.e., Medicines Control Agency and Medical Device Agency. This agency works to maintain safety, quality and ef□cacy of the drug product before it enters into the country. The main aim of this work is to know about the practice and the regulatory requirements for the registration of a drug in the UK as per the regulations of MHRA. They are responsible for ensuring that the medicines and medical devices are acceptably safe and don't cause any harm to the patients. MHRA provides a license which is a marketing authorization to the manufacturer, required before a drug is being used by the patients of that country. Good Manufacturing Practice (GMP) is the minimum requirement that a manufacturer should possess during the period of production of the drug product. New drugs are being invented and also being distributed as per the needs of the patients. It is known that no drug product is completely safe or is 100% safe for use, but MHRA tries to minimize as many problems regarding the
drug so that patients will be provided with the best drug with minimal risk.
Key words: MHRA, United Kingdom, Product license, eCT
A regulatory process by which a person/organization/sponsor/innovator gets authorization to launch a drug in themarket, is known as drug approval process. In general, a drug approval process comprises of various stages: application to conduct clinical trials, conducting clinical trials, application to marketing authorization of drug and post-marketing studies. Every country has its own regulatory authority, which is responsible to enforce the rules and regulations and issue the guidelines to regulate the marketing of the drugs. This article will focus the similarities and differences in drug approval process of various regulatory bodies.

Key Words: *Drug approval process, clinicaltrials, marketing.*

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INTRODUCTION:

National health authorities have the duty to ensure that available pharmaceutical products,whether imported or manufactured locally,are of good quality,safe and efficacious.This is particularly difficult for vaccines and biological products,the quality of which cannot be established entirely by tests on the material in the final container.A national control authority should therefore be established that is responsible for ensuring that the manufacturer is adhering to approved standards of good manufacturing practice and quality assurance specific to the product.The procedures through which the national control authority confirms the assurance of quality provided by the manufacturer will depend on the resources avalible and whether the product is manufactured locally or imported.

In general,biological products are distinguished from other drugs by being derived from living organisms(ranging from normal or genetically modified microorganisms to fluids and tissues derived from various animal and human sources) and frequently have a complex molecular structure.They require special quality considerations because of the biological nature of:(a) the starting materials; and /or (b) the manufacturing process;and/or (c)the test methods needed to characterize batches of the product.

Development in biological products have been extremely rapid in recent years,and the potential valve of such products in improving health care on a global scale is immense.There is an urgent need to match technological advances with appropriate mechanisms for assuring the safety,quality and efficacy of the products[1].

Laws & Regulations:

The Basics of the Regulatory Process:

Regulations are mandatory requirements that can apply to individuals, businesses, state or local governments, non-profit institutions, or others.

Congress passes the laws that govern the United States, but Congress has also authorized EPA and other federal agencies to help put those laws into effect by creating and enforcing regulations.

A basic description of how laws and regulations are developed, what they are, and where to find them, with an emphasis on environmental laws and regulations.

- Creating a law
- Putting the law to work
- Creating a regulation
- How you can get involved

Creating a law:

Step 1: Congress Writes a Bill

A member of Congress proposes a bill. A bill is a document that, if approved, will become law. To see the text of bills Congress is considering or has considered, go to Congress.gov

Step 2: The President Approves or Vetoes the Bill

If both houses of Congress approve a bill, it goes to the President who has the option to either approve it or veto it. If approved, the new law is called an act or statute. Some of the better-known laws related to the environment are the Clean Air Act, the Clean Water Act, and the Safe Drinking Water Act.

- Summaries of the laws EPA administers
- Congress.gov: for more information about the legislative process

Step 3: The Act is Codified in the United States Code

Once an act is passed, the House of Representatives standardizes the text of the law and publishes it in the United States Code (U.S.C.). The U.S.C. is the codification by subject matter of the general and permanent laws of the United States. Since 1926, the U.S.C. has been published every six years. In between editions, annual cumulative supplements are published in order to present the most current information.

United States Code: This database is available from the Government Printing

Office (GPO). GPO is the sole agency authorized by the federal government to publish the U.S.C.

Putting the law to work:

Once a law is official, here's how it is put into practice: Laws often do not include all the details needed to explain how an individual, business, state or local government, or others might follow the law. The United States Code would not tell you, for example, what the speed limit is in front of your house. In order to make the laws work on a dayto-day level, Congress authorizes certain government agencies - including EPA – to create regulations.

Regulations set specific requirements about what is legal and what isn't. For example, a regulation issued by EPA to implement the Clean Air Act might explain what levels of a pollutant - such as sulfur dioxide - adequately protect human health and the environment. It would tell industries how much sulfur dioxide they can legally emit into the air, and what the penalty will be if they emit too much. Once the regulation is in effect, EPA then works to help Americans comply with the law and to enforce it.

- Find out more about Compliance.
- Learn more about Enforcement.

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ROLE OF COPP IN PHARMACEUTICAL EXPORT

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Article Received: January 2024 Accepted: February 2024 Published: March 2024

ABSTRACT:
MHRA (Medicines And Health Products Regulatory Agency) is the regulatory authority body for pharmaceuticals approval in the UK union. MHRA is formed by the merging of two separate agencies in 2003 i.e., Medicines Control Agency and Medical Device Agency. This agency works to maintain safety, quality and ef cacy of the drug product before it enters into the country. The main aim of this work is to know about the practice and the regulatory requirements for the registration of a drug in the UK as per the regulations of MHRA. They are responsible for ensuring that the medicines and medical devices are acceptably safe and don't cause any harm to the patients. MHRA provides a license which is a marketing authorization to the manufacturer, required before a drug is being used by the patients of that country. Good Manufacturing Practice (GMP) is the minimum requirement that a manufacturer should possess during the period of production of the drug product. New drugs are being invented and also being distributed as per the needs of the patients. It is known that no drug product is completely safe or is 100% safe for use, but MHRA tries to minimize as many problems regarding the drug so that patients will be provided with the best drug with minimal risk.
Key words: MHRA, United Kingdom, Product license, eCT
This review includes basics of CoPP, origin of CoPP, types, types of drug includes in CoPP, procedure to obtain CoPP, requirement for CoPP, applicant, examples, format and content and benefits of CoPP. A CoPP is given by the drug regulator not before conducting an inspection of the manufacturing plant. Proper documentation is essential in almost every aspect of the pharmaceutical industry. Whether for product registration, factory inspection, or internal quality control, AdvaCare employs the latest technologies to streamline and process information. All facilities possess up-to-date Good Manufacturing Practice (GMP), CE, TUV, and/or ISO certificates that reflect high quality standards and WHO rules and regulations. Essential product registration documents, such as the Certificate of Pharmaceutical Product (COPP), Free Sales Certificate (FSC), Certificate of Origin (COO), and Marketing Authorizations are among the many documents our registration department frequently submit for registration purposes.

Keywords: *Pharmaceutical Industry, COPP , GMP , COO , Drug Regulator.*

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INTRODUCTION:

Certificate of pharmaceutical product : [1]

The certificate of pharmaceutical product (abbreviated: CPP) is a certificate issued in the format recommended by the World Health Organization (WHO), which establishes the status of the pharmaceutical product and of the applicant for this certificate in the exporting country. It is issued for a single product, because manufacturing arrangements and approved information for different pharmaceutical forms and strengths can vary. [2]

Scope:

The Certificate of a Pharmaceutical Product is needed by the importing country when the product in question is intended for registration (licensing, authorisation) or renewal (prolongation) of registration, with the scope of commercialisation or distribution in that country. Certification has been recommended by WHO to help undersized drug regulatory authorities or drug regulatory authorities without proper quality assurance facilities in importing countries to assess the quality of pharmaceutical products as prerequisite of registration or importation.

In the presence of such CPP, WHO recommends to national authorities to ensure that analytical methods can be confirmed by the national laboratory, to review and if necessary to adapt product information as per local labelling requirements, and to assess bio equivalence and stability data if necessary. [3]

However, regulatory practices often vary in importing countries. Thus, in addition to CPP, assessment of application dossiers to support drug registrations, with different levels and complexity of requirements are considered necessary to satisfy full assurance on the appropriate quality of drugs.[4]

Content and format:

The content of CPP consists of the following main data:

- Exporting (certifying) country
- Importing (requesting) country
- Name, dosage (pharmaceutical) form and composition of the product [active ingredient(s) and amount(s) per unit dose]
- Information on registration (licensing) and marketing (presence on the market) status of the product in the exporting country
- Number of product licence (including licence holder details, licence holder's involvement in manufacturing if any) and date of issue, if applicable
- Appended summary of technical basis on which the product has been licensed (if required by the issuing authority)
- Appended current product information
- Details on the applicant for the CPP
- If marketing authorisation is lacking in the exporting country, information about reasons

When applicable, information if the manufacturing site is periodically inspected by certifying authority and if the manufacturing site complies with Good Manufacturing Practice (GMP) as recommended by WHO.

