

**Review Article** 

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### An Extensive Review Study Of Solely Cloned Identical Antibodies -Monoclonal Antibodies

### Pooja Tiwari, Patel Pratixa, Mishra Satyam, Yadav Rubi

Rofel Shri G. M. Bilakhia college of pharmacy, namdha road vapi, valsad, gujarat-396191

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#### ABSTRACT

Since they were developed, monoclonal antibodies have been studied for potential therapeutic use. The forefront of modern medicine's move towards a new era of individualized therapy is the use of monoclonal antibodies to treat a range of ailments. Monoclonal antibodies can be employed for therapeutic, imaging, and diagnostic applications and have a very high clinical significance. Monoclonal antibodies have a variety of intriguing potential clinical uses. Because the monoclonal antibodies used were either produced in mice or rats, there is currently a risk of disease transfer from mice to people. There is no proof that the antibodies created by this procedure are completely virus-free, despite the refining process. Hybridoma technology is a common method for making monoclonal antibodies. Immunized mice are removed from their antibody-producing B lymphocytes and combined with immortal myeloma cell lines to produce hybrid cells, also referred to as hybridoma cell lines. One of the cutting-edge methods that have assisted in easing some of these limitations is genetic engineering. Modern methods are being developed to make lab-made monoclonal antibodies as similar to human as possible. This overview discusses the creation, therapeutic significance, and possible applications of monoclonal antibodies as well as their benefits and challenges. This review will focus on the historical development of monoclonal antibodies, including how it transitioned from time-consuming animal models to a more effective phage display system, some of the major clinical and financial drawbacks, and potential future innovations that are currently being studied to maximize their efficacy for use in the clinic. This review article has been prepared using various references from Google Scholar and Search Engine.

\*Corresponding Author: Pooja Tiwari Address: Rofel Shri G. M. Bilakhia college of pharmacy, namdha road vapi, valsad, gujarat-396191 Email : poojatiwari6520@gmail.com

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### **INTRODUCTION**

Monoclonal Antibodies (MAb) are defined as antibodies which are produced by single clone of cell or cell line which contain identical antibody molecules. They are basically used in the major fields like biomedical research, disease diagnosis and treatment, including for infections and cancer. The cells can be grown using either of these two techniques to produce the desired MAb: - by tissue culture (in-vitro) OR by injecting the desired MAb into the prepared mouse's abdominal cavity (invivo).<sup>[1]</sup>

The immune systems of vertebrates create antibodies, also known as immunoglobulin (Igs), which are crucial for preventing infections brought on by foreign substances such as bacteria and viruses. These are substantial glycoproteins with a "Y" shape that specialize in binding to foreign molecules or antigens.<sup>[2]</sup> Antigens are substances that satisfy the two immunological criteria of immunogenicity (the capacity of an antigen to activate the immune system in the body) and antigenicity (ability of antigen to combine specifically to antibody).<sup>[3]</sup> High affinity and specificity are the most crucial characteristics of antigen-antibody binding. An epitope in an antigen and an antigen-binding site in an antibody are said to bind together with a certain degree of affinity (paratope).<sup>[2]</sup>

### 2. MARKET AND PRODUCTION

Kohler and Milstein produced the first monoclonal antibody in 1975, which was utilized for immunotherapy and diagnostic purposes.<sup>[4]</sup> Humanized monoclonal antibodies are now the fastest-growing subset of biotechnology due to the explosive rise of genome sequencing and the translation of biomedical research into clinical application.<sup>[5]</sup> The market for antibodies is estimated to be worth \$20 billion annually worldwide. <sup>[6]</sup> The FDA has approved the use of about 30 monoclonal antibodies in treating a range of human diseases. <sup>[7]</sup> Monoclonal antibodies can be produced :-

### 2.1 BY HYBRIDOMA TECHNOLOGY

This method was developed in 1975 and was the result of the fusion of murine lymphocytes that secrete antibodies with myeloma cells in mice.<sup>[8,9,10]</sup>

Monoclonal antibodies are produced from a single B-cell clone and are monovalent antibodies that bind to the same epitope.

The process of producing hybridoma includes:

(a) Immunization of a particular species against a particular antigen epitope and collection of B-lymphocytes from the animal's spleen.

