Dr B.C Roy College of Pharmacy And Allied Health Sciences

Durgapur (W.B)

Under

Maulana Abul Kalam Azad University of Technology

ASSIGNMENT -I

Topic: Quality By Design

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ROLL NO...18901920015.....

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Paper Code: ...P.T.-611.....

B. Pharm 3rd Year, 6th Semester (Session:...2022-2023....)

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1. What is QBD and QBT? Give the objectives of QBD. What are the different elements of QBD? Discuss about different tools applied in QBD.

→ What is QBD and QBT –

- The Pharmaceutical Quality by Design (QbD) is a systematic approach to development that begins with predefined objectives and emphasizes product and process understanding and process control, based on sound science and quality risk management. Quality by Design (QbD) is emerging to enhance the assurance of safe, effective drug supply to the customer, and also offers premise to significantly improve manufacturing quality performance.
- With Quality by Test (QbT) is manufactured, then tested, then it is determined whether or not the product meets standards. If it doesn't, the manufacture process is started all over again. In QbT, products are tested after they have been manufactured.

→ Give the objectives of QBD –

1. The process is continually monitored and updated to allow for consistent quality over time.

2. More drug availability and less recall.
3. Less validation burden
4. More efficient technology transfer to manufacturing
5. Contributes substantially to realize the better, cheaper and safe mandate.

→ What are the different elements of QBD?

There are five elements of QbD. They are listed below—

1. Quality Target Product Profile (QTPP) and Define Critical Quality Attributes (CQAs)
2. Product Design and Understanding including the identification of critical material attributes (CMAs)
3. Link raw material attributes and process parameters to CQAs.
4. Design and implement a control strategy
5. Manage product lifecycle, including continuous improve-ment.

Another important element is to perform the risk assessment.

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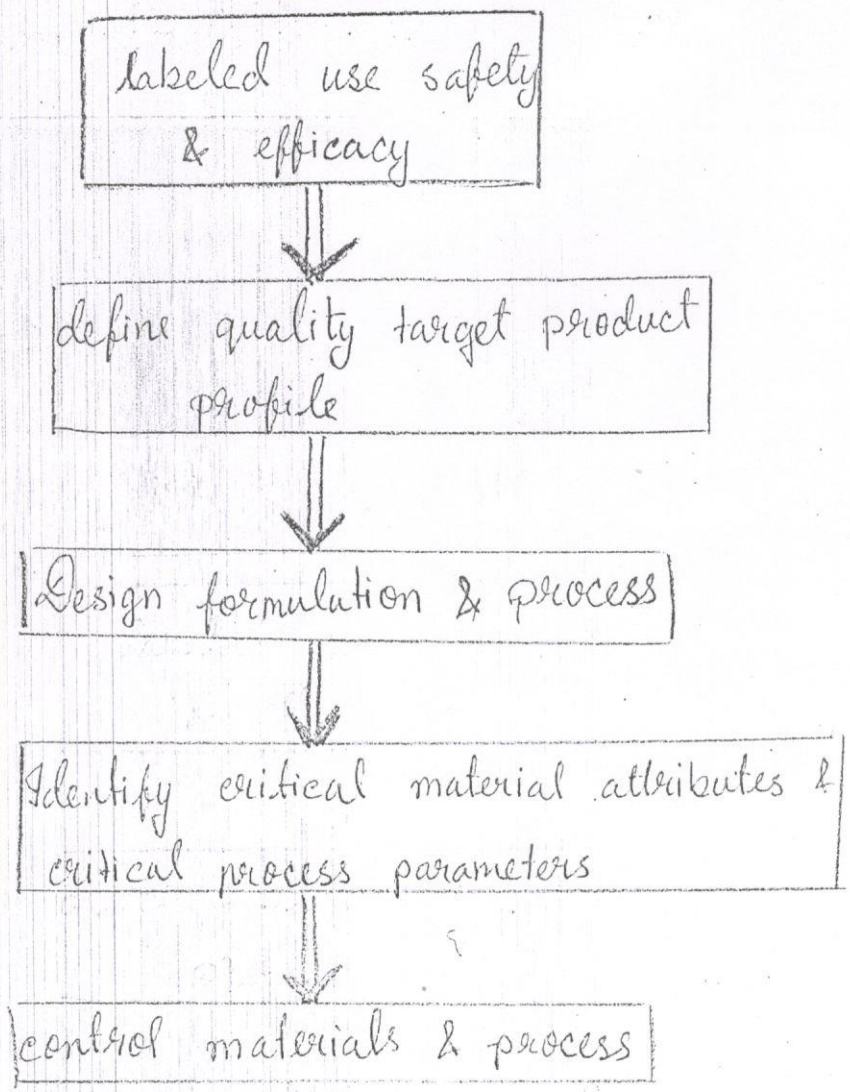


