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Formulations and Analytical Method Developments for Poor Soluble Drugs: A Review on Applications of Nano Chemistry

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Abstract- In this review, various approaches for nano-formulations for poor soluble and low permeable drugs are focused, advantages and future scope for the nono formulations in pharmaceutical industries are elaborated. For the manufacture of new medicines new manufacturing technology is needed. In the pharmaceutical formulations pellets dosage forms gives the improved results compare to tablet dosage forms. According to ICH BCS (BIOPHARMACEUTICS CLASSIFICATION SYSTEM) drugs class four, Low solubility, Low permeability drugs. Improved use of Low solubility, Low permeability drugs pelletized formulation at Nano level is proposed. Nano level pelletized drug formulations gives the better results compared to normal, micro level pelletized drug formulations.

Key words- Analytical method development, Nano-formulation, and Nano-chemistry

1. INTRODUCTION

Our daily life is depends on quality of the food we eat, the medicine we use the water we drink, and the air we breathe. The compound which is interacts with a biological organism to produce a biological response that may be favorable or harmful. Favorable is known as medicine, harmful is known as poison. Due to expressed development in the field of science and technology new medications are rapidly coming in to the market for new syndrome. For the manufacture of new medicines new manufacturing technology is needed. In the pharmaceutical formulations pellets dosage forms gives the improved results compare to tablet dosage forms. These dosage forms summarized in terms of safety, purity, efficacy and stability. Final pharmaceutical pellets dosage forms comprises an active pharmaceutical ingredient (API) combined with a varying number of excipients. Some of the Active pharmaceutical ingredients are Low solubility, Low permeability nature (BCS class four). To overcome the low solubility, low permeability problem we are proposing nano level formulations methodology. Very few researchers are worked on the Nano technology applications for drug molecules, even though not related to Nano pelletized formulations. Nano pelletized formulations gives the improved results in controlling of various types of diseases compare to normal, micro level formulations. Due to this reason we are concentrating on nano level pelletized formulations, and its analytical method development. Our ultimate aim is "Best medication for Healthier world" with lesser price.

2. OBJECTIVES

- Our daily life is mainly depends on quality of the air, water, food medicine, without these we are unable to assume our life.
- The compound which is interacts with a biological system to produce a biological response that may be Beneficial is known as medicine, harmful is known as poison.
- Manufacturing of medicines are regulated by Food and Drug administration (FDA): International conference on harmonization (ICH): Current good manufacturing practices (cGMP): Pre-approval Inspections (PAIS): World health organization (WHO), ultimate aim is quality of medicines for healthier world.
- The pharmacopeias (USP, B.P, IP, and E.P) necessities for a pharmaceutical dosage form may be summarizing in terms of safety, purity, efficacy and stability.
- Final pharmaceutical formulations comprises an active pharmaceutical ingredient (API) combined with a varying number of excipients.
- The word "Pellet" describes a variety of systematically produced, geometrically defined agglomerates obtained from various starting materials utilizing different processing conditions.

- Pellets have various therapeutic advantages over traditional single units, such as tablets and powder-filled capsules.
- According to ICH BCS (BIOPHARMACEUTICS CLASSIFICATION SYSTEM) drugs class four, Low solubility, Low permeability drugs.
- Improved use of Low solubility, Low permeability drugs pelletized formulation at Nano level is proposed.
- Nano level pelletized drug formulations gives the better results compared to normal, micro level pelletized drug formulations.
- In house Analytical methods have to be developed and validated for the Analysis of nano level drug formulations.
- Our ultimate aim is to produce the best medicines for healthier world with lesser cost.

3. IMPORTANCE OF THE PROPOSED AREA IN THE PRESENT CONTEXT

With the aim of producing "Quality medicines in low prices for healthier world", we are reviewing of Nano level pelletized formulations for low solubility, Low permeability drug materials. According ICH these are BCS (BIOPHARMACEUTICS CLASSIFICATION SYSTEM) drugs class four. Very lesser number of researchers doing the research work related to Nano technology applications to drugs formulations, but not doing pelletized formulations in Nano level. These formulations gives the effective medicines with lesser side effects compare to normal, micro level formulations. Nano level pelletized formulations advantages as follows.

