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Nanomedicine: Development, Problems and Opportunities

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ABSTRACT:
Nanotechnology, together with related concepts such as nanomaterials, nanostructures and nanoparticles, has become a priority area of scientific research and technology development. Nanotechnology, i. H. The production and use of materials and devices at the nanometer scale already has numerous applications in electronics and other fields. However, the greatest hopes lie in biotechnology and healthcare applications, which may have a direct impact on the quality of health in future societies. Connect, develop new treatments and improve existing treatments. Nanomedicine manipulates atoms and molecules to create nanostructures of the same size as biomolecules that interact with human cells. This process offers a range of new solutions for diagnosis and 'smart' treatment by stimulating the body's own repair mechanisms. This will improve early detection and treatment of diseases such as cancer, diabetes, Alzheimer's, Parkinson's and cardiovascular disease. Preventive medicine becomes a reality

KEYWORDS :
Nanomedicine; Nanostructures; early diagnosis; drug delivery, Nanotechnology, Nanomedicine, Nanomaterials, Pharmaceutical development, Nanotoxicology.

I. INTRODUCTION :-

The time period nanotechnology refers back to the capacity to measure, layout and manage substances at atomic, molecular and supramolecular stage so one can understand, create and observe systems and structures with precise capabilities because of their length. Nanotechnology classically refers to depend withinside the length variety of 1–a hundred nm, however it's far regularly prolonged to consist of substances under 1 µm in length. A key aim is to collect nanoparticles and combine them into ordered systems so one can reap beneficial substances. Although new, the arrival of nanomaterials changed into forecast as lengthy in the past as 1959 with the aid of using Richard P. Feynman.[1] Nanotechnology is a brand new subject of technology and engineering that has caused revolutionary procedures in lots of regions of medicine. Its packages withinside the screening, diagnosis, and remedy of sickness are together cited as ―nanomedicine‖—an rising area that has the ability to revolutionize character and population-primarily based totally fitness this century.[2] Nanotechnology has been embraced by multiple industrial sectors for application in the field of electronic storage systems[3]Once the prognosis is established, the combat in opposition to the sickness begins, with medicaments gambling a primary role. There are severa barriers to the improvement of novel tablets in opposition to sickness. Conventional tablets be afflicted by the primary quandary of unfavorable effects, the end result of the non-specificity in their action, and from a loss of effectiveness because of unsuitable or useless dosages, e.g., in most cancers chemotherapy and anti-diabetic therapy. Nanotechnology gives the opportunity of designing novel tablets with more mobileular specificity and new drug-launch structures that act selectively on unique goals and defend the drug from degradation en route. This permits the management of smaller however extra powerful doses, minimizing unfavorable effects.

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Nanotechnology also can be used to optimize drug formulations, growing drug solubility and changing the pharmacokinetics to maintain the discharge of the drug, thereby prolonging its bioavailability. The various structures of nanotechnology may be applied toexpand extra sophisticated, mobileular-centered remedies and to mix unique tablets right into a unmarried nanotherapeutic agent for synergistic healing blessings.[4]

II. NANOMATERIAL

Defination :-

According to the EC recommendation, nanomaterial refers to a natural, incidental, or manufactured material comprising particles, either in an unbound state or as an aggregate wherein one or more external dimensions is in the size range of 1– 100 nm for ≥50% of the particles, according to the number size distribution In cases of environment, health, safety or competitiveness concern, the number size distribution threshold of 50% may be substituted by a threshold between 1 and 50%. Structures with one or more external dimensions below1 nm, such as fullerenes, graphene flakes, and single wall carbon nanotubes, should be considered as nanomaterials. Materials with surface area by volume in excess of 60 m2/cm3are also included.[5]

Food and Drug Administration (FDA) has now no longer set up edits personal definition for "nanotechnology," "nanomaterial," "nanoscale," or different associated terms, as an alternative adopting the meanings generally hired when it comes to the engineering of substances which have at the least one measurement withinside the length variety of about 1 nanometer (nm) to one hundred nm. Based at the modern medical and technical information of nanomaterials and their characteristics, FDA advises that opinions of safety ,effectiveness, public fitness impact, or regulatory reputation of nanotechnology merchandise have to don't forget any precise houses and behaviors that the software of nanotechnology might also additionally impart (Guidance for Industry, FDA, 2014).[6]