So,

Target ⟶ Design ⟶ Implementation

→ Discuss about different tools applied in QBD.

Design of experiments (DOE), risk assessment and process analytical technology (PAT) are tools that may be used in the QbD process when appropriate. They are not check-box requirements. Control strategy, Product lifecycle Management and continual Improvement, Design Space are also used for developments.

Quality Target Product Profile (QTPP)

⇒ It mainly focus on the safety and efficacy. The Quality target product profile forms the basis of design for the development of the product. It includes —

Dosage strength, Contain closure system, Drug product quality criteria → (e.g - sterility, purity, stability)

The benefits of these is an iterative, learning process for optimizing decision making and the therapeutic outcomes for the patient benefit.

Critical Quality Attributs:

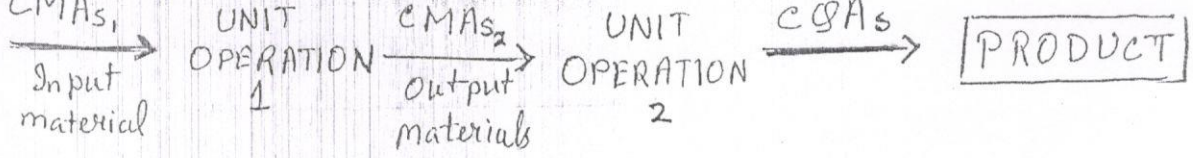
A CQA is a physical, chemical, biological or microbiological property that should be within an appropriate limit, range to ensure the desired product quality. It associated with the drug substance, excipients and drug products. CQAs of solid oral dosage form are typically those aspects affecting product purity, strength. It for other delivery systems can additionally include more products specific aspects sterility for parenterals.

Risk assessment:

Risk assessment is a valuable science-based process used in quality risk management that can aid in identifying which material attributes and process parameters potentially have an

Once the significant parameters are identified they can be further studied (mathematical models, A combination of design of experiments) to achiere a higher level of process understanding.

CMAs, CPPs and CQAs



CONTROL STRATEGY: control Strategy includes input material attributes, inprocess control, Finished product specification, Methods and frequency of monitoring and control.

Root Cause Analysis: RCA is a problem solving technique used to identify the underlying causes of an issue or deviation. It involves a structured approach to identify the immediate, underlying and systemic cause of a problem and to develop effective corrective action.

Overall, these tools are used in QBD to Develop a thorough understanding of the product and process and to ensure that the product consistently meets the desired quality attributes.

So,
QBD has gain importance in the area of pharmaceutical processes like drug development, formulation, analytical method and biopharmaceuticals. QBD approch gives quality product with cost effective procedures and that is the basic need. Moving within design space would not required post approval changes there by

GRADING RUBRICS FOR POWER POINT PRESENTATION

GRADING →	5	4	3	2	1
CONTENT	Content is accurate and information is presented in a logical order.	Content is accurate but some information is not presented in a logical order, but is still generally easy to follow.	Content is accurate but some information is not presented in a logical order making it difficult to follow.	Content is questionable and information is not presented in a logical order making it difficult to follow.	Content is inaccurate and information is not presented in a logical order making it difficult to follow.
SLIDE CREATION	Presentations flows well and logically presentation, reflects extensive use of tools in a creative way, correct number of slides.	Presentations flows well, tools used correctly, correct number of slides, overall presentation is interesting.	Presentations flows well, some tools used to show acceptable understanding, correct number of slides.	Presentations is unorganized, tools are not used in a relevant manner, lacking in number of slides.	Presentation has no flow, no tools used, insufficient number of slides.
SLIDE TRANSITIONS	Transitions are smooth and interesting, transitions enhance the presentation.	Smooth transitions are used on most slides.	Smooth transitions are used on some slides.	Very few transitions are used and/or they distract from the presentation.	No transitions used
MECHANICS	No spelling errors, no grammar errors, text is in authors own words.	Few spelling errors, few grammar errors, text is in authors own words.	Some spelling errors, some grammar errors, text is in authors own words.	Some spelling errors, some grammar errors, Most of text is in authors own words.	Many spelling errors and/or text is copied.
TECHNOLOGY CONNECTION	Comprehensive use of technology in apparent.	General understanding of technology.	Acceptable understanding of technology.	Little understanding of technology.	No understanding of technology.