Although issuing authorities claim that their CPP conform to WHO format (a statement to confirm whether or not the document is issued in the format recommended by WHO should be included in the certificate), their format and content may vary from an issuing country to another. Also, some authorities do not issue CPP if the respective drug is not licensed in the exporting country (e.g. Italy). In this last case, a Certificate of Exportation is issued instead, with a format and content similar to those of CPP.

Special considerations in importing countries:

Most competent authorities in importing countries require CPP to be issued by the country of origin.
Also, even though this certificate is released in its original form, addressed to a specific importing country and stamped with the seal of issuing authority on each page, many authorities in importing countries may unnecessarily request authentication of such a document in the form of legalisation by their embassy in the exporting country or by apostillation ("Abuse of scheme").

Proper documentation is essential in almost every aspect of the pharmaceutical industry. Whether for product registration, factory inspection, or internal quality control, AdvaCare employs the latest technologies to streamline and process information. All facilities possess up-to-date Good Manufacturing Practice (GMP), CE, TUV, and/or ISO certificates that reflect high quality standards and WHO rules and regulations. Essential product registration documents, such as the Certificate of Pharmaceutical Product (COPP), Free Sales Certificate (FSC), Certificate of Origin (COO), and Marketing Authorizations are among the many documents our registration department frequently submit for registration purposes. Likewise, technical files are repeatedly checked for consistency and accuracy for both internal quality control purposes and in preparation of inspections.

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A NEW SIMPLE AND SENSITIVE RP-HPLC METHOD FOR THE SIMULTANEOUS ESTIMATION OF NORTRIPTYLINE AND PREGABALIN IN BULK AND TABLET DOSAGE FORM

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Abstract:

A rapid, precise, accurate, specific and simple RP-HPLC method was developed for the simultaneous estimation of Nortriptyline and Pregabalin in bulk and its combined pharmaceutical dosage form. A High performance liquidchromatograph WATERS, software: Empower 2, 2695 separation module, 996 PDA detector, using Phenomenex Luna C18 (4.6mm×250mm) 5 µm or equivalent column, with mobile phase composition of Methanol: Phosphate Buffer pH-3.0 (70:30v/v) was used. The flow rate of 1.0 ml min-1 and effluent was detected at 230 nm. The retention time of Nortriptyline and Pregabalin was found to be 1.870min and 2.499minutes respectively.Linearity was observed over concentration range of 10-50µg ml-1 for Nortriptyline and 16-80µg ml-1 for Pregabalin respectively. The accuracy of the proposed method was determined by recovery studies and the Nortriptyline was found to be 99.1% and Pregabalin was found to be 98.8% respectively. The proposed method isapplicable to routine analysis of Nortriptyline and Pregabalin in bulk and pharmaceutical formulations. The proposed method was validated for various ICHparameters like linearity, limit of detection, limits of quantification, accuracy, precision, range and specificity.

Key Words: *Nortriptyline, Pregabalin, RP-HPLC, Robustness and ICH Guidelines.*

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INTRODUCTION:

Strategy of method development:

Method development ought to be supported many issues. It's desirable to possess most sample data to form development quick and desired for meant analytical technique application, physical and chemical properties area unit most desirable as primary data. Moreover, separation goal has to outline at starting so; acceptable technique is developed for the aim. AN LC technique development is extremely vast space for even prescribed drugs with restrictive demand of international standards. So, before technique validation and usage at internal control several aspects have to be compelled to focus as per ICH tips. Method development is supported a sample and goals moreover as offered resources for action however few basic steps for technique development area unit is mentioned as given below.

Steps in technique development:

1. Sample data ,define separation goals
2. Sample pre-treatment, want of special HPLC procedure
3. choice of detector and detector settings
4. choice of LC method; preliminary run; estimate best separation conditions
5. Optimize separation conditions
6. Check for issues or demand for special procedure
7. technique validation

Sample information:

1. variety of compounds gift
2. Chemical structure of compounds
3. Chemical nature
4. relative molecular mass of compounds
5. pKa Value(s) of compounds
6. Sample solubility
7. Sample stability and storage
8. Concentration vary of compounds in sample
9. Ultraviolet illumination spectra of compounds or properties for detection of compounds

RP-HPLC continues to be comparatively new technique, and literature isn't invariably offered on operative conditions for a selected application. The primary step in developing AN RP-HPLC analysis, or the other variety of natural process analysis, is to outline the matter and state the aim of study. So as to outline the matter, the subsequent question ought to be asked:

1. Is that the analysis aiming to be used habitually for an oversized variety of samples? Is case of operation and ease of nice importance?
2. May be a qualitative and / or qualitative analysis required?
3. Is it necessary to separate all the constituents within the sample or solely a tiny low cluster of constituents?
4. Area unit the constituents similar in structure or wide diverse?
5. Area unit the constituents gift in similar concentrations, or is one constituent presenting an oversized quantity and alternative solely in trace amounts?
6. Will sample be simply ready for RP-HPLC analysis?
7. Area unit there compounds gift that will interfere with the analysis of constituents of interest?
8. Will peaks within the recording be promptly identified?

The next step may be a literature search to find-out if these compounds are separated mistreatment alternative natural process techniques.

For example: The conditions utilized in thin-layer action (TLC) or open chromatography usually are adopted for HPLC; this is a place to begin and saves a valuable time.

A total RP-HPLC technique involves the subsequent steps:

1. Sample assortment
2. Sample preparation
3. Chromatography
4. Peak identification
5. Quantification
6. Information analysis and interpretation of results (Validation)

1. Sample assortment

The primary step within the analysis of biological and a few alternative samples sometimes needs sample filtration. Since RP-HPLC columns use 3-5 um packing materials, the column water is sometimes protected with a 2um frit or screen. Sample filtration is performed mistreatment membrane kind filters with zero.2 - 0.5 um pore sizes.

Several ways of macromolecule removal is used: immoderate filtration, precipitation of proteins with robust acid or organic solvents, ammonia sulphate precipitation, denaturation by heat etc.

2. Sample preparation

Usually within the analysis of complicated samples, solely variety of compounds area unit of interest. Therefore, it's not necessary to realize separation of

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Review

Current Trends In Regulatory Actions Against Misbrandind And Adulteration

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Abstract

MHRA (Medicines And Health Products Regulatory Agency) is the regulatory authority body for pharmaceuticals approval in the UK union. MHRA is formed by the merging of two separate agencies in 2003 i.e., Medicines Control Agency and Medical Device Agency. This agency works to maintain safety, quality and efficacy of the drug product before it enters into the country. The main aim of this work is to know about the practice and the regulatory requirements for the registration of a drug in the UK as per the regulations of MHRA. They are responsible for ensuring that the medicines and medical devices are acceptably safe and don't cause any harm to the patients. MHRA provides a license which is a marketing authorization to the anufacturer, required before a drug is being used by the patients of that country. Good Manufacturing Practice (GMP) is the minimum requirement that a manufacturer should possess during the period of production of the drug product. New drugs are being invented and also being distributed as per the needs of the patients. It is known that no drug product is completely safe or is 100% safe for use, but MHRA tries to minimize as many problems regarding the drug so that patients will be provided with the best drug with minimal risk.

Keywords: MHRA, United Kingdom, Product license, eCT

INTRODUCTION

Introduction to regulatory affairs in pharmaceutical industry

Introduction to regulatory affairs

Regulatory Affairs (RA), also called Government Affairs, is a profession within regulated industries, such as pharmaceuticals, medical devices, energy, and banking. Regulatory Affairs also has a very specific meaning within the healthcare industries (pharmaceuticals, medical devices, Biologics and functional foods). Most companies, whether they are major multinational pharmaceutical corporations or small, innovative biotechnology companies, have specialist departments of Regulatory Affairs professionals. The success of regulatory strategy is less dependent on the regulations than on how they are interpreted, applied, and communicated within companies and to outside constituents.

This department is responsible for knowing the regulatory requirements for getting new Products approved. They know what commitments the company has made to the regulatory agencies where the product has been approved. They also submit annual reports and supplements to the agencies. Regulatory Affairs typically communicates with one of the Centers (e.g., Center for Drug Evaluation and Research) at the FDA headquarters, rather than the FDA local district offices. Gimps do not directly apply to Regulatory Affairs; however, they must understand and evaluate changes to drug manufacturing and testing activities to determine if and when the FDA must be notified.

Importance of regulatory affairs

In today's competitive environment the reduction of the time taken to reach the market is critical to a product's and hence the company's success. The proper conduct of its Regulatory Affairs activities is therefore of considerable economic importance for the company.