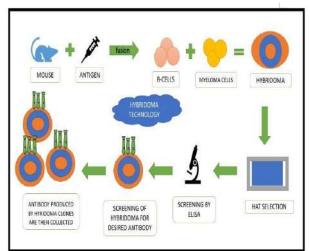
(b) The immortal myeloma cell line that lacks the HGPRT (Hypoxanthine Guanine Phospho-Ribosyl Transferase) gene and doesn't include any other immunoglobulin-producing cells is subsequently fused with these B-lymphocytes via chemical or virus-induced procedures.

(c) These hybridoma cells are then cultured invitro in selective medium, or medium containing hypoxanthine-aminopterin-thymidine, where only hybridoma cells (i.e., cells formed from the fusion of B-lymphocytes and myeloma cells) survive because they have the properties of immortality inherited from myeloma cells as well as resistance to B-lymphocytes (as there is lack of HGPRT in myeloma cells they cannot synthesis nucleotides by de novo as it is inhibited by aminopterin in the selective medium). <sup>[11]</sup>

At the beginning, this culture will contain a variety of antibodies derived from various primary Blymphocyte clones, each of which secretes a unique, particular antibody into the culture media, making them polyclonal. The appropriate Blymphocytes can be cultivated from positive wells and then re-cloned and checked for activity. The desired clone can be isolated by dilution into several culture wells. Monoclonal antibodies and positive hybridomas can be kept apart in liquid nitrogen storage. <sup>[12]</sup>



### STEPS :-



### Fig-1 Steps of hybridoma technology

- 1. Immunization
- 2. Isolation of B-lymphocytes or spleen cells
- 3. Preparation of myeloma cell liners
- 4. Cell fusion
- 5. Hybridoma selection
- 6. Screening of hybridoma cells
- 7. Cloning and propagation of hybridoma cells.<sup>[13]</sup>

### 2.2. BY PHAGE DISPLAY METHOD

This is an additional technique for the creation of monoclonal antibodies. <sup>[14]</sup>

It involves-

(a) Isolating B-lymphocytes from human blood, separating the mRNA (messenger- Ribonucleic acid), and using PCR (Polymerase Chain Reaction) to turn it into cDNA (complementary deoxyribonucleic acid) in order to amplify the VH(Variable fragment Heavy chain) and VL(Variable fragment Light chain) portions.

(b) Before being utilized to infect Escherichia coli (E.coli) and form a library, these segments can be cloned into a vector alongside the bacteriophage's protein.

(c) Bacteriophages with VH and VL segments can then be secreted by E. coli as a component of the bacteriophage coat.

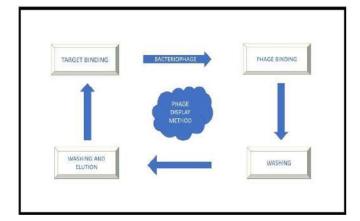
(d) The bacteriophage can then be used to reinoculate E.coli with specific VH and VL segments against the antigen. It is thus possible to separate and sequence plasmid-containing cells. <sup>[15,16]</sup>

VH and VL gene libraries can be created from: -•Immunized individuals who have developed an immunological response to a particular antigen,

•non immunized donors,

•using antibody fragments from a synthetic library. [17,18]





### Fig-2 Steps of phage display method

- 1. Target binding
- 2. Phage binding
- 3. Washing
- 4. Elution and Amplification. <sup>[19]</sup>

In summary, the advantages and disadvantages of both the methods are listed in table 1.

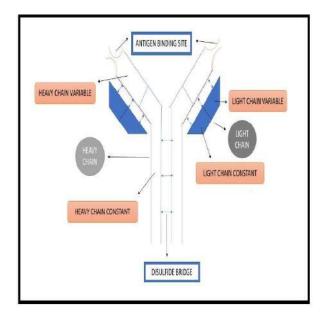


METHOD	ADVANTAGES	DISADVANTAGES		
HYBRIDOMA	Large scale production	Long generation time		
TECHNIQUE	High antibody yield	Incomplete epitope		
	High specificity	identification		
	High antibody sensitivity	Often requires		
	Lower cost	humanization		
PHAGE	Great control over selection process	More expensive		
DISPLAY	Easy to screen large diversity of	Binders may lower affinity		
	clone	Technically more difficult		
	Possible to screen toxic antigens			
	No clone viability issues			
	No immunogenicity issues			
	Direct access to sequence			
	No animal use for new libraries			

Table-1 Advantages and Disadvantages of production methods. <sup>[20]</sup>

### **3. ANTIBODY STRUCTURE**

Antibodies are Y-shaped proteins consisting of heavy and light chains, which have different ends from one antibody to the next.