Shobhan Bose
(IC_Exam)

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23/11/23

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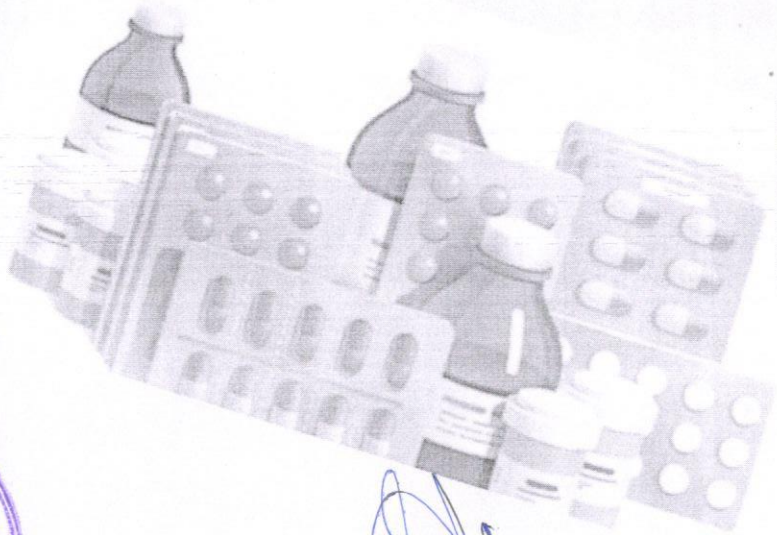
Topic:

Eeffect Of Various Route of Administration on Drug ADME



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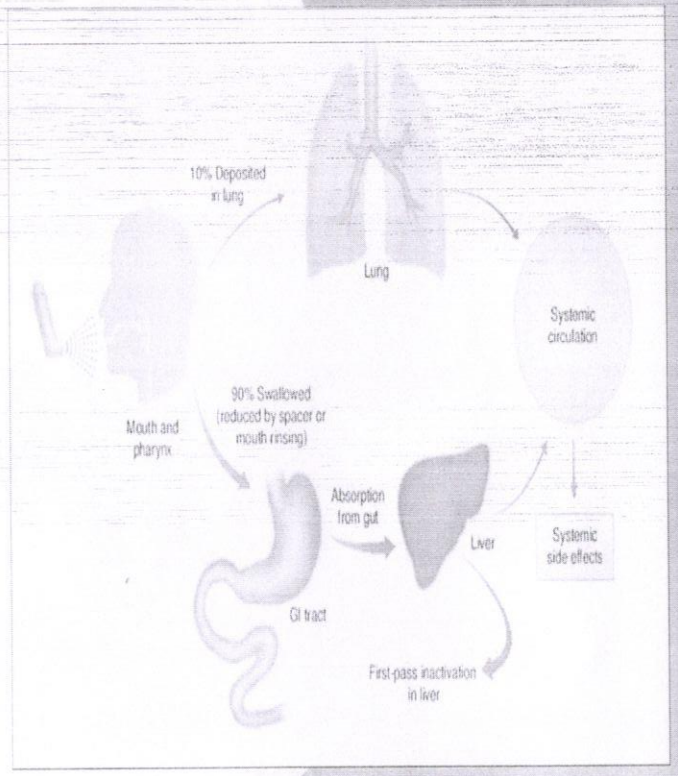
INTRODUCTION:-

- The route of administration is the way through which the dosage form is administered into the body for treatment of various diseases and disorders. Various routes of administrations play a marked role in the bioavailability of the active drug in the body.