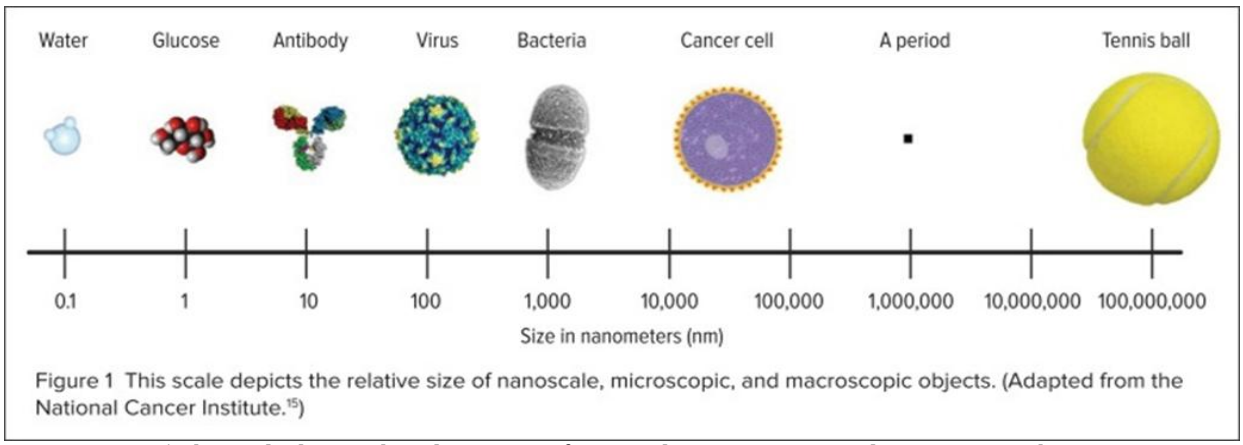

Figure 1 This scale depicts the relative size of nanoscale, microscopic, and macroscopic objects. (Adapted from the National Cancer Institute.[15])

Fig 1| This scale depicts the relative size of nanoscale, microscopic, and macroscopic objects

Nanotechnology Products on the Market:

Nanotechnology has the potential to spread widelyProduct range including pharmaceuticals, electronics, cosmetics and food1,13-15. According toEmerging Countries ProjectNanotechnology at Woodrow Wilson International CenterOver 800 products based on nanotechnology for academics Already on the market.9Nanotechnology is used in laptopsPersonal computers, mobile phones, digital cameras, water purification systems,Nanotechnology research is also ongoing.Improving the bioavailability of dietary nutrients and developing foodsPackaging that detects and prevents spoilage.

Projected Growth of Nanotechnology:

Nanotechnology has additionally been implemented to enhance some of clinical merchandise and processes;[7] those encompass drugs, clinical imaging, antimicrobial materials, clinical devices, sunscreens, burn and wound dressings, dental-bonding agents, sunscreens, and defensive coatings for eyeglasses.[7]Nanotechnology has stepped forward drug focused on and bioavailability, diagnostic imaging, biomarker detection sensitivity, and drug-transport efficiency.[8] Nanotechnology has the capability for use in a extensive variety of merchandise, which includes medicines, electronics, cosmetics and foods.[9,10,11] Some nanomedicines which can be presently available in the marketplace encompass doxorubicin HCl liposome injection (Doxil, Ortho

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Biotech) for ovarian cancer; daunorubicin citrate liposome injection (DaunoXome, Diatos) for superior AIDS-associated Kaposi's sarcoma; and amphotericin B liposome injection (AmBisome, Gilead) for fungal infections.[12,13]

According to the US National Science Foundation (NSF), by 2020, one-third of patents and start-ups in the nanotechnology field will involve biomedical applications.[14]

The NSF also predicts that nearly half of future pharmaceuticals will contain some form of nanotechnology component.[15]

III. Physical Features of Nanoparticles

The physical characteristics of NPs can differ in many ways that influence function. A discussion of several of these physical features follows

Size

NPs are small in nature and can be particulates as small as 5 meters (μm) in size, but have at least one dimension in the range of 1–100 nm. [17]"Agglomerate means particles that are tightly bound or fused together"—andthe external surface area may be less than the sum of the surface areas of the individual particles.[18] They can retain the properties of unbound particles and can break down to nanosizes.[19]