- Solubility of the drugs can be increases.
- Permeability of the drug in biological matter can be increases.
- Lesser amount of drug dosage is required to control the disease.
- Side effects are less compare to normal and micro level drug dosage formulations.
- Consumption of drugs dosage frequency is less.

Due to above advantages proposed Review i.e Nano level Pelletized formulations place important role in invention of Medicines.

The compound which is interacts with a biological organism to produce a biological response that may be favorable or harmful. favorable is known as medicine, harmful is known as poison. for example, penicillin reacts with bacterial cause to kill them.

Penicillin

Penicillin is a medicine for Humans due to it interacts with bacteria and kills them. In case of bacteria it is a (biological system) poison.

The articulated development in the field of science and technology utilized as on date merged with relatively stringent new regulations, namely federal drug authority, latestly called as food and drug administration (FDA):International conference on harmonization (ICH): Current good manufacturing practices(cGMP): Pre-approval Inspections(PAIS):World health organization(WHO), like organizations are now serving as a legal binding specifically for the pharmaceutical formulations and drug analysis.

4. ROLE OF API'S IN DRUG FORMULATIONS

APIs are core active substances mixed with a carrier in any medication. When any of the active substance is not easily absorbed by the human body; the substance is dissolved into or mixed with an excipient so that the human body easily receives it. Further these actives are used as medications.

4.1. According to ICH BCS (BIOPHARMACEUTICS CLASSIFICATION SYSTEM) drugs class four, Low solubility, Low permeability drugs. Consider example for API(Active pharmaceutical Ingredient)

- ACECLOFENAC (C16H13Cl2NO4), chemically [(2-{2, 6-dichlorophenyl) amino} phenylacetooxyacetic acid],
- Acyclovir (ACV): It also known as acyclovir is an antiviral medication. It is primarily used for the treatment of virus infections, chickenpox, and shingles.

4.2. Pellets

The word "Pellet" has been used to exemplify a variety of systematically produced, geometrically defined agglomerates obtained from various starting materials utilizing different processing conditions. Pellets range in size, typically, between 0.5 – 2.0 mm, though other sizes could be prepared.

4.3. Low solubility, Low permeability drugs pelletized formulations in Nano level, are useful as better medications for various types of diseases. Very few researchers did the work on Nano technology applications for drug molecules, even though not related to Nano pelletized formulations. So we are concentrating on the Nano level pelletized formulations for BCS drugs class four. These

formulations are use full for the society to control the various types' diseases with lesser side effects. Our ultimate aim is "Best medication for Healthier world" with lesser price.

4.4. Analytical Method Development: In house Analytical method is useful for the Analysis of Nano level formulated drugs to check the dissolution profile, Assay, stability of the various dosage forms; the method must be validated according to ICH guidelines, Parameters for approval

5. RESEARCH AND DEVELOPMENT IN THE SUBJECT

Review subject, Nano level pelletized formulations, literature reveals that

- Nano suspension drug delivery system (DDS) was firstly developed in 1994 for the poorly soluble drugs.
- Pharmaceutical medicinal products "curcumin nano crystal" have a significant role in treatment of various types diseases such as cancers of pancreas or colon or even multiple myeloma, psoriasis or myelodys plastic syndromes (Goel et al., 2008., Liu et al., 2013).
- In recent times all drugs with low solubility like curcumin can be approached by Nano crystal methods,
- One more important study in the field of Nano-formulated curcumin was done by Agarwal et al in 2007 (Garodia et al., 2007). In a study, curcumin was encapsulated with more than 97.5% potency in PLGA and PEG. It has been proved that nano-formulated curcumin represents more efficacy and faster cellular uptake than free curcumin in vitro.

Literature survey reveals that very lesser number of researchers did the work on Nano level pelletized formulations, but it reveals that excellent scope is present on this work because advantages are more on Nano level pelletized formulations

6. CONCLUSION

In order to be classified as a "nano pharmaceutical", we suggest the drug product has to meet two major criteria. First, nano engineering has to play a major role in the manufacturing process. Second, the nano material used has to be either essential for the therapeutic activity or has to confer additional and unique properties to the active drug entity. Above literature reviles that Worldwide very less research work is going on Nano level pelletized formulations.

Nano level pelletized drug formulations gives the better results compared to normal, micro level pelletized drug formulations.

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