- The main aim of drug development is to get a compound that has a therapeutic effect into the form of a medicine we can dose to patients. A drug must reach the site of action, exert its pharmacological effects, and be eliminated in a reasonable timeframe - preferably to allow once-per-day dosing. Characterization of (ADME) properties help to explore and explain how pharmacokinetic processes happen, so as to provide safety considerations of a new drug on which risk-based assessments can be made.



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VARIOUS ROUTES OF DRUG ADMINISTR

The various routes of administrations are classified into following categories: -

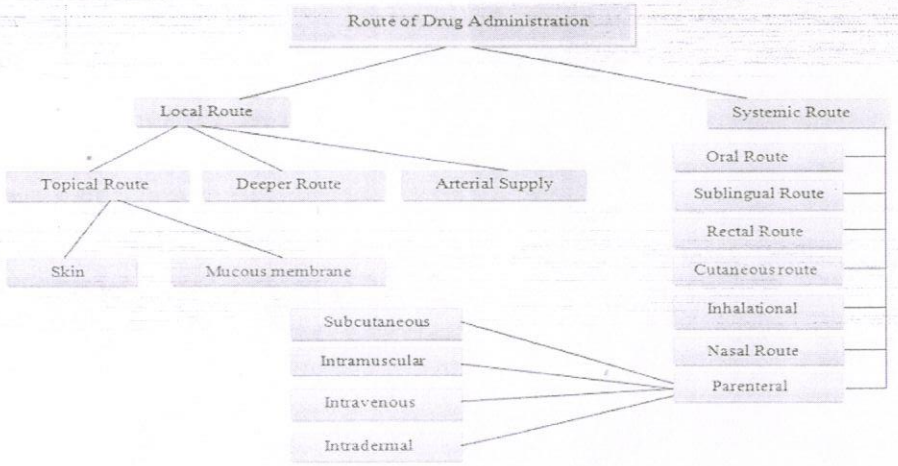
1. Systemic Route

A) Enteral route;

- ✓ Oral
- ✓ Sublingual
- ✓ Rectum

(B) Parenteral route;

- ✓ Intramuscular injection
- ✓ Subcutaneous injection
- ✓ Intravenous injection
- ✓ Intradermal injection



2. TOPICAL

3. INHALATION

- ✓ Vaporization
- ✓ Gas inhalation

ORAL ROUTE:-

- **Absorption:** Oral drugs started its absorption mainly in small intestine. It goes under first pass metabolism by the hepatic portal vein.
- **Distribution:** After the ending of the first pass metabolism its goes into the systemic circulation and some amount of drug which is absorbed in the small intestine that goes into the systemic circulation directly. Then the Heart (left ventricle) pump the blood which carrying the drug molecules goes into the body compartment.
- **Metabolism:** After doing the desired pharmacological activity the drug return to liver where it gets metabolized that's called as biotransformation. Here two phases are happened Phase I- make the drug water soluble by oxidation, reduction, hydrolysis and Phase II- conjugation of functional groups (glucuronidation), which is carried out by CYP450 family enzyme.
- **Excretion:** Then the drug excreted by urine through kidney and faeces or bowel.

Advantages;

- **Convenient-** Can be self administered, pain free, easy to take.
- **Absorption-** Takes place along the whole length of the gastro-intestinal tract.
- **Cheap-** Compared to most other parenteral routes.

Disadvantages;

- **Sometimes inefficient-** only part of the drug may be absorbed
- **Irritation to gastric mucosa-** nausea and vomiting
- Destruction of drugs by gastric acid and digestive juices
- Effect too slow for emergencies