Surface Area

A characteristic of NPs that gives them unique physical properties is their large surface area relative to size. Increased surface area means a greater proportion of atoms on the surface of the particle compared to the core. This phenomenon makes NPs more reactive compared to their conventional larger molecules and solid counterparts. The increased surface area is also responsible for the enhanced water solubility and bioavailability that NPs often exhibit.[20] This phenomenon makes NPs more reactive compared to their traditional larger molecule and solid counterparts. The increased surface area is also responsible for the increased water solubility and bioavailability commonly found in NPs. Even if the surface area related to volume is smaller than the specified 60 m2/cm3, the particle size distribution makes it

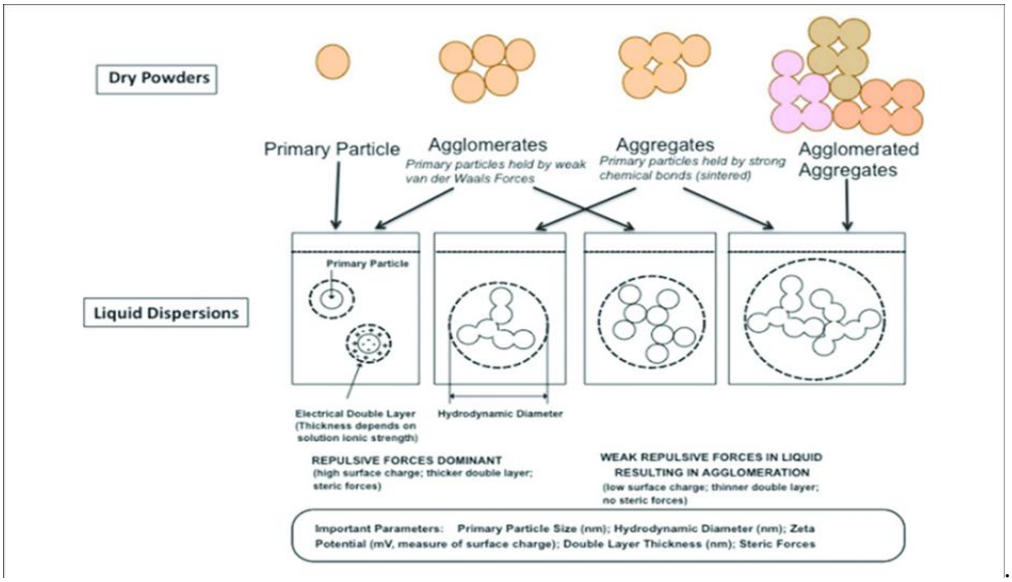

fig2

Schematic representation of the different forms of particles: primary particle, aggregate, and agglomerate (reproduced with permission from Oberdörster,2010)

Shape

NPs come in a variety of shapes, including spheres, discs, hemispheres, cylinders, cones, tubes, and wires.6,9 NPs can also be hollow, porous, or solid.[22] These characteristics of NPs can be selected on the basis of interactivity, loading capacity, and transport capabilities.6 For example, a hollow NP may be an attractive carrier for drug therapies or imaging contrast agents.[16]

Permeability

When properly designed, the small size of NPs allows them to cross physiological barriers and deliver drugs to sites normally inaccessible by conventional means. For example, the increased

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permeability of NPs may enable the delivery of anticancer drugs to tumors by passing through angiogenic pores less than 1 μm in diameter. Enhanced permeability of NPs may also allow them to cross the blood-brain barrier using different uptake mechanisms.[16]