Inadequate reporting of data may prevent a timely positive evaluation of marketing application. A new drug may have cost many millions of pounds, Euros or dollars to develop and even a three-month delay in bringing it to the market has considerable financial considerations. Even worse1 failures to fully report all the available data or the release of product bearing incorrect labeling, may easily result in the need for a product recall. Either occurrence may lead to the loss of several millions of units of sales, not to mention the resulting reduction in confidence of the investors, health professionals and patients.

A good Regulatory Affairs professional will have a 'right first time' approach and will play a very important part in coordinating scientific endeavor with regulatory demands throughout the life of the product, helping to maximize the cost-effective use of the company's resources.

The Regulatory Affairs department is very often the first point of contact between the government authorities and the company. The attitudes and actions of the Regulatory Affairs professionals will condition the perceptions of the government officials to the company for better, or worse Officials respond much better to a company whose representatives are scientifically accurate and knowledgeable than to one in which these qualities are absent.

The importance of the Regulatory Affairs function is such that senior Regulatory Affairs professionals are increasingly being appointed to boardroom positions, where they can advise upon and further influence the strategic decisions of their companies.

Responsibility of Regulatory Affairs Professional's

The Regulatory Affairs professional's job is to keep track of the ever-changing legislation in all the regions in which the company wishes to distribute its products. They also advise on the legal and scientific restraints and requirements, and collect, collate, and evaluate the scientific data that their research and development colleagues are generating. They are responsible for the presentation of registration documents to regulatory agencies, and carry out all the subsequent negotiations necessary to obtain and maintain marketing authorization for the products concerned. They give strategic and technical advice at the highest level in their companies, right from the beginning of the development of a product, making an important contribution both commercially and scientifically to the success of a development program and the company as a whole.

It may take anything up to 15 years to develop and launch a new pharmaceutical product and problems may arise in the process of scientific development and because of a changing regulatory environment. Regulatory Affairs professionals help the company avoid problems caused by badly kept records, in appropriate scientific thinking or poor presentation of data. In most product areas where regulatory requirements are imposed, restrictions are also placed upon the claims which can be made for the product on labeling or in advertising.

Need of regulatory affairs in the pharmaceutical industry

Regulatory affairs professionals are the link between pharmaceutical industries and worldwide regulatory agencies. They are required to be well versed in the laws, regulations, guidelines and guidance of the regulatory agencies. There is a growing need to incorporate the current requirements of pharmaceutical industries in the standard curriculum of pharmacy colleges to prepare the students with the latest developments to serve the industries.

As the pharmaceutical industries throughout the world are moving ahead towards becoming more and more competitive, these are realizing that the real battle of survival lies in executing the work by understanding the guidelines related to various activities carried out to give an assurance that the process is under regulation. Pharmaceutical Industry, being one of the highly regulated industries in immense need of people than ever before who are capable of handling issues related to regulatory affairs in a comprehensive manner.

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Review

A New Current Regulations For Clinical Trials

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Abstract

Regulatory process, by which a person/organization/sponsor/innovator gets authorization to launch a drug in the market, is known as drug approval process. In general, a drug approval process comprises of various stages: application to conduct clinical trials, conducting clinical trials, application to marketing authorization of drug and post-marketing studies. Every country has its own regulatory authority, which is responsible to enforce the rules and regulations and issue the guidelines to regulate the marketing of the drugs. This work focuses on the drug approval process in India and USA.

Keywords: Drug approval process, Clinical trials, marketing.

INTRODUCTION

Introduction to regulatory affairs in pharmaceutical industry
Introduction to regulatory affairs:

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Importance of regulatory affairs

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Inadequate reporting of data may prevent a timely positive evaluation of marketing application. A new drug may have cost many millions of pounds, euros or dollars to develop and even a three-month delay in bringing it to the market has considerable financial considerations. Even worse1 failures to fully report all the available data or the release of product bearing incorrect labeling, may easily result in the need for a product recall. Either occurrence may lead to the loss of several millions of units of sales, not to mention the resulting reduction in confidence of the investors, health professionals and patients.

A good regulatory affairs professional will have a 'right first time' approach and will play a very important part in coordinating scientific endeavor with regulatory demands throughout the life of the product, helping to maximize the cost-effective use of the company's resources.

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The importance of the regulatory affairs function is such that senior regulatory affairs professionals are increasingly being appointed to boardroom positions, where they can advise upon and further influence the strategic decisions of their companies.

Responsibility of regulatory affairs professional's

The regulatory affairs professional's job is to keep track of the ever-changing legislation in all the regions in which the company wishes to distribute its products. They also advise on the legal and scientific restraints and requirements, and collect, collate, and evaluate the scientific data that their research and development colleagues are generating. They are responsible for the presentation of registration documents to regulatory agencies, and carry out all the subsequent negotiations necessary to obtain and maintain marketing authorization for the products concerned. They give strategic and technical advice at the highest level in their companies, right from the beginning of the development of a product, making an important contribution both commercially and scientifically to the success of a development program and the company as a whole.

It may take anything up to 15 years to develop and launch a new pharmaceutical product and problems may arise in the process of scientific development and because of a changing regulatory environment. Regulatory affairs professionals help the company avoid problems caused by badly kept records, in appropriate scientific thinking or poor presentation of data. In most product areas where regulatory requirements are imposed, restrictions are also placed upon the claims which can be made for the product on labeling or in advertising.

Need of regulatory affairs in the pharmaceutical industry

Regulatory affairs professionals are the link between pharmaceutical industries and worldwide regulatory agencies. They are required to be well versed in the laws, regulations, guidelines and guidance of the regulatory agencies. There is a growing need to incorporate the current requirements of pharmaceutical industries in the standard curriculum of pharmacy colleges to prepare the students with the latest developments to serve the industries.

As the pharmaceutical industries throughout the world are moving ahead towards becoming more and more competitive, these are realizing that the real battle of survival lies in executing the work by understanding the guidelines related to various activities carried out to give an assurance that the process is under regulation. Pharmaceutical industry, being one of the highly regulated industries in immense need of people than ever before who are capable of handling issues related to regulatory affairs in a comprehensive manner.

In India import, manufacturing, sale and distribution of drug is regulated under drugs and cosmetics act 1940 and drugs and cosmetic rules 1945 (hereinafter refer as act) made there under. At present, bulk drug (active pharmaceutical ingredients) and finished formulations are regulated under the said act. Any substance falling within the definition of drug (section 3b of the act) required to be registered before import into the country. Not only drug but the manufacturing site needs to be registered for import. If the drugs, fall within the definition of new drug (rule 122 e of the act), the new drug approval is the pre-requisite for submission of application for registration and or import of drug. The application for registration and import can be made to the licensing authority under the act i.e. To the drugs controller general (i) at cdsco, fda bhawan, kotla road, near bal bhawan,

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Research

Formulation And In Vitro Characterisation Of Milnacipran Hydrochloride Orodispersible Tablets

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Abstract

Present study is aimed at the development of oral dispersible tablets of Milnacipran Hydrochloride using natural superdisintegrants. Indion 414, Polyplasdone XL 10, Primogel for the preparation of oraldispersible tablets by direct compression method. The blends were evaluated for the pre-compression parameters and all the formulations were found to possess good flow properties. Tablets were compressed by direct compression technique, evaluated for weight variation, hardness, thickness, friability, water absorption, disintegration time, dispersion time drug content and dissolution studies. The drug release profiles of the three superdisintegrants were compared. The optimized formulation F2 was showed good results disintegrated in 3.15 min with 98.89 % drug release.

Keywords: Oral dispersible tablets , Milnacipran Hydrochloride, Indion 414, Polyplasdone XL 10, Primogel super disintegranrts , direct compression tablets.

INTRODUCTION

The oral route of administration is considered as the most widely accepted route because of its convenience of self administration, compactness and easy manufacturing. But the most evident drawback of the commonly used oral dosage forms like tablets and capsules is difficulty in swallowing, leading to patients incompliance particularly in case of paediatric and geriatric patients, but it also applies to people who are ill in bed and to those active working patients who are busy or travelling, especially those who have no access to water.[1]

For these reasons, tablets that can rapidly dissolve or disintegrate in the oral cavity have attracted a great deal of attention. Oral dispersible tablets are not only indicated for people who have swallowing difficulties, but also are ideal for active people.[2]

A Fast dissolving tablet (FDT) is a solid dosage form that contains medicinal substances and disintegrates rapidly (within seconds) without water when placed on the tongue. The drug is released, dissolved, or dispersed in the saliva, and then swallowed and absorbed across the GIT.

US FDA defined FDT tablets as "A solid dosage form containing medicinal substances which disintegrates rapidly usually within a matter of seconds, when placed upon the tongue".

Recently European Pharmacopoeia used the term 'Fast dissolving tablet' as a tablet that is to be placed in the mouth where it disperses rapidly before swallowing.