### Fig-3 Antibody structure with its binding sites

Disulfide bonds bind the two heavy and two light chains together. Each heavy-light chain mixture binds to a particular antigen binding site. These glycoprotein chains are folded into 110 amino acid domains that are twisted into immunoglobulins, which are held together by disulfide linkages. A constant domain and a variable domain are present in each chain to bind the host effector molecule (to bind to target antigen). Light chains have one variable and one constant domain, whereas heavy chains have one variable and three to four constant domains, depending on the isotype class. The antigen is identified by three areas found in each variable domain known as "hypervariable loops" or "complementarity determining regions (CDRs)". The additional amino acids in the variable domain are referred to as framework residues, and they serve as a scaffold to support the loops. The interaction between the CDR amino acid sequences and the targeted antigen is quite varied. <sup>[21]</sup>

Based on the amino acid makeup of their heavy chains, human immunoglobulins are categorized into 5 classes or isotopes –

Mu (µ) denoted as IgM

Alpha ( $\alpha$ ), denoted as IgA

Delta ( $\delta$ ), denoted as IgD

Epsilon ( $\mathcal{E}$ ), denoted as IgE

Gamma (y), denoted as IgG.<sup>[22]</sup>

Types of immunoglobulins with their location and functions are listed in table 2.



TYPES	LOCATION	FUNCTION	
lg A	IT IS PRESENT IN SALIVA, TEARS, AND BREAST MILK.	IT PROVIDE PROTECTION AGAINST PATHOGENS OR FOREIGN SUBSTANCES.	
lg D	IT IS THE PART OF B-CELL RECEPTOR PRESENT IN BODY.	ACTIVATION OF BASOPHILS AND MAST CELLS IS ITS FUNCTION.	
lg E	IT IS ATTACHED TO EFFECTOR CELLS LIKE MAST CELLS AND BASOPHILS .	ALLERGIC REACTIONS ARE DUE TO THIS.	
lg G	IT IS SECRETED BY CELLS OF PLASMA IN BODY.	IT IS ABLE TO REACH FETUS BY CROSSING PLACENTA.	
lg M	IT MAY BE ATTACHED TO B- LYMPHOCYTES OR FOUND INTO BLOOD.	IT IS RESPONSIBLE FOR EARLY IMMUNE STAGE.	

### Table-2 Types, location and functions of different Igs.<sup>[25]</sup>

# 4. FDA REGULATION FOR THE USE OF MAB

Antibodies are regarded as biopharmaceuticals by the FDA (Food and Drug Administration). The Center for Biologics Evaluation and Research (CBER) and the Center for Drug Evaluation and Research (CDER) oversee MAb application submissions . Because viral and cellular DNA from antibody-producing cells with malignant morphologies may be incorporated into host cells following transformation, the agencies recommendations aim to protect human health.

Based on ICH safety criteria, the agencies have also released a guidance document titled S6 Preclinical Safety Assessment of Biotechnology Derived Medicines. The product should have its metabolism, carcinogenicity, and genotoxicity assessed. The guidance also lists the chemicals that must be utilized in the production of monoclonal antibodies. Every class of antibodies, including those made via a phage display technology or transgenic plants and animals, can be tested and manufactured in accordance with FDA guidelines. <sup>[24,25]</sup>

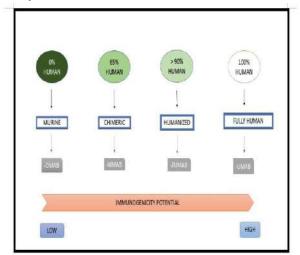
Some of the FDA approved drugs are mentioned in table 3.