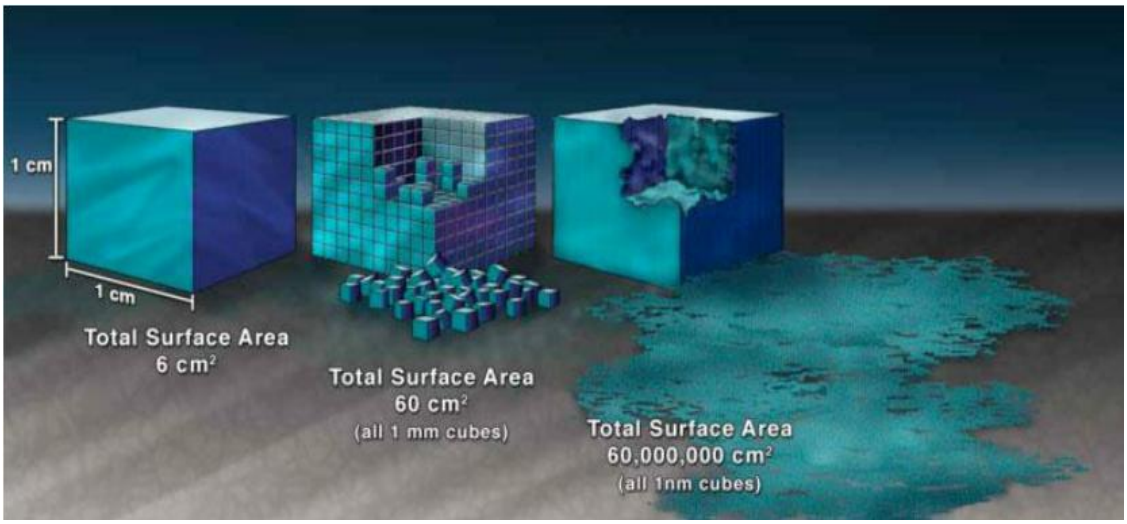

Fig 3 Illustration depicting the exponential increase in surface area that occurs with nanoscale materials. (Adapted from the National Technology Initiative.)[37]

IV. Specific Nanoparticles and Materials

A wide variety of NPs and materials are used in nanomedicine, depending on the application.among the most common using Liposomes, Polymers, Quantum Dots (QDs) and Iron Oxide(IO) particles, carbon nanotubes and nanoshells.[16]

Liposomes

Liposomes are spherical vesicles composed of a lipid bilayerhave a membrane and an empty core, usually aqueous solution.[13]Liposomes are typically 90–150 nm in diameter, slightly larger than conventional NPs. Liposomes are often designed to carry surface-bound biomolecules (eg, monoclonal antibodies,antigens) as ligands.[13]

Liposomes are often used in nanomedicine research.They have many unique properties.Components of liposomesSimilar to natural human cell membranes. so lend meLiposomal drug delivery with multiple inherent advantages.Liposomecirculate in the bloodstream for a relatively long time. It is a non-liposomal drug and provides a longer therapeutic effect.[13]Liposomes also accumulate in tumors and sites of infection.Localize them naturally and deliver higher concentrations of active substances to themObjectives. Liposomes are either hydrophilic or carrier and delivery.Hydrophobic treatment that can be stored in an empty core.[16] Using lipids with different fatty acid chain lengths allows scientists to do thisto construct temperature- or pH-sensitive liposomes,Allow only controlled release of contentWhen exposed to special environmental conditions.[13]

Polymers

Safety and efficacy data unlike other materialsMany polymers already exist. Hence the polymer NPsWidely used in nanomedical research.3Polymer NPs areManufactured in various grades and sizes.10 nm to 1 μm.[12,13] Some polymeric NPs can facilitate drug release[12],[13,16]Therefore, macromolecular NPs are considered promising carriers for many patients.Drugs, including those used for cancer and cardiovascular diseasetreatment of disease and diabetes; bone healing therapy; andImmunization.[12]Contrast agents can also be conjugatedIt is the surface of polymer NPs and can be used for diagnostic imaging.[13]

Biodegradable polymers are of particular interest because they are completely metabolized and eliminated from the body.6 Poly-lactic-co-glycolic acid (PLGA) is of particular interest.Examples of biodegradable polymers as relative proportions of polylactic acid (PLA) and polyglycolic acid (PGA) can be used to fine-tune the biodegradability of PLGA.[16]

V. Nanomedicine platforms/ OPPORTUNITIES

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Nanotechnology has made important contributions to oncology over the past several decades (FIG. 2; TABLE 1). Liposomes (for example, liposomal doxorubicin (LD); Doxil and Myocet) were the first class of therapeutic NPs to receive clinical approval for cancer.