Orally disintegrating tablets are also called as mouth-dissolving tablets, fast disintegrating tablets, fast dissolving tablets, Fast dissolving tablets, rapimelts, porous tablets, quick dissolving tablet[3].

The US Food and Drug Administration responded to this challenge with the 2008 publication of Guidance for Industry: Orally Disintegrating Tablets [4].Three main points stand out in the final guidance:

- FDTs should have an *in vitro* disintegration time of approximately 30sec or less.
- Generally, the FDT tablet weight should not exceed 500 mg, although the combined influence of tablet weight, size, and component solubility all factor into the acceptability of an FDT for both patients and regulators.
- The guidance serves to define the upper limits of the FDT category, but it does not supersede or replace the original regulatory definition mentioned. In other words, disintegration within a matter of seconds remains the target for an FDT.

The concept of orodispersible tablet emerged with an objective to improve patient's compliance. These dosage forms rapidly disintegrate and/or dissolve to release the drug as soon as they come in contact with saliva, thus without the need for water during administration, an attempts that makes them highly attractive for pediatric and geriatric patients[5] . Difficulty in swallowing conventional tablets and capsules is common among all age groups, especially in elderly and dysphagic patients. This disorder of dysphagia is associated with many medical conditions including stroke, Parkinson's disease, AIDS etc. One study showed that 30% out of 1600 patients experienced difficulty in swallowing tablets due to their large size and by their surface, shape and taste. Elderly patients may find the administration of the conventional oral dosage forms difficult as they regularly require medicines to maintain a healthy life. Children may also have difficulty in ingesting because of their underdeveloped muscular and nervous systems. The problem of swallowing tablets is also evident in travelling patients. Above mentioned problems can be resolved by means of orodispersible Tablets (ODTs)[6]. ODTs are known by various names such as "fastmelting, fast-dissolving, mouth disintegrating Tablet or (MDTs)". Suitable drug candidates for such systems include neuroleptics, cardiovascular agents, analgesics, antiallergics. ODTs disintegrate and/or dissolve rapidly in saliva; therefore, water is not required during administration. Some tablets are designed to dissolve in saliva within few seconds, and are true fast-dissolving tablets. Others contain agents to enhance the rate of tablet disintegration in the oral cavity and are more appropriately termed as fast-disintegrating tablets, as they may take about one minute to disintegrate completely. ODTs offers several advantages over other dosage forms like effervescent tablets, dry syrups and chewing gums or tablets, which are commonly used to enhance patient's compliance[7]. Administering effervescent tablets/granules and dry syrups involve unavoidable preparation that include the intake of water. Elderly patients cannot chew large pieces of tablets or gums and sometimes experience the bitter or unpleasant taste of the drug in the dosage form if the taste masking is not done in proper way.

MATERIALS

Milnacipran HCL-Procured From Mylan Laboratories Ltd., New Delhi. Provided by SURA LABS, Dilsukhnagar, Hyderabad, Indion 414-Shreya Life Sciences, Aurangabad i, India, Polyplasdone XL 10-Shreya Life Sciences, Aurangabad i, India, Primogel-Shreya Life Sciences, Aurangabad i, India, Aerosil- Shreya Life Sciences, Aurangabad i, India, Aspartame-Shreya Life Sciences, Aurangabad i, India, Avicel PH 102-Shreya Life Sciences, Aurangabad i, India

METHODOLOGY

Buffer Preparation

Preparation of 0.2M Potassium dihydrogen orthophosphate solution: Accurately weighed 27.218 gm of monobasic potassium dihydrogen orthophosphate was dissolved in 1000 mL of distilled water and mixed.

Preparation of 0.2M sodium hydroxide solution: Accurately weighed 8 gm of sodium hydroxide pellets were dissolved in 1000 mL of distilled water and mixed

Preparation of pH 6.8 phosphate buffer: Accurately measured 250 mL of 0.2M potassium dihydrogen ortho phosphate and 112.5 mL of 0.2M NaOH was taken into the 1000 mL volumetric flask. Volume was made up to 1000 mL with distilled water.

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Research

Preparation And In Vitro Characterisation Of Indomethacin Sustained Release Tablets

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Abstract

The aim of the present study was to develop sustained release formulation of Indomethacin to maintain constant therapeutic levels of the drug for over 24hrs. By using different ratios of synthetic polymers like Methyl cellulose, HPMC K4 M, Hydroxyethyl cellulose (HEC). All the formulations were passed various physicochemical evaluation parameters and they were found to be within limits. Whereas from the dissolution studies it was evident that the formulation (F8) showed better and desired drug release pattern i.e., 99.27% in 24 hours. It contains the Hydroxyethyl cellulose 1:1 ratio as sustained release material. It followed Kors mayer peppas release kinetics mechanism.

Keywords: Indomethacin Sustained release system, Methyl cellulose, HPMC K4 M, HEC.

INTRODUCTION

A drug delivery system (DDS) is defined as for formulation or a device that enables the introduction of a therapeutic substance in the body and improves its efficacy and safety by controlling the rate, time and place of release of the drugs in the body. This process includes the administration of the therapeutic product, the release of the active ingredients by the product, and the subsequent transport of the active ingredients across the biological membranes to the site of action. The term therapeutic substance also applies to an agent. Sustained release tablets are commonly take only once or twice daily, compared with counterpart conventional forms that may have to take three or four times daily to achieve the same therapeutic effect . the advantage of administering a single close of a drug that is released over an extended period of time to maintain a near – constant or uniform blood level of a drug often translates into better patient compliance, as well as enhanced clinical efficacy of the drug for its intended use[5,6] .

The first sustained release tablets were made by Howard press in New Jersy in the early 1950's.The first tablets release under his process patent were called 'Nitro Glvn' and made under License by Key Corp.in Florida.

Sustained release, prolonged release, modified release, extended release or depot formulations are terms used to identify drug delivery systems that are designed to achieve or extend therapeutic effect by continuously releasing medication over an extended period of time after administration of a single dose.

The goal in designing sustained delivery systems is to reduce the frequency of the dosing or to increase effectiveness of the drug by localization at the site of action, reducing the dose required or providing uniform drug delivery. So, sustained release dosage form is a dosage form that release one or more drugs continuously in predetermined pattern for a fixed period of time, either systemically or to a specified target organ[7,8].

Sustained release dosage forms provide a better control of plasma drug levels, less dosage frequency, less side effect, increased efficacy and constant delivery. There are certain considerations for the Preparation of extended release formulations.

- ✓ If the active compound has a long half-life, it is sustained on its own,
- ✓ If the pharmacological activity of the active is not directly related to its blood levels,
- ✓ If the absorption of the drug involves an active transport and
- ✓ If the active compound has very short half-life then it would require a large amount of drug to maintain a prolonged affective dose.

The above factors need serious review prior design.

Introduction of matrix tablet as sustained release (SR) has give a new breakthrough for novel drug delivery system in the field of Pharmaceutical technology. It excludes complex production procedures such as coating and Pelletization during manufacturing and drug release rate from the dosage form is controlled mainly by the type and proportion of polymer used in the preparations. Hydrophilic polymer matrix is widely used for formulating an SR dosage form. Because of increased complication and expense involved in marketing of new drug entities, has focused greater attention on development of sustained release or controlled release drug delivery system. Matrix systems are widely used for the purpose of sustained release. It is the release system. which prolongs and controls the release of the drug that is dissolved or dispersed[9].

In fact, a matrix is defined as well-mixed composite of one or more drugs with gelling agent i.e. hydrophilic polymers. By the sustained release method therapeutically effective connection can be achieved in the systemic circulation over an extended period of time, thus achieving better compliance of patients. Numerous SR oral dosage forms such as membrane controlled system, matrices with water soluble/insoluble polymers or waxes and osmotic systems have been developed, intense research has recently focused on the designation of SR systems for poorly water soluble drugs.

1.1 Rationale for extended release dosage forms:

Some drugs are inherently long lasting and require only one-a-day oral dosing to sustain adequate drug blood levels and the desired therapeutic effect. These drugs are formulated in the conventional manner in immediate release dosage forms. However, many other drugs are not inherently long lasting and require multiple daily dosing to achieve the desired therapeutic result. Multiple daily dosing is inconvenient for the patient and can result in missed doses, made up does, and noncompliance with the regimen. When conventional immediate-release dosage forms are taken on schedule and more than once daily, they cause sequential therapeutic blood level peaks and valleys(troughs) associated with the taking of each dose. However, When does are not administered on schedule, the resulting peaks and valleys reflect less than optimum drug therapy. For example, if doses are administered too frequently, minimum toxic concentrations of drug may be reached, with toxic side effects resulting. If does are missed, periods of sub therapeutic drug blood levels or those below the minimum effective contraction may result, with no benefit to the patient. Extended-release tablets and capsules are commonly taken only once or twice daily, compared with counterpart conventional forms that may have to take three or four times daily to achieve the same therapeutic effect.