DRUGS	TRADE	USES	
	NAME		
Abciximab	ReoPro®	To lessen the chance of	
		heart attack in people	
		who need PCI	
		(percutaneous coronary	
		intervention)	
Basiliximab	Simulect®	To prevent organ	
		(kidney) rejection	
		during transplant	
Cetuximab	Erbitux®	In treatment of	
		colorectal, head and	
		neck cancer	
Daclizumab	Zenapax®	In treatment of multiple	
		sclerosis	
Rituximab	Rituxan®	In treatment of cancer	
		and autoimmune	
		disease like- RA, IBD,	
		multiple sclerosis	

 Table- 3 Some of the FDA approved drugs.
 [26]

Based on the immunogenicity criteria nomenclature of monoclonal antibodies can be of 4 types-

- 1.Murine (0% human)
- 2.Chimeric (65% human)
- 3.Humanized (>90% human)
- 4.Fully human (100% human)



### Fig-4 Schematic representation of MAbs nomenclature

Murine or mouse monoclonal antibody is mainly used for the immunodiagnostic purpose while the others are used for immunotherapy. Murine or mouse monoclonal antibody has higher potential to immunogenicity as compared to fully human



monoclonal antibody which has the lower potential for the immunogenicity. <sup>[28]</sup>

The suffix which shows the degree of human versus non-human components or in other words the nomenclature of MAbs is mentioned in table 4.

TYPES	SUFFIX	EXAMPLES
MURINE	-momab	Moxetumomab
CHIMERIC	-ximab	Rituximab
HUMANIZED	-zumab	Bevacizumab
FULLYHUMAN	-umab	Nivolumab

 Table-4 Nomenclature of MAb. <sup>[29]</sup>

### 5. APPLICATION OF MONOCLONAL ANTIBODIES

#### 5.1-THERAPEUTIC APPLICATIONS 5.1.1 CANCER

Cancer is a disease in which some cells of the body start growing uncontrollably and spreads to different part of the body.<sup>[30]</sup> Anticancer drugs work by the following mechanism-

•Flagging the cancer cells

•Triggering cell-membrane destruction

•Blocking cell growth

•Preventing blood vessel growth

•Blocking immune system inhibitor

•Binding of cancer and immune cells. <sup>[27]</sup>

According to NATIONAL CANCER INSTITUTE,

A TUMOURS (or neoplasm) is a mass of abnormal tissue that develops when cells divide more frequently than they need to or do not die when they ought to. <sup>[33]</sup> Types of tumors are discussed in table 5.

Benign	Pre-malignant	Malignant
=These tumors are not	=In this type, the cells have	=These tumors are
cancerous.	not become cancerous yet but	cancerous.
=They do not spread to other	they can become cancerous	
parts of the body.	potentially.	
=Once removed from the body		=They can spread to different
they do not regrow.		parts of the body.
		=As they spread too other
		parts they become or are life
		threatening.

Table-5 Types of tumors. <sup>[33</sup>

Anticancer drugs with their action, use, and adverse drug reaction (ADR) are listed in table 6.

DRUG	TRADE NAME	MECHANISM OF ACTION	USES	ADR
Atezolizumab	Tecentriq®	It selectively binds to PD- 11 to stop the interaction between PD-1 and B7.1(ie.CD80 receptors) but it still lows interaction between PD-12 and PD-1	carcinoma, NSCLC, SCLC,	Hepatotoxicity, fatigue, Musculo- skeletal pain ,hyper- sensitivity reactions, infusion reaction ,embryo-fetal toxicity.



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Bevacizumab	Avastin®	It binds to circulating VEGF whose receptors are present on endothelial cells, and the binding with these receptors produces angiogenesis. Inhibition of VEGF decreases the formation of new blood vessels ,that plays an important role in growth and spread of cancer cells.	NSCLC ,ovarian cancer, renal	Hepatotoxicity, fatigue, stomach ,bowel or nasal septum perforation ,hemorrhage, renal dysfunction.
Blinatumomab	Blincyto®	It has bispecific reactivity to both CD3 cell surface antigen found on normal T- cells and CD19 antigen which is Overexpressed on B-cell malignancies. The MAb binds to T-cells and bring them in contact with malignant B-cells, allowing them to recognize and eliminate blasts.	Relapsed or refractory acute lymphoblastic leukemia(ALL)	Hepatotoxicity, cutaneous reactions (stevens Johnson syndrome), pancreatitis, neurological toxicities, anemia.
Nivolumab	Opdivo®	Inhibition of PD-1 receptors on the surface of activated T-cells prevent down regulation of activation and proliferation of T-cells by programmed cell death pathway.	hepatocellular, Hodgkin disease, colorectal, gastric,	Musculo-skeletal pain, arthralgia ,hepatitis, nephritis.
Rituximab	Rituxan ®	It induces killing of CD20+ cells via different mechanism including- complement-mediated cytotoxicity (direct effect) and Structural changes ,apoptosis, and sensitization of cancer cells to chemotherapy(indirect effect)	chronic lymphocytic leukemia (CLL) and also for autoimmune	Hepatotoxicity Cutaneous reaction(stevens Johnson syndrome), Reactivation of TB, cardiac arrhythmias, renal toxicity, bowel obstruction.