Treatment23 and along with other lipid-based NPs, still represent a large proportion of clinical-stage nanotherapeutics. Although encapsulating drugs in liposomes has been broadly shown to improve PK and biodistribution, as yet no marketed liposomal therapeutic agents have exhibited an overall survival (OS) benefit when directly compared with the conventional parent drug.[24]

More intriguingly, our understanding of nano–bio interactions and the arsenal of nanomedicine platforms are expanding rapidly. The total number of papers related to 'nanoparticle' on PubMed nearly doubled every 2 years between 2000 and 2014, surpassing the remarkable rise of the number of publications on 'monoclonal antibody' (mAb) in the 1980s. In the case of mAb this translated to the development of important therapeutics, and we expect a similar transformative impact from the rise of nanomedicine in the years to come.

Beyond their widely reported use as carriers for chemotherapeutics, NPs have shown potential for the delivery of various new anticancer therapeutic agents, including molecularly targeted agents,[24] antisense oligonucleotides,[25,26] small interfering RNA (siRNA), Examples include the use of adeno-associated virus, approved by the European Commission for lipoprotein lipase deficiency[27] entivirus currently in various clinical trials for cell-based gene therapy and immunotherapy of various diseases including cancer[28] and engineered plant viruses (for example, tobacco mosaic virus and potato virus X) for cancer therapy in animal models.[29,30]

We are also already seeing in-depth innovation in nanomedicine strategies. By integrating diagnostic and therapeutic functions into a single NP formulation, theranostic nanomedicine offers a promising strategy to monitor the PK and accumulation of therapeutics and the progression of disease, giving important insights into heterogeneities both within tumours and between patients for potential personalized treatment.[30]

We have also seen profound innovation in nanomedicine strategy. By integrating diagnostics and therapeutic functions in a single NP formulation, therapeutic nanomedicine offers a promising strategy for monitor thepharmacokinetics and accumulation of therapeutic drugs and disease progression, providing important information in heterogeneity both within the tumorand between patients forpersonalized treatment.[38,39]

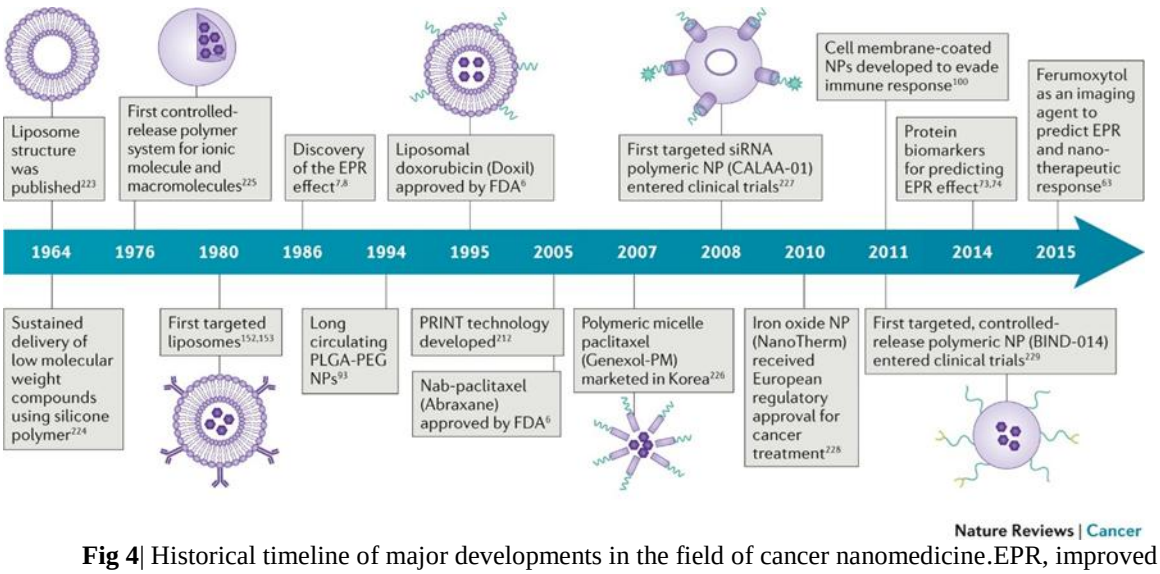

Fig 4| Historical timeline of major developments in the field of cancer nanomedicine.EPR, improved permeability and retention. FDA, US Food and Drug Administration; nab, albumin-binding nanoparticles. NP, nanoparticles. PLGA-PEG, poly(d,l-lactic-co-glycolic acid)-b-poly(ethylene glycol); PRINT, replication of particles in a non-wetting matrix.siRNA, small interfering RNA.