MATERIALS

Indomethacin-Procured From Ranbaxy Laboratories Ltd., New Delhi.Provided by SURA LABS, Dilsukhnagar, Hyderabad, Methyl Cellulose-Merck specialities Pvt Ltd, Mumbai, India, HPMC K4 M-Merck specialities Pvt Ltd, Mumbai, India, HEC-Merck specialities Pvt Ltd, Mumbai, India, PVP-Merck specialities Pvt Ltd, Mumbai, India, Aerosil-Merck specialities Pvt Ltd, Mumbai, India,Sodium Stearyl Fumerate-Merck specialities Pvt Ltd, Mumbai, India, Mannitol-Merck specialities Pvt Ltd, Mumbai, India

METHODOLOGY

Analytical method development

a) Determination of absorption maxima

100mg of Indomethacin pure drug was dissolved in 15 ml of Methanol and make up to 1000ml with 0.1N HCL (stock solution-1). 10ml of above solution was taken and make up with 100ml by using 0.1N HCL (stock solution

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Research

A simple, robust and specific reverse phase-hplc method development and validation for estimation of rosiglitazone and glimepiride in active pharmaceutical ingredient and its pharmaceutical dosage form

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Abstract

An accurate, precise, simple, efficient and reproducible, isocratic Reversed Phase-High Performance Liquid Chromatography (RP-HPLC) method was developed and validated for the simultaneous estimation of Rosiglitazone and Glimepiride in bulk and combined pharmaceutical tablet dosage forms. Rosiglitazone and Glimepiride were separated by using a Symmetry ODS C18 (4.6mm×150mm) 5µm Particle Size; Waters Alliance e2695 HPLC system with 2998 PDA detector and the mobile phase contained a mixture of Methanol: 0.1% Orthophosphoric acid (64:36% v/v). The flow rate was set to 1ml/min with the responses measured at 224nm. The retention time of Rosiglitazone and Glimepiride was found to be 2.808min and 3.880min respectively with resolution of 5.68. Linearity was established for Rosiglitazone and Glimepiride in the range of 20-100µg/ml for Rosiglitazone and 60-140µg/ml for Glimepiride with correlation coefficient 0.999. The percentage recovery was found to be is 100.30% for Rosiglitazone and 100.21% for Glimepiride respectively. Validation parameters such as specificity, linearity, precision, accuracy and robustness, limit of detection (LOD) and limit of quantitation (LOQ) were evaluated for the method according to the International Conference on Harmonization (ICH) Q2 R1 guidelines. The developed method was successfully applied for the quantification of bulk and active pharmaceutical ingredient present and in combined tablet dosage form.

Keywords: Rosiglitazone and Glimepiride, RP-HPLC, Validation, Accuracy, Precision.

INTRODUCTION

Analytical chemistry[1] is the branch of chemistry involved in separating, identifying and determining the relative amounts of the components making up a sample of matter. It is mainly involved in the qualitative identification or detection of compounds and the quantitative measurement of the substances present in bulk and pharmaceutical preparation.

Measurements of physical properties of analytes such as conductivity, electrode potential, light absorption or emission, mass to charge ratio, and fluorescence, began to be used for quantitative analysis of variety of inorganic and biochemical analytes. Highly efficient chromatographic and electrophoretic techniques began to replace distillation, extraction and precipitation for the separation of components of complex mixtures prior to their qualitative or quantitative determination. These newer methods for separating and determining chemical species are known collectively as instrumental methods of analysis. Most of the instrumental methods fit into one of the three following categories viz spectroscopy, electrochemistry and chromatography

HPLC

HPLC[3] is a type of liquid chromatography that employs a liquid mobile phase and a very finely divided stationary phase. In order to obtain satisfactory flow rate liquid must be pressurized to a few thousands of pounds per square inch.

The rate of distribution of drugs between Stationary and mobile phase is controlled by diffusion process. If diffusion is minimized faster and effective separation can be achieved .The techniques of high performance liquid chromatography are so called because of its improved performance when compared to classical column chromatography advances in column chromatography into high speed, efficient ,accurate and highly resolved method of separation.

For the recent study Clonazepam and Propranolol was selected for estimation of amount of analyte present in formulation and bulk drug. The HPLC method is selected in the field of analytical chemistry, since this method is specific, robust, linear, precise and accurate and the limit of detection is low and also it offers the following advantages

- Speed many analysis can be accomplished in 20min (or) less.
- Greater sensitivity (various detectors can be employed).
- Improved resolution (wide variety of stationary phases).
- Re usable columns (expensive columns but can be used for many analysis).
- Ideal for the substances of low viscosity.
- Easy sample recovery, handling and maintenance.
- Instrumentation leads itself to automation and quantification (less time and less labour).
- Precise and reproducible.
- Integrator itself does calculations.
- Suitable for preparative liquid chromatography on a much larger scale.

HPLC components

The essential components[4] of a complete HPLC system are solvent delivery system (Pump), detector, fixed volume injector loop or auto sampler, solvent reservoirs, packed column, data system and recorder. A schematic of a simplified HPLC system is shown in Fig 1.

Column

The column is probably the heart of HPLC system. The development of this column technology leads to the evolution of the HPLC instrumentation systems used today. The conventionally used HPLC columns are particle packed columns. The key of column selection when previous separation is not available resides in knowing the chemistry of the sample. Columns should never be dry. A dry column will eventually have voids because the packing will shrink away from the wall, which would result in band broadening. Before running a sample in HPLC the column should be equilibrated. Usually column equilibrium is achieved after passage of 10 – 20 column volumes of the new mobile phase through the column. Insufficient column equilibrium usually leads to retention difference.

Pump

The solvent delivery system or as it is commonly called the pump includes two major types, constant volume or flow and constant pressure. Constant volume pumps are mechanically driven systems, most commonly using screw driven syringes or reciprocating pistons. On the other hand, constant pressure pumps are driven or controlled by gas pressure.

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Research

Validated rp-hplc method for simultaneous estimation of valsartan and sacubitril in bulk and tablet dosage form.

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Abstract

A rapid and precise reverse phase high performance liquid chromatographic method has been developed for the validated of Valsartan and Sacubitril, in its pure form as well as in tablet dosage form. Chromatography was carried out on an Sunfire C18 (4.6×250mm) 5µ column using a mixture of Water and Acetonitrile (60:40% v/v) as the mobile phase at a flow rate of 0.9ml/min, the detection was carried out at 220nm. The retention time of the Sacubitril and Valsartan was 3.0, 3.8±0.02min respectively. The method produce linear responses in the concentration range of 5-25µg/ml of Sacubitril and 75-375µg/ml of Valsartan. The method precision for the determination of assay was below 2.0%RSD. The method is useful in the quality control of bulk and pharmaceutical formulations.

Keywords: Sacubitril, Valsartan, RP-HPLC, validation.

INTRODUCTION

Analysis may be defined as the science and art of determining the composition of materials in terms of the elements or compounds contained in them. In fact, analytical chemistry is the science of chemical identification and determination of the composition (atomic, molecular) of substances, materials and their chemical structure.

Chemical compounds and metallic ions are the basic building blocks of all biological structures and processes which are the basis of life. Some of these naturally occurring compounds and ions (endogenous species) are present only in very small amounts in specific regions of the body, while others such as peptides, proteins, carbohydrates, lipids and nucleic acids are found in all parts of the body. The main object of analytical chemistry is to develop scientifically substantiated methods that allow the qualitative and quantitative evaluation of materials

with certain accuracy. Analytical chemistry derives its principles from various branches of science like chemistry, physics, microbiology, nuclear science and electronics. This method provides information about the relative amount of one or more of these components. [1]

Every country has legislation on bulk drugs and their pharmaceutical formulations that sets standards and obligatory quality indices for them. These regulations are presented in separate articles relating to individual drugs and are published in the form of book called "Pharmacopoeia" (e.g. IP, USP, and BP). Quantitative chemical analysis is an important tool to assure that the raw material used and the intermediate products meet the required specifications. Every year number of drugs is introduced into the market. Also quality is important in every product or service, but it is vital in medicines as it involves life.

There is a time lag from the date of introduction of a drug into the market to the date of its inclusion in pharmacopoeias. This happens because of the possible uncertainties in the continuous and wider usage of these drugs, report of new toxicities and development of patient resistance and introduction of better drugs by the competitors. Under these conditions standard and analytical procedures for these drugs may not be available in Pharmacopoeias. In instrumental analysis, a physical property of the substance is measured to determine its chemical composition. Pharmaceutical analysis comprises those procedures necessary to determine the identity, strength, quality and purity of substances of therapeutic importance. [2]

Pharmaceutical analysis deals not only with medicaments (drugs and their formulations) but also with their precursors i.e. with the raw material on which degree of purity and quality of medicament depends. The quality of the drug is determined after establishing its authenticity by testing its purity and the quality of pure substance in the drug and its formulations.