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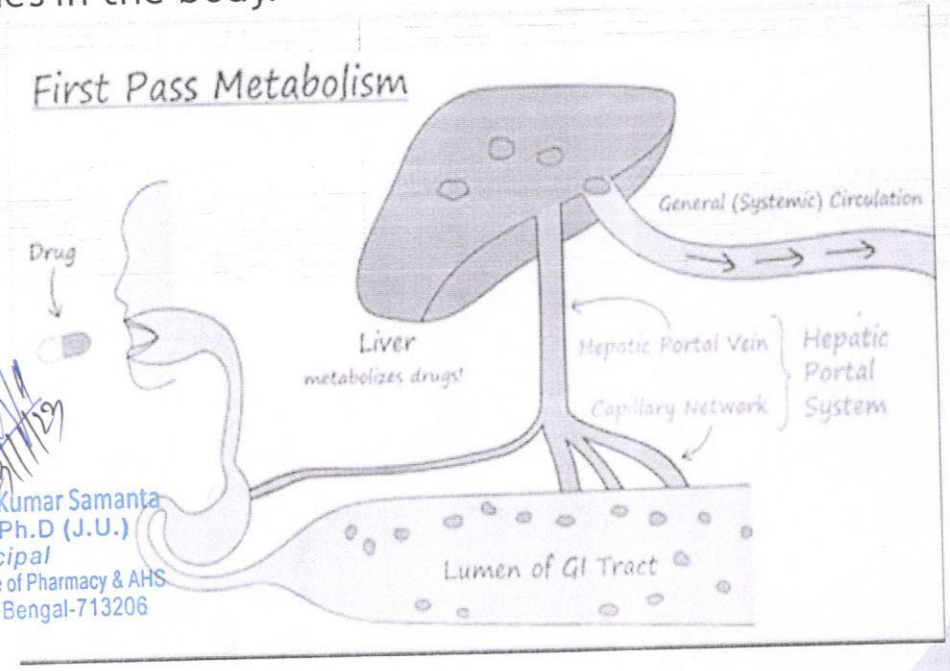
FIRST PASS METABOLISM:-

- The first pass effect is a phenomenon in which a drug gets metabolized at a specific location in the body. That results in a reduced concentration of the active drug upon reaching its site of action or the systemic circulation.
- The first pass effect can occur in the lungs, vasculature, gastrointestinal tract, and other metabolically active tissues in the body.



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MOLECULE DESIGN AND MOLECULAR SCREENING OF VARIOUS COMPOUNDS FOR ALZHEIMER'S DISEASE BY MOLECULAR DOCKING

Submitted by - PRIYA RAY

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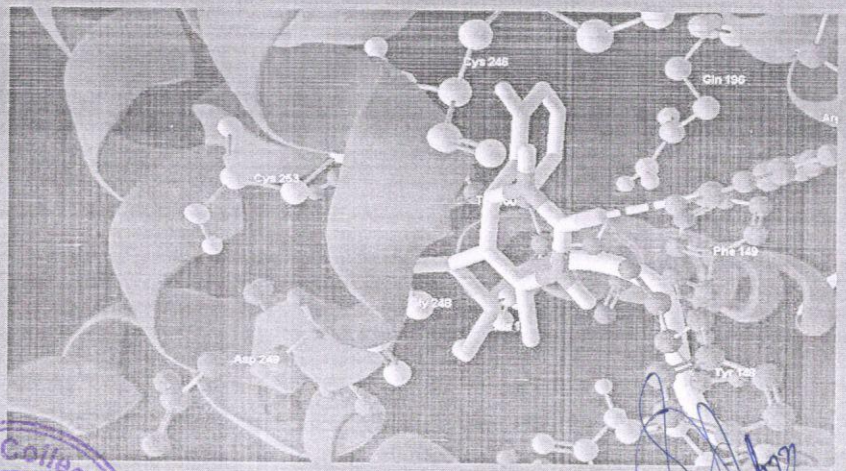

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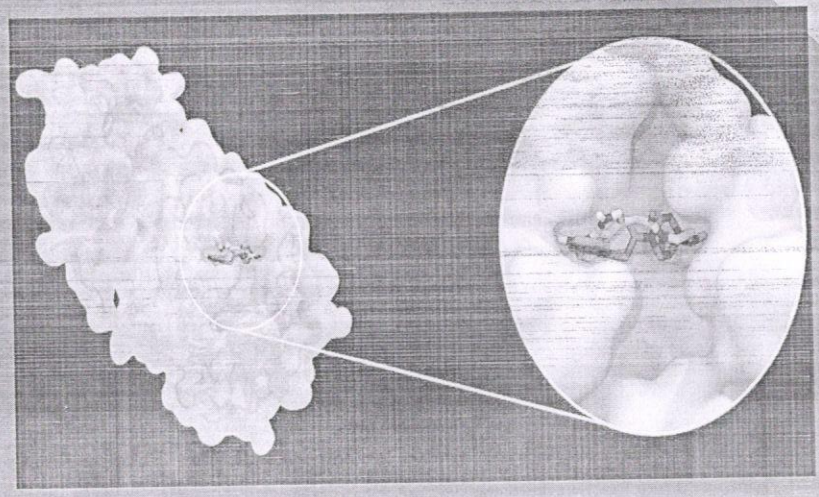
CONTENT:-

