Project on

" COMPARISON BETWEEN DIFFERENT BRAND WHICH HAVING SAME API "

By

MR. MALI BHUSHAN (B.PHARM)
MISS.MORE AMRAPALI (B.PHARM)
MISS.KOTHAVDE SAYLI (B.PHARM)

Submitted to

KAVAYITRI BAHINABAI CHAUDHARI NORTH MAHARASHTRA UNIVERSITY, JALGAON (M.S)

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Under the Guidance of

MR.PROF. IQRAR ANSARI (M.PHARM)

(DEPARTMENT OF PHARMACEUTICS)

PROF. RAVINDRA NIKAM COLLEGE OF PHARMACY,

GONDUR, DHULE-424005

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PROJECT BY

MR. MALI BHUSHAN (B.PHARM)

MISS.MORE AMRAPALI (B.PHARM)

MISS.KOTHAVDE SAYLI (B.PHARM)

DECLARATION BY THE CANDIDATE

This is to certify that this project entitled **"COMPARISON BETWEEN DIFFERENT BRAND WHICH HAVING SAME API "** is a bonafide and genuine research work carried out by me under the guidance of PROF. IQRAR ANSARI Assistant Professor, Department of Pharmaceutical chemistry, Prof Ravindra Nikam College of Pharmacy, Gondur, Dhule.

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MR. MALI BHUSHAN (B.PHARM)

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CERTIFICATE BY THE GUIDE

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Place: Gondur,

DhuleDate: 15/06/23

15.06.23

MR.PROF. IQRAR ANSARI
(M. Pharm.)
Assistant Professor Department Pharmaceutical Chemistry
Prof. Ravindra Nikam College of Pharmacy,Gondur, Dhule

The Future of Healthcare..

Prof. Ravindra Nikam College of Pharmacy
Gondur, Dhule

ENDORSEMENT BY THE PRINCIPAL

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Place: Gondur
Date:15/6/2023

Prof. Ravindra Nikam College of Pharmacy (B.Pharmacy) Gondur, Dhule. OBVS

Dr. A. V. Patil
(Principal)
Prof. Ravindra Nikam College of Pharmacy, Gondur, Dhule.

Dr. Avinash Vishwanath Patil
Principal
OBVS
Prof. Ravindra Nikam College of Pharmacy At Gondur, Dist. Dhule (M.S.)

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INTRODUCTION:

Glucose is essential for providing energy for normal body functions. In diabetes the blood glucose levels are increased due to relative or absolute deficiency of insulin. Insulin is a hormone. A Hormone is a chemical secreted by one of the glands in our body. This gland is situated in abdomen and is known as pancreas.Insulin acts as a gatekeeper that allows entry of glucose into the cell.

If the amount of insulin is abnormal or the function of insulin is at fault excess of glucose accumulates in the body with harmful effects on the cells of various organs. Diabetes is a metabolic disorder in which body is unable to handle glucose for its energy requirements. As we have already discussed, insulin is essential for entry of glucose in to the cell that is why –

1) Cells cannot adequately utilise glucose
2) Body tries to produce more glucose (gluconeogenesis).

The meaning and origin of diabetes mellitus: Diabetes comes from Greek, and it means a "siphon". Atreus the Cappadocian, a Greek physician during the second century A.D., named the condition diabainein. He described patients who were passing too much water (polyuria) - like a siphon. The word became "diabetes" from the English adoption of the Medieval Latin diabetes. In 1675, Thomas Willis added mellitus to the term, although it is commonly referred to simply as diabetes. Mel in Latin means "honey"; the urine and blood of people with diabetes has excess glucose, and glucose is sweet like honey. Diabetes mellitus could literally mean "siphoning off sweet water". In ancient China people observed that ants would be attracted to some people's urine, because it was sweet. The term "Sweet Urine Disease" was coined.