Quality control is a concept which strives to produce a perfect product by series of measures designed to prevent and eliminate errors at different stages of production. The decision to release or reject a product is based on one or more type of control action. With the growth of pharmaceutical industry during last several years, there has been rapid progress in the field of pharmaceutical analysis involving complex instrumentation. Providing simple analytical procedure for complex formulation is a matter of most importance. So, it becomes necessary to develop new analytical methods for such drugs. In brief the reasons for the development of newer methods of drugs analysis are:

1. The drug or drug combination may not be official in any pharmacopoeias.
2. A proper analytical procedure for the drug may not be available in the literature due to Patent regulations.
3. Analytical methods for a drug in combination with other drugs may not be available.
4. Analytical methods for the quantitation of the drug in biological fluids may not be available.
5. The existing analytical procedures may require expensive reagents and solvents. It may also involve cumbersome extraction and separation procedures and these may not be reliable.[1,2]

DIFFERENT METHODS OF ANALYSIS

The following techniques are available for separation and analysis of components of interest.

Spectral methods

The spectral techniques are used to measure electromagnetic radiation which is either absorbed or emitted by the sample. E.g. UV-Visible spectroscopy, IR spectroscopy, NMR, ESR spectroscopy, Flame photometry, Fluorimetry.2

Electro analytical methods

Electro analytical methods involved in the measurement of current voltage or resistanceas a property of concentration of the component in solution mixture. E.g. Potentiometry, Conductometry, Amperometry.[2]

Chromatographic methods

Chromatography is a technique in which chemicals in solutions travel down columns or over surface by means of liquids or gases and are separated from each other due to their molecular characteristics. E.g. Paper chromatography, thin layer chromatography (TLC), High performance thin layer chromatography (HPTLC), High performance liquid chromatography (HPLC), Gas chromatography (GC).[2]

Miscellaneous Techniques

Mass Spectrometry, Thermal Analysis.

Hyphenated Techniques

GC-MS (Gas Chromatography–Mass Spectrometry), LC-MS (Liquid Chromatography–Mass Spectrometry), ICP-MS (Inductivity Coupled Plasma- Mass Spectrometry), GC-IR (Gas Chromatography–Infrared Spectroscopy), MS-MS (Mass Spectrometry–Mass Spectrometry).

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Research

Formulation And Evaluation Of Cytarabine Microspheres For Sustained Drug Delivery

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Abstract

The Drug Cytarabine has short half life and hence requires frequent administration. Therefore the possible way for formulating a sustained release formulation of mucoadhesive microspheres. These formulations are prepared by solvent evaporation technique by using polymers HPMC15cps+Carbopol 934p and HPMC15000cps +Carbopol 934p. Various evaluation parameters assessed, with a view to obtain sustained release of Cytarabine. In the present study six formulations are formulated by using Sodium Alginate and HPMC15cps+Carbopol 934p and HPMC15000cps +Carbopol 934p various proportions. The prepared Cytarabine microspheres are then subjected to IR, SEM, particle size, % yield, Swelling Index, Micrometric, % Drug entrapment efficiency, *In-vitro* mucoadhesion test and *in vitro* dissolution studies. The IR Spectra revealed that, there is no interaction between the polymer and Cytarabine. Cytarabine microspheres are spherical in nature, which was confirmed by SEM. The Optimized formulation C3 was found to release the drug for 12 h (99.13%) and follows peppas drug release kinetics model in dissolution studies.

Keywords: Cytarabine, HPMC15cps +Carbopol 934p, HPMC15000cps+Carbopol 934p and solvent evaporation technique.

INTRODUCTION

Oral route drug administration is by far the most preferable route for taking medications. However, their short circulating half life and restricted absorption via a defined segment of intestine limits the therapeutic potential of many drugs. Such a pharmacokinetic limitation leads in many cases to frequent dosing of medication to achieve therapeutic effect. Rational approach to enhance bioavailability and improve pharmacokinetic and pharmacodynamics profile is to release the drug in a controlled manner and site specific manner.

One of the most challenging areas of research in pharmaceuticals is the development of novel delivery systems for the controlled release of drugs and their delivery at the targeted site in the body to minimize the side effects and enhance the therapeutic efficacy of drugs[2,3]. The basic principle behind the controlled drug delivery system is to optimize the biopharmaceutic, pharmacokinetic and pharmacodynamics properties of drug in such a way that its efficacy is maximized by reducing side effects, dose frequency and cure the disease in short time by using low amount of drug administered with the most suitable route [4,5, 6,7].

In 1997, first time microspheres were prepared for the sustained action of the drug. Since then, microparticles have proved to be good candidates for sustained and controlled release of drug and become an alternative of conventional or immediate release formulations. These particles are also a beneficial to deliver the active pharmaceutical ingredients which are pharmacologically active but are difficult to deliver due to limited solubility in water. In such type drugs, the attainment of required therapeutic concentrations of drug in the blood is problematic enabling to attain higher C_{max}, T_{max} and area under curve. Microsphere – based formulations can release a constant amount of drug in the blood or to target drugs to specific site in the body [8,9].

For many decades, medication of an acute disease or a chronic disease has been accomplished by delivering drugs to the patients via various pharmaceutical dosage forms like tablets, capsules, pills, creams, ointments, liquids, aerosols, injectables and suppositories as carriers. To achieve and then to maintain the concentration of drug administered within the therapeutically effective range needed for medication, it is often necessary to take this type of drug delivery systems several times in a day. This results in a fluctuated drug level and consequently undesirable toxicity and poor efficiency. This factor as well as other factors such as repetitive dosing and unpredictable absorption leads to the concept of controlled drug delivery systems. The word new or novel in the relation to drug delivery system is a search for something out of necessity. An appropriately designed sustained or controlled release drug delivery system can be major advance toward solving the problem associated with the existing drug delivery system.

The objective of controlled release drug delivery includes two important aspects namely spatial placement and temporal delivery of drug. Spatial placement relates to targeting a drug to a specific organ or tissue, while Temporal delivery refers to controlling the rate of drug delivery to the target tissue.

Oral controlled release dosage forms have been developed over the past three decades due to their considerable therapeutic advantages such as ease of administration, patient compliance and flexibility in formulation. However, this approach is be dilled with several physiological difficulties such as inability to restrain and locate the controlled drug delivery system within the desired region of the gastrointestinal tract (GIT) due to variable motility and relatively brief gastric emptying time (GET) in humans which normally averages 2-3 h through the major absorption zone, i.e., stomach and upper part of the intestine can result in incomplete drug release from the drug delivery system leading to reduced efficacy of the administered dose.[10,11]

The objective in designing a controlled release system is to deliver the drug at a rate necessary to achieve and maintain a constant drug blood level. This rate should be similar to that achieved by continuous intravenous infusion where a drug is provided to the patient at a rate just equal to its rate of elimination. This implies that the rate of delivery must be independent of the amount of drug remaining in the dosage form and constant over time, i.e release from the dosage form should follow zero-order kinetics.[12]

Definition and general description

Microspheres can be defined as solid, approximately spherical particles ranging in size from 1 to 1000 μm. They are made of polymeric, waxy, or other protective materials, that is, biodegradable synthetic polymers and modified natural products such as starches, gums, proteins, fats, and waxes. The natural polymers include albumin and gelatin9-10 the synthetic polymers include polylactic acid and polyglycolic acid. Fig. 1.2 shows two types of microspheres: Microcapsules, where the entrapped substance is completely surrounded by a distinct capsule wall, and micromatrices, where the entrapped substance is dispersed throughout the microsphere matrix.

The potential use of microspheres in the pharmaceutical industry has been considered since the 1960s for the following applications:

Taste and odor masking Conversion of oils and other liquids to solids for ease of handling Protection of drugs against the environment (moisture,light, heat, and/or oxidation) and vice versa (prevention of pain on injection) Delay of volatilization Separation of incompatible materials (other drugs or excipients such as buffers) Improvement of flow of powders Safe handling of toxic substances Aid in dispersion of water-insoluble substances in aqueous media,[13] and Production of sustained-release, controlled-release, and targeted medications Reduced dose dumping potential compared to large implantable devices Microencapsulation has also been used medically for the encapsulation of live cells and vaccines. Biocompatibility can be improved by the encapsulation of artificial cells and biomolecules such as peptides, proteins, and hormones, which can prevent unwanted immunological reactions that would lead to inactivation or rejection. Microspheres are used for isolating materials until their activity is needed. The biotechnology

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Research

Formulation Development And In Vitro Characterisation Of Deflazacort Extended Release Matrix Tablets

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Abstract

The aim of the present study was to develop Extended release formulation of Deflazacort to maintain constant therapeutic levels of the drug for over 12 hrs. HPMC K100M, HPMC (K4M) and Carbopol 71G were employed as polymers. All the formulations were passed various physicochemical evaluation parameters and they were found to be within limits. Whereas from the dissolution studies it was evident that the formulation (F6) showed better and desired drug release pattern i.e., 98.85% in 12 hours. It contains the HPMC (K4M) as Extended release material. It followed peppas release kinetics mechanism.