- INTRODUCTION
- LITERATURE REVIEW
- AIM & OBJECTIVE FLOW CHART
- MATERIALS
- METHOD
- SAR OF BAICALEIN
- CHEMICAL MODIFICATION OF BAICALEIN
- DOCKING RESULTS & INTERACTIONS
- CONCLUSION
- REFERENCE



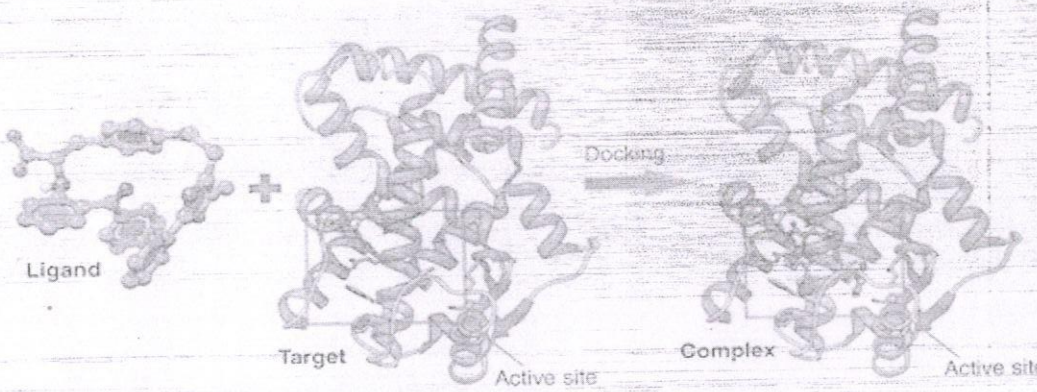
• INTRODUCTION

***DOCKING**:-*

Molecular docking is a method to predict the preferred orientation of one molecule to a second when bound to each other to form a stable complex.

***RECEPTOR**:- The "receiving" molecule, most commonly a protein.*

***LIGAND**:- The complementary partner molecule which binds to the receptor.*



***ALZHEIMER'S DISEASE**

Alzheimer's Disease (AD) is a progressive and fatal neurodegenerative disorder manifested by progressive impairment of activities of daily living, cognitive and memory deterioration, and a variety of neuropsychiatric symptoms and disturbances[1].

***B- AMYLOID HYPOTHESIS**

The β- Amyloid is a by-product of the protein Amyloid Precursor Protein (APP) whose function is believed to be involved in neuronal degradation . The Aβ unit is cleaved by γ-secretase to give Aβ-40 which contains 40 amino acid containing residues. In case of Alzheimer disease instead of α-secretase, an abnormal β-secretase cleaves APP followed by γ-secretase and produces Amyloid-β protein and Tangles are fibres of tau protein that builds inside the cells[2].

LITERATURE REVIEW

1)Review on major protein target

β-secretase (BACE-1) is the first protein that acts on amyloid precursor protein (APP) in the production of amyloid-β (Aβ). The BACE-1 enzyme has long been observed as an important therapeutic target for AD in the development of inhibitor drugs for reduction of Aβ (Fig.1)[3,4]. Presently, β-secretase is a major drug target for AD, and the development of its inhibitor drugs is being pursued in many research laboratories around the world.