❖ Some Key Aspects of Diabetes

- Diabetes is a long-term condition that causes high blood sugar levels.
- In 2013 it was estimated that over 382 million people throughout the world had diabetes.
- Type 1 Diabetes - the body does not produce insulin. Approximately 10%of all diabetes cases are type 1.
- Type 2 Diabetes - the body does not produce enough insulin for proper function. Approximately 90% of all cases of diabetes worldwide are ofthis type.
- Gestational Diabetes - this type affects females during pregnancy.
- The most common diabetes symptoms include frequent urination, intense thirst and hunger, weight gain, unusual weight loss, fatigue, cuts and bruises that do not heal, male sexual dysfunction, numbness and tingling in hands and feet.
- If you have Type 1 and follow a healthy eating plan, do adequateexercise, and take insulin, you can lead a normal life.

➢ What is diabetes?

- Diabetes is a condition that happens when your blood sugar (glucose)is too high.
- It develops when your pancreas doesn't make enough insulin or any at all, or when your body isn't responding to the effects of insulin properly. Diabetes affects people of all ages.
- Most forms of diabetes are chronic (lifelong), and all forms are manageable with medications and/or lifestyle changes.
- Glucose (sugar) mainly comes from carbohydrates in your food anddrinks. It's your body's go-to source of energy. Your blood carries glucose to all your body's cells to use for energy.
- When glucose is in your bloodstream, it needs help - a "key" - toreach its final destination. This key is insulin (a hormone).
- If your pancreas isn't making enough insulin or your body isn't using itproperly, glucose builds up in your bloodstream, causing high blood sugar (hyperglycemia).
- Over time, having too much glucose in your blood can cause health problems. Although diabetes has no cure, you can take steps to manageyour diabetes and stay healthy.
- Symptoms include excessive excretion of urine (polyuria), thirst (polydipsia), constant hunger, weight loss, vision changes, and fatigue. These symptoms may occur suddenly.

❖ What are the different types of diabetes?

The most common types of diabetes are type 1, type 2, and gestational diabetes.

1. Type 1 diabetes:

- If you have type 1 diabetes, your body does not make insulin.

  Your immune system attacks and destroys the cells in your pancreas that make insulin.

- Type 1 diabetes is usually diagnosed in children and young adults, although it can appear at any age. People with type 1 diabetes need to take insulin every day to stay alive.

2. Type 2 diabetes

- If you have type 2 diabetes, your body does not make or use insulin well. You can develop type 2 diabetes at any age, even during childhood.
- However, this type of diabetes occurs most often in middle-aged and older people. Type 2 is the most common type of diabetes.

➢ Gestational diabetes

- Gestational diabetes develops in some women when they are pregnant. Most of the time, this type of diabetes goes away after the baby is born. However, if you've had gestational diabetes, you have a greater chance of developing type 2 diabetes later in life.
- Sometimes diabetes diagnosed during pregnancy is actually type 2 diabetes.

➢ **Other types of diabetes**

- Less common types include monogenic diabetes, which is an inherited form of diabetes, and cystic fibrosis-related diabetes.

- **Diabetes causing Factor:**

I. Demographic Factors: Age, Sex, Race and Ethnicity Genetic Risk Factors: Gene Environment Interaction

II. Behavioural and lifestyle Factors: Nutrition, Dietary Carbohydrate and Fibre, Dietary fat, Micro nutrition, Sugar Sweetened Beverages, Coffee, Alcohol Consumption, Dietary Pattern, Physical Inactivity, Obesity

III. Metabolic Risk Factors: Impaired fasting Glucose and Impaired glucose Tolerance, Beta Cell Dysfunction, Proinsulin, Insulin Sensitivity