Keywords: Deflazacort, HPMC K100M, HPMC (K4M), Carbopol 71 G and Extended release system.

INTRODUCTION

The oral route is the most popular route used for administration of drugs, which is due in part to the ease of administration and to the fact that gastrointestinal physiology offers more flexibility in dosage form design than most other routes. The terms Sustained release, prolonged release, modified release, extended release or depot formulations are used to identify drug delivery systems that are designed to achieve or extend therapeutic effect by continuously releasing medication over an extended period of time after administration of a single dose. [1,2]

There are several reasons for attractiveness of these dosage forms: provides increased bioavailability of drug product, reduction in the frequency of administration to prolong duration of effective blood levels, reduces the fluctuation of peak trough concentration and side effects and possibly improves the specific distribution of the drug. If one were to develop an ideal drugdelivery system, two pre-requisites would be required: Firstly single dose for the

duration of treatment whether for days or weeks as with infection, diabetes orhypertension. Second it should deliver the active entity directly to the site of action minimizing the side effects.

There are certain considerations for the preparation of extended release formulations: If the active compound has a long half-life, it is sustained on its own, If the pharmacological activity of the active is not directly related to its blood levels, If the absorption of the drug involves an active transport and If the active compound has very short half-life then it would require a large amount of drug to maintain a prolonged effective dose. The above factors need serious review prior to design.[3]

Extended release formulations make the drug available over extended time period after oral administration. The extended release product will optimize therapeutic effect and safety of a drug at the same time improving the patient convenience and compliance. By incorporating the dose for 24 hrs into one tablet/capsule from which the drug is released slowly. This formulation helps to avoid the side effects associated with low and high concentrations. The ideal drug delivery system should show a constant zero-order release rate and maintain the constant plasma concentrations.

It is desirable to maintain a therapeutic blood concentration in order to achieve the desirable pharmacological effects. To maintain a narrow range of therapeutic blood concentration it is desirable to have a dosage form that can deliver the drug in a more sustainable or controlled way to achieve the desired results. Extended release tablets and capsules are commonly taken once or twice daily, compared with counterpart conventional forms that may have to be taken three or four times daily to achieve the same therapeutic effect. Typically, extended release products provide an immediate release of drugs that promptly produces the desired therapeutic effect, followed by gradual release of additional amount of drugs to maintain this effect over a predetermined period. The sustained plasma drug levels provided by extended release products often eliminate the need for night dosing, which benefits not only the patient but the patient but the caregiver as well.[4]

Rationale of Extended Drug Delivery[5]

The main objective to formulate an API in an extended drug delivery system is related to its pharmacokinetics parameters. An appropriate formulation can make the absorption, distribution, metabolism and elimination (ADME) profile of a drug much more favourable. This change of the ADME can have a profound impact on many aspects of the clinical use of the drug from patient compliance and convenience to its very efficacy, tolerance and safety parameters.

Pellets

Pelletization is an agglomeration process, that converts fine powder blend of drug(s) and excipients into small, free flowing, spherical units, referred to as pellets. Rationale of extended release pellets Pellets provide the development scientist with a high degree of flexibility during the design and development of oral dosage forms. They can be divided into desired dose strengths without formulation or process changes, and can also be blended to deliver incompatible bioactive agents simultaneously or particles with different release profiles at the same site or at different sites within the gastrointestinal tract.

Mechanism

A matrix system consists of active and inactive ingredients, which are homogeneously dispersed and mixed in the dosage form. According to the materials used, the matrix systems have different mechanisms toward the controlled action. The release from matrix type formulations is governed by Fick's first law of diffusion.

Types of matrix systems

1. Slowly Eroding Matrix
2. Inert plastic Matrix

There are two types of matrix systems which are as follows

It consists of materials or polymers which erode over a period of time such as waxes, glycerides, Stearic acid, cellulosic materials etc. The Portion of drug intended to have extended action is combined with lipid or cellulosic material and then granulated. Untreated drug granulated both mixed. The rate controlling release ingredients of hydrophilic matrix are polymers which act by swelling when it contact with aqueous solution and form a gel layer on the surface of the system. Swelling or dissolution can be the effective factor for a specific type of polymers, in most cases drug release kinetics is a result of a combination of these two mechanisms.

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Research

Pharmacological Screening And Phytochemical Evaluation Of Anti-Diabetic Activity Of Anchusa Officinalis In Alloxan Induced Diabetic Rats

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Abstract

In India, the number of people suffering from diabetes is believed to be rising steadily and the current antidiabetic therapies are frequently reported to have adverse side effects. Ethno medicinal plant use has shown promise for the development of cheaper, cost-effective antidiabetic agents with fewer side effects.

The aim of this study was to investigate the antidiabetic activity and mechanism of action of aqueous leaf extract prepared from *Anchusa Officinalis.* Since this claim has not been investigated scientifically, the aim of this study was to evaluate the antidiabetic effect and phytochemical screening of alloxan-induced diabetic rats.

The result demonstrated the beneficial biochemical effects of *Anchusa Officinalis* extract by inhibiting α–amylase improving serum lipid profile levels. The leaves crude extract are effective in lowering blood glucose levels in diabetic and hypoglycemic rat. The claimed traditional use as antidiabetic has scientific ground.

The present study suggested that the isolation of active constituents from Ethanolic extract of *Anchusa Officinalis* leaf and characterize the compounds by using preliminary phytochemical studies.

Keywords: Diabetes mellitus, Herbal medicine, *Anchusa Officinalis*, Alloxan, Anti diabetic activity.

INTRODUCTION

Diabetes Mellitus (DM)

Diabetes is one of the most common non-communicable diseases and a serious life-long condition appearing worldwide. The etiology of diabetes is a complex interaction of genetic and environmental factors. It is a heterogeneous group of metabolic disorders characterized physiologically by dysfunction of pancreatic beta cells and deficiency in insulin secretion or insulin activity and clinically by hyperglycemia or impaired glucose tolerance and

other manifestable disorders. It is an endocrinological syndrome abnormally having high levels of sugar in the blood. This may be either due to insulin not being produced at all, is not made at sufficient levels, or is not as effective as it should be.

Diabetes is still a serious health problem all over the world since it is associated with increased morbidity and mortality rate. When compared with the general population, mortality and morbidity increase in diabetes is mainly due to the associated chronic complications both specific (microvascular) and nonspecific (macrovascular). Since the disease prevails in both genders and in all age groups, the general public has a concern about its control and treatment[1].

Classification of DM

Diabetes is classified by underlying cause. The most common forms of diabetes are categorized as

Type 1, or insulin-dependent diabetes mellitus (IDDM) - an autoimmune disease in which the body's own immune system attacks the pancreatic beta cells, rendering it unable to produce insulin and

Type 2, or non-insulin-dependent diabetes mellitus (NIDDM) - in which there is resistance to the effects of insulin or a defect in insulin secretion.

Type 2 diabetes commonly occurs in adults associated with obesity. There are many underlying factors that contribute to the high blood glucose levels in these individuals. An important factor is the resistance to insulin in the body essentially ignoring its insulin secretions. A second factor is the decreased production of insulin by the cells of the pancreas. Therefore, an individual with Type 2 diabetes may have a combination of deficient secretion and deficient action of insulin. In contrast to Type 2 diabetes, Type 1 diabetes most commonly occurs in children and is a result of the body's immune system attacking and destroying the beta cells. The trigger for this autoimmune attack is not clear, but the result is the end of insulin production[2].

Multiple risk factors for the development of Type 2 diabetes mellitus[3]:

- Family history (parents with diabetes).
- Obesity (i.e., ≥20% over ideal body weight or body mass index ≥25kg/m^2).
- Habitual physical inactivity.
- Impaired glucose tolerance.
- Hypertension (≥140/90mm Hg in adults).
- High density lipoprotein (HDL) cholesterol ≤ 35mg/dl and/or triglyceride level ≥ 250mg/dl.

History

The term “Diabetes” was first used around 250 B.C. It is a Greek word meaning “to syphon”, reflecting how diabetes seemed to rapidly drain fluid from the affected individual. The Greek physician Aretaeus noted that affected individuals passed increasing amounts of urine as if there was “liquefaction of flesh and bones into urine”. The complete term “diabetes mellitus” was coined in 1674 by Thomas Willis. Mellitus is Latin for honey, which is how Willis described the urine of diabetics[5].