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reviews and websites of pharmaceutical companies supplying/developing these drugs).

Drug product	Active ingredient	Manufacturer	Indications	FDA approved date/clinical trial status
Doxil (Caelyx)	Pegylated doxorubicin	Orthobiotech, Schering-Plough	Ovarian/breast cancer	November 1995
Abraxane	Albumin-bound Paclitaxel nanospheres.	Abraxis Bioscience, Astrazeneca	Various cancers	Jan-05
	Nab paclitaxel in combination with gemcitabine	Celgene	Metastatic pancreatic cancer	September 2013
Myocet	Liposome-encapsulated Doxorubicin	Elan Pharmaceuticals / Sopherion Therapeutics	Breast cancer	2000, Approved in Europe and Canada
DaunoXome	Liposome-encapsulated Daunorubicin	Gilead Science	HIV-related Kaposi sarcoma	Apr-96
DepoCyt	Liposomal Cytarabine	Skye Pharma, Enzon	Lymphomatous meningitis	Apr-99
Oncaspar	PEGasparaginase	Enzon	Acute Lymphocytic Leukemia	Feb-94
Onco-TCS	Liposomal Vincristine	Inex	Non-Hodgkin Lymphoma	In clinical phase I/II
LEP-ETU	Liposomal Paclitaxel	Neopharma	Ovarian/breast/lung cancers	In clinical phase I/II
Aroplatin	Liposomal Cisplatin analog	Antigenics, Inc.	Colorectal cancer	In clinical phase I/II
OSI-211	Liposomal Lurtotecan	OSI	Lung cancer/recurrent ovarian	In clinical phase II
SPI-77	Stealth Liposomal Cisplatin	Alza	Head & Neck cancer/Lung cancer	In clinical Phase III
EndoTAG-I	Paclitaxel	Medigene/SynCore Biotechnology	Breast cancer/Pancreatic cancer	In clinical phase II
Marqibo	Vincristine	Talon Therapeutics	Philadelphia chromosome-negative lymphoblastic leukemia	Aug-12
ThermoDox	Doxorubicin	Celsion Corporation	Hepatocellular carcinoma	In clinical phase III

Table 1 | Examples of clinical-stage nanomedicines for cancer therapy.

In addition to drug delivery, nanotechnology is gaining importance in the cancer field immunotherapy. NPs are becoming more and more attractive. As a potent antigen or adjuvant carrier for the development of synthetic vaccines with improved tissue penetration and/or lymphatic access Sustained release of antigen by antigen-presenting

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cellsor adjuvant and NP-mediated phagosomeCross-presentation antigens. [40,41,42]

VI. Challenges In Pharmaceutical Development

The transition of nanotechnology from the bench to the market has presented several challenges. General aspects to consider in the development ofphysicochemical characterization, biocompatibility and nanotoxicology evaluation, pharmacokinetic and pharmacodynamic evaluation, process control and scale-up reproducibility in nanomedicine are described below. section.

Physicochemical Characterization

Characterization of nanomedicine is necessary to understand its behavior in the human body and provide guidance for process control and safety assessment. Figure 4 | Schematic representation of the various 'barriers' encountered during the development of nanomedical products. This characterization is not based on consensus regarding the number of parameters required for an accurate and complete characterization. The use of internationally standardized methods and reference nanomaterials is key to reconciling all differing opinions on this topic.[32]

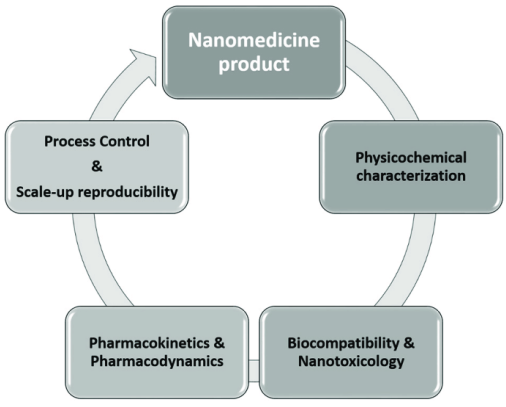

Fig 5| Schematic representation of the several "barriers" found throughout the development of a nanomedicine product.