Table-6 Monoclonal antibodies and their use in cancer treatment. <sup>[31,32]</sup>

### **5.1.2 AUTOIMMUNE DISEASES**

When healthy body tissues are attacked and destroyed by the immune system on its own, autoimmune illnesses or disorders develop. More than 80 different autoimmune disorders exist.

The body triggers a reaction that causes normal tissues to be destroyed when the immune system is unable to distinguish between healthy tissues and potentially dangerous antigens.

Autoimmune disease may result in: -

- The destruction of body tissues
- Abnormal organ growth
- Change in organ function

The body triggers a reaction that causes normal tissues to be destroyed when the immune system is unable to distinguish between healthy tissues and potentially dangerous antigens. The goal of the treatment is to-



• Maintain body's ability to fight disease

Drugs used in different autoimmune diseases are mentioned in table 7.

- Reduce symptoms
- Control the autoimmune process. <sup>[34]</sup>

DRUG	TRADE NAME	MECHANISM OF ACTION	USES	ADR
Adalimumab	Humira® and	It inhibits TNF and blocks its	Rheumatoid arthritis,	Europal
Adaininumad	Imraldi®		· · · · · · · · · · · · · · · · · · ·	Fungal
	IIIIalui®	action on effects of symptom arising from systemic	psoriatic arthritis, Crohn's disease,	infections(histoplasmosis ,candidiasis.)
		inflammation.	ulcerative colitis,	,candidiasis.) Bacterial
		It also plays role in cell survival,	-	
		1 5	juvenile idiopathic arthritis and uveitis	infections(legionella, listeria.)
		proliferation, Differentiation, and cellular	artifitits and uverus	Causes TB and also
		death .		reactivate the latent TB,
		deaui.		
				CVS and neurological disorders and autoimmune
Eculizumab	Soliris®		D	disease (lupus syndrome)
Ecunzumad	Souris®	It is a terminal complement activation inhibitor. The	Paroxysmal	Meningococcal infections,
			nocturnal	streptococcus pneumonia,
		terminal complement complex	hemoglobinuria,	and Users and billing influences
		is a component of innate	Myasthenia gravis,	Hemophilus influenzae
		mechanism which disrupts cell	atypical hemolytic	type B (HIB)
		membrane leading to cell lysis	uremic syndrome and	
		and death.	neuromyelitis optic	
	T 1 0		spectrum disorder.	
Natalizumab	Tysabri®	It reduces the interaction	Multiple sclerosis	Herpes infection,
		between immune cells and	and Crohn's disease.	hepatotoxicity
		adhesion receptors on blood		,hypersensitivity
		vessel walls of the affected		,immunosuppression,
		tissue/organ, thus reducing		thrombocytopenia.
D' 1	D' O	inflammation.		
Rituximab	Rituxan®	It works by targeting proteins	Originally used for	Reaction to infusion like
		called cytokines which are	cancer treatment.	fever.
		responsible for inflammation	Also used in	Pneumonia, UTI,
		caused by immune system		hypersensitivity, change in
		response.	rheumatoid arthritis	BP.
		Rituximab only affects B-cells	along with	
		cytokines at mature stage of	methotrexate.	
		their development.	[26	

 Table -7 Monoclonal antibodies used in autoimmune disorders.
 [35,36]

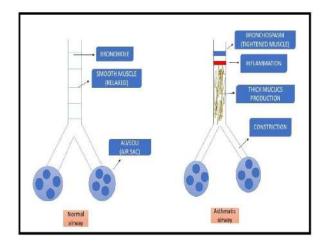
### **5.1.3 ASTHMA**

Asthma is an inflammatory disease of airways to the lungs. It makes breathing difficult and can make some physical activity difficult. The airways get narrow and swollen and are blocked by excess mucus.