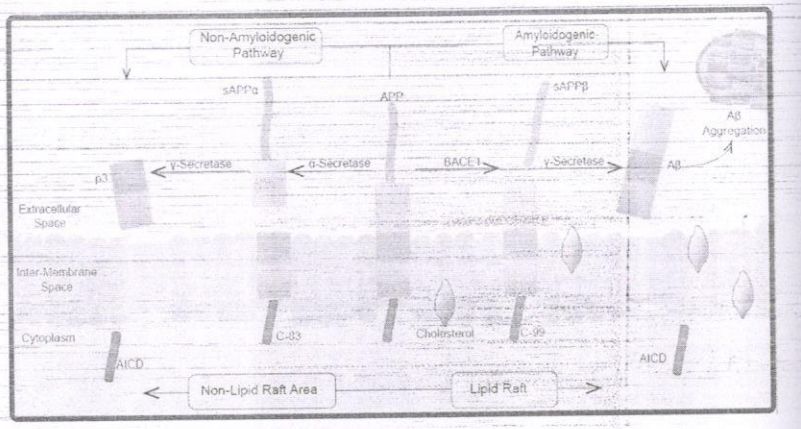


Fig1:- Amyloid-β pathway

BACE-1 **(PDB ID:2WJO)** has an N-terminal end, a C-terminal end and the active site cleft is located between the N- and C-terminal lobes. The active site is partially shielded by an anti-parallel hairpin loop known as "flap," which controls substrate access and proteolytic specificity. The binding site of BACE-1 which interacts with key residue **Asp228**, establishing force of interaction with **Thr232** at **S3** pocket, interact with **Tyr71** and **Thr72** of **β-hairpin flap** and stabilizing the binding by hydrogen bonding with **Gly11** at **loop 10s**. To compliment with this, **Ile126** and **Arg128** is essential for interaction which is located near loop **113s** present opposite to that of **loop 10s**(Fig. 2)[5-8].

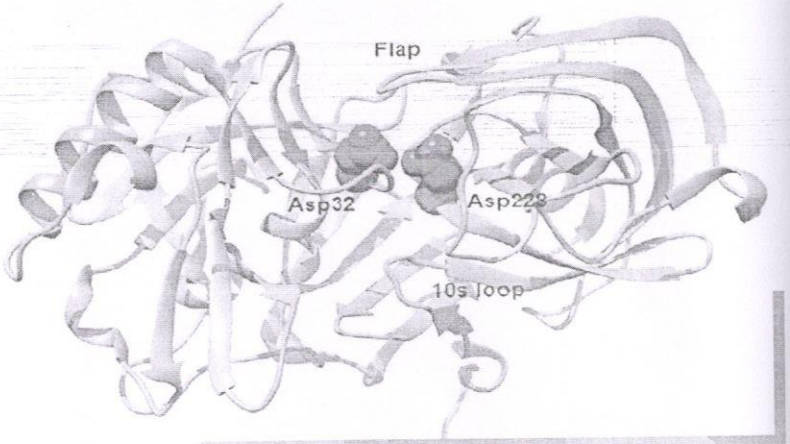


Fig2:-Active site of BACE-1 protein

2)Review of Natural products against Alzheimer's disease

BAICALEIN (Flavonoid)

Baicalein (5, 6, 7-trihydroxyflavone) is a flavone, originally isolated from roots of Scutellaria baicalensis and Scutellaria lateriflora. It has a wide range of roles as an antioxidant, hormone antagonist, radical scavenger, anti-inflammatory, anti-microbial, neuroprotective, apoptosis inducer etc [9]. As a flavonoid with two pro-hydroxyl groups, Baicalein exhibit strong antioxidant activity by direct scavenging of hydroxyl and superoxide radicals. The position and availability of hydroxyl groups is essential for radical scavenging activity The presence of an ortho-dihydroxy group or catechol structure in the A ring which is essential for an intrinsic antioxidant property. Neuroprotective effect of baicalein may be due to the increasing the number of dopaminergic neurons and caused by anti-apoptotic, mechanisms of Baicalein[10].

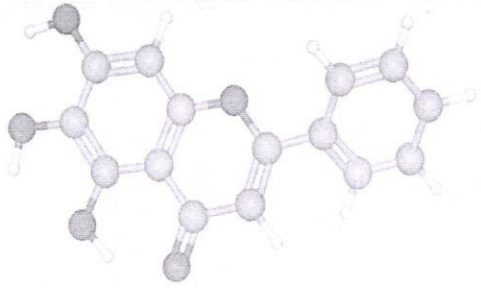


Fig3: 3D Structure of BAICALEIN