In terms of chemical composition, nanomaterials can be classified as organic, inorganic, crystalline, or amorphous particles, organized as single particles, aggregates, agglomerated powders, or dispersed in matrices, suspensions, emulsions, nanosheets, or films.[33]

Counting Methods

Counting methods allow us to individualize, measure different sizes, and visualize morphologies of the different particles that make up nanomaterials. Particle visualization is preferably performed using microscopy, including several variations of these techniques. Transmission Electron Microscopy (TEM), High Resolution TEM, Scanning Electron Microscopy (SEM), Cryo-SEM, Atomic Force Microscopy and Particle Tracking Analysis are just a few examples. A major drawback of these methods is their operation at high vacuum, but recent developments in cryo-SEM.[34]

Fractionation Methods

These methods include two sample processing steps. The particles are separated into monodisperse fractions and each fraction is subsequently detected. Field flow fractionation(FFF), analytical centrifugation (AC), and differential mobility analysis are some of the techniques that can be applied. FFF techniques include various methods of separating particles according to an applied force field. AC separates particles by centrifugal sedimentation.[35]

Ensemble Methods

The ensemble method allows you to specify intensity-weighted particle sizes. The evolution of the measured signal over time gives the size distribution of the particles extracted from the combined signal. Examples are dynamic light scattering (DLS), small-angle X-ray scattering (SAXS), and X-ray diffraction (XRD). DLS and QELS are based on the Brownian motion of the sample. XRD is an excellent technique for obtaining information on chemical composition, crystalstructure, andphysical properties (35).

Nanomedicine Applications

Nanomedicine applications are grouped below in three interrelated areas: analytical/diagnostic tools, drug delivery and regenerative medicine (Figure 5).

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Volume 3, Issue 2, Mar.-Apr. 2023, pp: 444-454 www.ijhssm.org

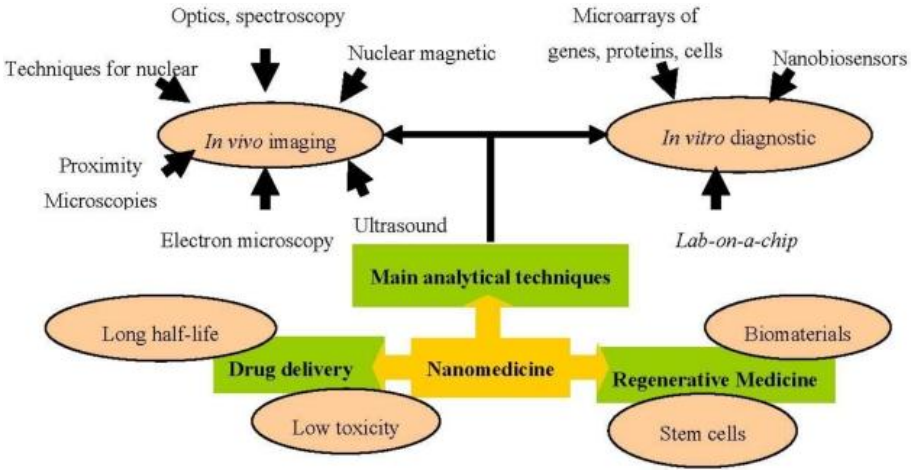

Fig 6 | Nanomedicine application areas.

Analytical and Diagnostic Tools

Nanodiagnosis is defined as the use of nanotechnology for clinical diagnostic purposes,[43,44] was developed to meet the demand for increased sensitivity and early disease detection in clinical diagnostics.

Applications of micro- and nano-biotechnology in medical diagnostics can be divided into his two broad categories: in vitro diagnostics and in vivo imaging. Research in this area is highly interdisciplinary, with close links between diagnostics, drug delivery, and regenerative medicine. These are described in the next section.

Nanobiosensor

macrophage inflammatory proteins, aptamers,peptide nucleic acid) recognition elements.[44,45] Interaction between connectionsMicroorganism of interest and recognition element generate one or more mutationsPhysico-chemical properties (e.g. pH, electron transfer, heat, potential, mass, optical properties, etc.)recognized by the converter. The resulting electronic signal indicates the presence of the analytethe target and its concentration in the sample. These sensors can be electronically controlled to respondSingle-molecule binding. Prototype sensors have been successfully used to detect nucleic acids.proteins and ions. They can be operated in the liquid or gas phase, which opens up a great variety of possibilities.downstream application. These detection systems use low-cost, low-voltage measurement methodsDetecting binding events directly eliminates the need for expensive, complex, and time-consuming steps.