When one breathes normally, the muscles around the airways are relaxed and so the air moves in easily. During the asthma attack, 3 things occur-

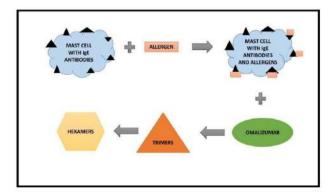
- Bronchospasm (airways muscle contract or tightens)
- Inflammation (lining of airways become swollen)
- Mucus production (thick mucus clogs the airways). <sup>[37]</sup>





## Fig-5 Schematic representation of asthmatic airways

Monoclonal antibody used for the treatment of asthma is OMALIZUMAB (XOLAIR®). It is also used to treat nasal polyps and urticaria (hives). <sup>[38]</sup>



### Fig-6 Mechanism of action of Omalizumab

By generating trimers and hexamers, Omalizumab binds free IgE in the serum. IgE linked to the drug cannot bind to its receptor on mast cells or basophils because the drug binds to IgE at the same place as the high-affinity IgE receptor (Fc-epsilon-RI). <sup>[39]</sup>

Adverse effects :- Anaphylaxis (serious systemic allergic reaction) , cardiovascular or cerebrovascular diseases. <sup>[38]</sup>

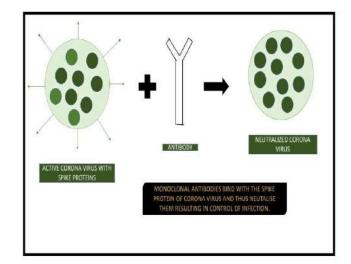
### 5.1.4 COVID-19

In order to combat COVID-19 (Corona Virus Disease – 2019), Monoclonal antibodies functions similar to body's own immune system. Monoclonal antibodies have been successfully

used to assist in lowering hospitalization and emergency room visits ever since they were initially authorized for usage in emergency situations in November 2022.

The spike proteins that protrude from the corona virus which causes COVID-19 are bound by monoclonal antibodies as they enter the body and prevents its entry into cell.

Infection progression is slowed by this.



### Fig-7 Mechanism of action of MAb for covid-19 treatment

Additionally, it can shorten the duration of COVID-19 infection and make other therapies more effective.

Recently, FDA (Food and Drug Administration) has authorized clinical trials of –

### •TOCILIZUMAB (ACTEMRA®)

### •BEBTELOVIMAB<sup>[40]</sup>

•**BAMLANIVIMAB** + **ETESEVIMAB** -used to treat infections that are mild to moderate.

•CASIRIVIMAB + IMDEVIMAB - utilized when there is no need for oxygen therapy but there is a mild to moderate infection and the patient is at danger of acquiring a serious illness. <sup>[41]</sup>

### **5.2– DIAGNOSTIC APPLICATIONS**

The lab diagnosis of numerous diseases has been transformed by monoclonal antibodies. MAbs can be used as diagnostic reagents for biochemical



analysis or as instruments for disease imaging diagnostic for this purpose. <sup>[42]</sup>

### **5.2.1 IN BIOCHEMICAL ANALYSIS**

Radioimmunoassay (RIA) and Enzyme-linked immunosorbent assays (ELISA) are common laboratory diagnostic procedures based on the use of MAbs as reagents. These assays measure the concentration of circulating-

- Hormones like insulin, renin, gastrin, growth hormone, progesterone, thyroid stimulating hormone (TSH), human chorionic gonadotrophin (hCG).
- Several other tissue and cell products like blood clotting factors, blood group antigens, interferon and interleukins, histocompatibility antigens, tumor markers.

Recently, many diagnostic kits using MAbs are available which helps in early diagnosis of-

- Pregnancy (by hCG hormone detection)
- Cancer (by estimation of tumor markers)
- Hormonal disorders (by analysis of thyroxine (T4), triiodothyronine (T3) and TSH for thyroid disorder)
- Infectious disease (by detecting circulatory levels of antigens specific to infectious agent)

### **5.2.2 IN DIAGNOSTIC IMAGING**

Immunoscintigraphy, a method that uses radiolabeled-MAbs, is the name of the procedure employed in illness diagnosis. Iodine-131 and technetium-99 are the most often utilized radioisotopes for tagging MAb. Patients receive intravenously administered doses of the radioisotope-tagged MAb.