Historical accounts reveal that as early as 700-200 BC, diabetes mellitus was a well recognized disease in India and was even distinguished as two types, a genetically based disorder and other one resulting from dietary indiscretion. Ancient Hindu writings document how black ants and flies were attracted to the urine of diabetics. The Indian physician Sushruta in 400 B.C. described the sweet taste of urine from affected individuals, and for many centuries to come, the sweet taste of urine was a key to the diagnosis.

Physicians have observed the effects of diabetes for thousands of years. One of the effects of diabetes is the presence of glucose in the urine (glucosuria). For much of the time, little was known about this fatal disease that caused weight loss of body, extreme thirst, and frequent urination. It was in 1922 that the first patient was successfully treated with insulin. Till the mid-1800s, the treatments offered for diabetes varied tremendously. A breakthrough in the puzzle of diabetes came in 1889. German physicians Joseph von Mering and Oskar Minkowski surgically removed the pancreas from dogs. The dogs immediately developed diabetes. Now that a link was established between the pancreas and diabetes, research focused on isolating the pancreatic extract that could treat diabetes. Dr. Frederick Banting succeeded in his experiments of isolating a pancreatic extract. The diabetic dog was kept alive for eight days by regular injections until supplies of the extract, at that time called "isletin", was exhausted. Experiments on dogs showed that extracts from the pancreas caused a drop in blood sugar, caused glucose in the urine to disappear, and produced a marked improvement in clinical condition.

A young boy, Leonard Thompson, was the first patient to receive insulin treatment in the year 1922 and lived for thirteen years. Over the next 70 years, insulin was further refined and purified. A revolution came with the production of recombinant human DNA insulin in 1978. Instead of collecting insulin from animals, new human insulin could be synthesized. In 1923, Banting and Macloed were awarded the Nobel Prize for the discovery of insulin. In his Nobel Lecture, Banting concluded the following about their discovery: “Insulin is not a cure for diabetes; it is a

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Research

Anti Analgesic Activity By Holoptelea Integrifolia

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Abstract

Holoptelea integrifolia (Ulmaceae) is a common weed occurring throughout the globe. In traditional medicine its decoction has been used for treatment of many infectious and degenerative diseases. This work was therefore designed to assess the phytochemical constitution of *Holoptelea integrifolia* dried roots extracts and to evaluate their analgesic and anti-inflammatory activity in rats. Fresh and crushed roots of *Holoptelea integrifolia* were collected and then extracted with ethanol. The ethanolic extract at the doses of 100 mg/kg, 200 mg/kg body weight was subjected to evaluation of analgesic and anti-inflammatory activities in experimental animal models. Analgesic activity was evaluated by Hot-plate and tail –flick method in albino Wistar rats; acute and chronic anti-inflammatory activity was evaluated by carrageenan-induced paw oedema and formalin-induced paw edema in Wistar albino rats. Diclofenac sodium and Indomethacin were employed as reference drugs for analgesic and anti-inflammatory studies, respectively. In the present study, the ethanolic extract of *Holoptelea integrifolia* demonstrated significant analgesic and anti-inflammatory activities in the tested models.

Keywords: *Holoptelea integrifolia*, hot-plate, tail-flick, Carragenan-induced paw edema model, Formalin-induced paw edema model, Analgesic and anti-inflammatory activity.

INTRODUCTION

INFLAMMATION

Inflammation is an important physiological reaction which occurs in response to a wide variety of injurious agents (e.g. bacterial infection, physical trauma, chemicals or any other phenomenon) ultimately aiming to perform the dual function of limiting damage and promoting tissue repair [1]. Inflammatory processes are required for immune surveillance, optimal repair, and regeneration after injury [2]. The inflammatory process protects our body from diseases by releasing cells and mediators that combat foreign substances and prevent infection [3]. However, sustained, excessive or inappropriate inflammation is the cause of numerous diseases including rheumatoid arthritis, psoriasis and inflammatory bowel disease [4].

Inflammation is a major component of the damage caused by autoimmune diseases, and is a fundamental contributor of various infectious and non-infectious diseases such as cancer, diabetes, cardiovascular disease,

rheumatoid arthritis, Alzheimer's and arteriosclerosis. Depending on the intensity of this process, mediators generated in the inflammatory site can reach the circulation and cause fever [5, 6].

Inflammation is a complex pathophysiological process mediated by a variety of signalling molecules produced by leucocytes, macrophages and mast cells undergoing various cellular responses such as phagocytic uptake, and the production of inflammatory mediators such as nitric oxide (NO), prostaglandin E2 (PGE2) and tumour necrosis factor (TNF)-α [7], that bring about edema formation as a result of extravasation of fluid and proteins and accumulation of leucocytes at the inflammatory site [8]. In addition, it is broadly accepted that cytokines, produced by either immune or central nervous system cells, might directly sensitize the peripheral nociceptors [9].

Inflammation is an important cellular response triggered by various mechanical, chemical or immunological stress factors and it is regulated by a delicate balance between local factors that finally determine the outcome of the disease process: progression or resolution. The inflammatory response is a complex and highly regulated sequence of events that start with an initial production of pro-inflammatory mediators that recruit professional inflammatory cells to the site of injury to clear the offending trigger [10]. This is followed by an anti-inflammatory phase, in which resident tissue cells may acquire the potential for protecting themselves from further activation and injury. More recently, inflammation was described as "the succession of changes which occurs in a living tissue when it is injured provided that the injury is not of such a degree as to at once destroy its structure and vitality" or "the reaction to injury of the living microcirculation and related tissues" [11].

Although, in ancient times inflammation was recognised as being part of the healing process, up to the end of the 19th century, inflammation was viewed as being an undesirable response that was harmful to the host. Based on visual observation, the ancients characterised inflammation by five cardinal signs, namely redness (rubor), swelling (tumour), heat (calor; only applicable to the body extremities), pain (dolor) and loss of function (functio laesa). The first four of these signs named by Celsus in ancient Rome (30-38 B.C.) and the last by Galen (A.D. 130-200) [12].

The classical description of inflammation accounts for the visual changes seen. The sensation of heat is caused by the increased movement of blood through dilated vessels into the environmentally cooled extremities. Redness is due to the additional number of erythrocytes passing through the area. Swelling (edema) is the result of increased passage of fluid from dilated and permeable blood vessels into the surrounding tissues, infiltration of cells into the damaged area, and in prolonged inflammatory responses deposition of connective tissue. Pain is due to the direct effects of mediators, either from initial damage or that resulting of sensory nerves due to oedema. Loss of function refers to either simple loss of mobility in a joint, due tothe oedema and pain, or to the replacement of functional cells with scar tissue.

Inflammatory process has two phases: acute and chronic. Acute and chronic inflammations are known to be complicated processes induced by several different classes of chemical mediators, e.g. prostaglandins, leukotrienes and platelet-activating factor, etc. Anti inflammatory agents exert their effect through a spectrum of different modes of action. [13]

Acute inflammatory response is characterized by an increase in vascular permeability and cellular infiltration leading to oedema formation as a result of extravasation of fluid and proteins and accumulation of leukocytes at the inflammatory site for short time [14].

Chronic inflammation is the reaction arising when the acute response is insufficient to eliminate the pro-inflammatory agents. Chronic inflammation includes a proliferation of fibroblasts and infiltration of neutrophils with exudation of fluid. It occurs by means of development of proliferative cells which can either spread or form granuloma. Chronic inflammation may also occur due to the persistence of infection or antigen, recurring tissue injury, or a failure of endogenous anti-inflammatory mechanisms.

Chronic (or acute) inflammation is a multiple process mediated by activating inflammatory or immune cells[15], among which macrophages play a central role in managing many different immunopathological phenomena including the overproduction of proinflammatory cytokines and inflammatory mediators, generated by activated COX-2. Under inflammatory conditions, immune cells are also stimulated by adhesion molecule activation signals in order to enhance the migration capacity to inflamed tissue and finally to form heterotypic cell clustering between the immune cells, endothelial cells and inflamed cells.

Macrophages in the inflammatory reaction initially requires an interaction between surface receptors such as Toll-like receptors (TLR) and stimuli, and subsequent up-regulation of intracellular signalling events mediated by enzymes such as phosphoinositide 3-kinases (PI3K) and mitogen activated protein kinases (MAPKs) as well as transcription factors (e.g., nuclear factor [NF]-κB and activator protein [AP]-1) (Sekine et al., 2006). Overall, these events lead macrophages to express pro-inflammatory genes such as inducible NO synthase (iNOS) and cyclooxygenase (COX)-2. Because large amounts of macrophage-derived inflammatory mediators can cause collateral or severe damage such as septic shock, rheumatoid arthritis and arteriosclerosis, the effective blockade of these inflammatory responses is an important therapeutic target. Inflammatory diseases are a major cause of morbidity of the work force throughout the world. These have been called the "King of Human Miseries".