B. When using chemical labels, e.g. fluorescent dyes, or for bulky and expensive optical detection systems.

This makes these sensors cheap to manufacture and portable[43]. Therefore, the nanobiosensorIt will revolutionize in vitro diagnostics of disease and have a profound impact on human health. SheIt enables healthcare professionals to simultaneously measure multiple clinical parameters in a simple way.Effective and Accurate Testing. These devices are ideal for high-throughput screening andDetection of a single disease in different samples or different diseases in a single sample[46]

VII. Problems /issues

The high-risk, high-return global nanotechnology phenomenon is in full swing. Major technological advances at the intersection of engineering, biotechnology, medicine, natural sciences, and information technology are driving new directions in research, education, commercialization, and technology transfer. Of course, nanotechnology will continue down this interdisciplinary path.

There is great excitement and anticipation about the potential impact of nanotechnology on all aspects of society. Early predictions for commercialization efforts are encouraging, but bottlenecks also exist. Some formidable challenges include legal, environmental, safety, ethical, and regulatory issues, as well as a new thicket of overlapping patent claims.[36]

Some of the greatest impacts of nanotechnology have occurred in the context of biology, biotechnology, and medicine. This field of nanotechnology is commonly referred to as

nanomedicine and sometimes commonly referred to as bio-nanotechnology. Several nanomedicine-related products are already on the market4, and many other potential applications are being investigated and developed But will nanomedicine make a valuable contribution to medicine and healthcare in the long term? Will nanomedicine bring many almost incremental improvements to existing technology, or will it catalyze a large-scale technological and medical revolution? It is difficult to predict whether it will function as The current state of nanomedicine, though exciting in its own right, is clearly a milestone on the road to introducing truly revolutionary technology. Given the complexity of clinical trials and the reluctance of innovative technologies to collaborate, these are only done over decades. However, there are some bright spots where development is accelerating. In this essay he will focus on one area of nanomedicine that has already produced significant results.

Drug delivery accounts for 78% of global nanomedicine sales and 58% of patent applications worldwide. For example, site-specific drug delivery systems with the potential to address unmet medical needs and personalized medicine (as a result of advances in pharmacogenetics and pharmacogenomics) are on the horizon. Another more futuristic approach to targeted drug delivery is the 'nanofactory'. Here, biomolecules found in vivo can be converted into active biotherapeutics to target local pathologies of interest

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VIII. CONCLUSION AND PROSPECTS

The reformulation of existing drugs and the development of new drugs has been greatly facilitated by increasing research in nanomedicine. Changes in toxicity, solubility, and bioavailability profiles are some of the modifications that nanotechnology introduces to drugs.

EMA recognizes the importance of making recommendations to guide the development and approval of nanomedicine. Nanotechnology methods for the development of nanomedicine pose new challenges to the currently used regulatory framework.

Over the past decades, we have helped bring multiple applications of nanomedicine to clinical use, from medical devices to nanopharmaceuticals. However, there is still a long way to go before nanomedicine is fully regulated. From creating harmonized definitions across Europe to developing protocols for the characterization, evaluation and process control of nanomedicine. A generally accepted definition of nanomedicine does not yet exist and may not be feasible or even useful at all. These agents cover a wide range of types and structures and are used in various indications of acute and chronic diseases. In addition, ongoing research leads to the emergence of more sophisticated nanostructure designs that require a thorough understanding of the pharmacokinetic and pharmacodynamic properties of nanomedicine as determined by their chemical composition and physicochemical properties. are rapidly connecting, thus posing additional regulatory challenges.

Equivalence of complex pharmaceuticals is another issue that poses scientific and regulatory challenges. Sufficient similarity evidence should be gathered in a careful, step-by-step, preferably consensual, process. With all the scientific and technological innovations, the number of nanotechnology-based medicines is expected to increase in the coming years. Due to the common understanding among various stakeholders, the development of guidelines for the development and evaluation of nanomedicine is essential to enable new and innovative nanomedicine in the pharmaceutical market. This process should be conducted in conjunction with interagency harmonization efforts to support rational decisions related to scientific, regulatory, funding and market access issues.

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