These MAbs concentrate at particular locations, such as tumors, which can be identified by imaging the radioactivity. Single photon emission computed tomography (SPECT) cameras have been utilized recently to produce a more sensitive three- dimensional view of the locations localized by radiolabeled-MAbs.

Compared to other imaging methods like CT scanning, ultrasound imaging, and magnetic

resonance imaging, immunoscintigraphy is a more effective diagnostic tool. Since radiolabeled-MAbs are tumor specific, immunoscintigraphy, for instance, can distinguish between malignant and non-cancerous development. Other imaging methods are unable to accomplish this. Cardiovascular disorders, malignancies, and the locations of bacterial infections can all be successfully imaged for diagnosis using monoclonal antibodies.

Disease which can be diagnosed using this includes :-

- Cardiovascular (CVS) disease
  - Myocardial infarction
  - Deep vein thrombosis (DVT)
  - Atherosclerosis
- Cancers
- MABs in hematopoietic malignancies
- Bacterial infections. [42]

### **5.3– PROTEIN PURIFICATION**

It is the procedure for separating valuable proteins from the mixture.<sup>[36]</sup>Because they make it possible to produce purified hormones, DNA polymerase, reverse transcriptase, and antibodies that bind to a specific epitope of interest, purified proteins are utilized as biochemical reagents.

Any protein can be the target of monoclonal antibodies. Additionally, the purification of the protein against which it was grown is easily accomplished using the MAb that was so created. By fusing MAbs to cyanogen bromide-activated Sepharose, MAbs columns can be created (chromatographic matrix). For the immunoaffinity approach of protein purification, the immobilized MAbs are particularly helpful.<sup>[44]</sup>

### 5.4– MISCELLANEOUS APPLICATIONS 5.4.1 CATALYTIC MAbs (ABZYMES)

Enzymes are involved in catalysis. The fact that both enzymes and antibodies are proteins is their main point of connection. Additionally, the bonding of an antibody to its antigen is similar to that of an enzyme to its substrate. Both times, weak



non-covalent contacts and specific, high affinity binding are present (electrostatic, hydrogen and Vander Waals forces). The obvious distinction is that while the antigen attached to antibody is unaffected, the enzyme changes the substrate to a product.

Researches have been enticed to consider the idea of utilizing antibodies in catalysis because of few similarities between the interactions between enzyme and substrate and antibodies and antigens. The catalytic antibodies are known as antibody enzymes or abzymes.

### 5.4.2 AUTOANTIBODY FINGERPRINTING

Several diseases, including rheumatoid arthritis, are caused by autoantibodies. Individual Specific (IS) autoantibodies, a new category, have just been found.

IS-autoantibodies can also be detected and people can be identified using monoclonal antibodies made against them. As a result, this method is known as autoantibody fingerprinting and is helpful for the discovery of criminals, rapists. It is possible to employ the autoantibodies extracted from saliva, sperm, blood, and tears. <sup>[42]</sup>

# 6.ADVANTAGES OF MONOCLONAL ANTIBODIES

Although being expensive, monoclonal antibodies are cheap to produce as compared to other conventional dugs because it is based on tested technology.

- Side effects can be treated or reduced
- Used in treatment of various diseases
- It has high specificity and high affinity thus causes less damage to other cells.

# 7.DISADVANTAGES OF MONOCLONAL ANTIBODIES

- It is a time-consuming process because it takes near about 6-9 months
- It is a very expensive process and needs considerable effort to produce them
- Culture of hybridoma may be contaminated

- Small peptide and fragment antigens may not recognize the original antigen
- System only uses few animals and not suitable for other animals
- More than 99% of the cells do not survive during fusion process. <sup>[44]</sup>

### CONCLUSION

According to their specificity and adaptability, monoclonal antibodies offer a compelling alternative for the development of novel therapeutics for a wide range of common disorders. Targeting antigens or markers on the surface of cancer cells is possible with monoclonal antibodies made by recombinant biotechnology. They choose certain antigens to assault and enlist immune cells to do so. Additionally, they can obstruct cell signaling, which aids in preventing the spread and communication of tumor cells. Approximately 80 MAbs have thus far received FDA approval for the detection, diagnosis, and treatment of a wide range of disorders.

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