- **What health problems can people with diabetes develop?**

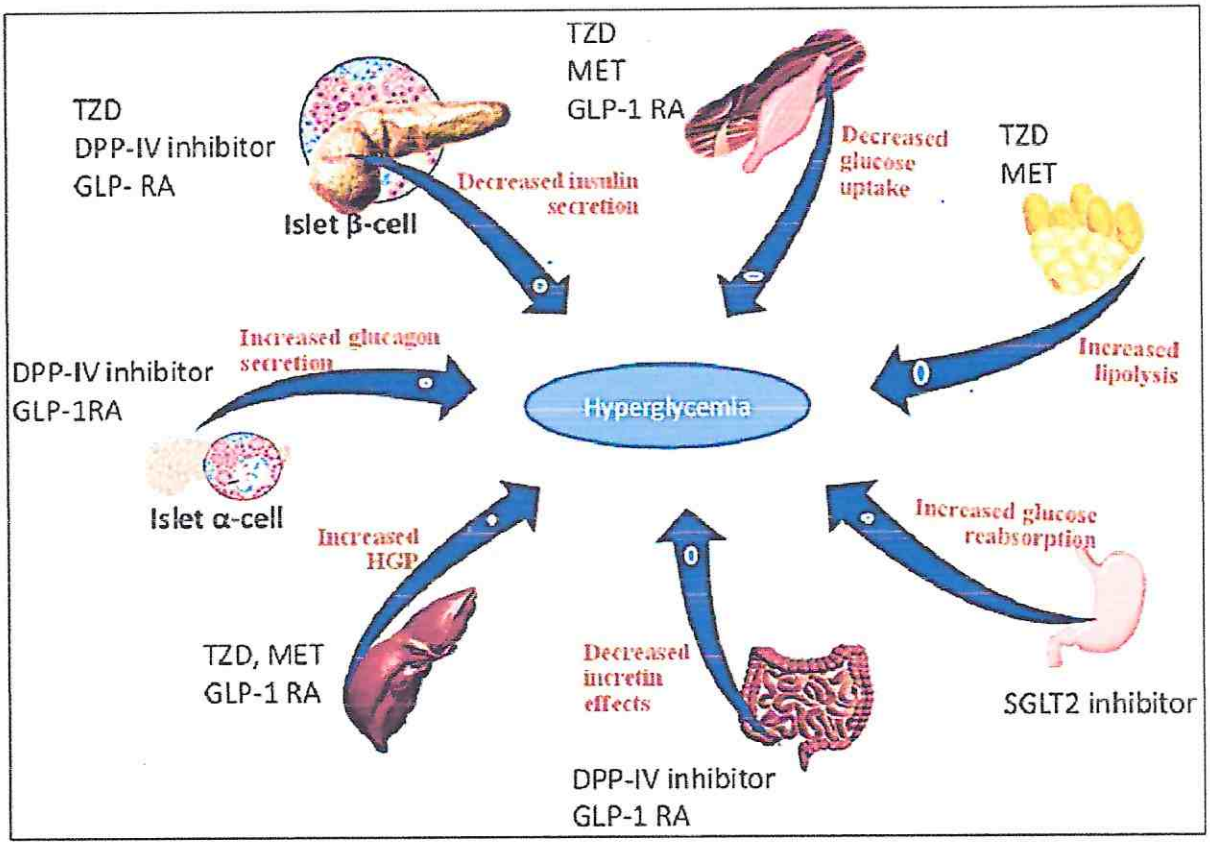
Over time, high blood glucose leads to problems such as

1. Heart disease
2. Stroke
3. Kidney disease
4. Eye problems
5. Dental disease
6. Nerve damage
7. Foot problems

❖ Approaches For Treatment of Diabetes mellitus

There are many parameters present which shows better treatment and efficiency for the Diabetes Mellitus like Dietary management, physicalactivity, Insulin therapy, many oral medications.

Among all the oral medications some most effective drugs for treatment ofDiabetes Mellitus is mentioned as follows:



□ Health impact:

- Over time, diabetes can damage the heart, blood vessels, eyes, kidneys, and nerves.
- Adults with diabetes have a two- to three-fold increased risk of heartattacks and strokes.

- Combined with reduced blood flow, neuropathy (nerve damage) in the feet increases the chance of foat ulcers, infection and eventual need for limb amputation.
- Diabetic retinopathy is an important cause of blindness and occurs asa result of long-term accumulated damage to the small blood vessels in the retina. Close to 1 million pe.ople are blind due to diabetes.
- Diabetes is among the leading causes of kidney Failure.
- People with diabetes are more likely to have poor outcomes for several infectious diseases, including COVID-19.

□ **Prevention:**

Lifestyle changes can help prevent the onset of type 2 diabetes, the most common form of the disease. Prevention is especially important if you're currently at an increased risk of type 2 diabetes because of excess weight or obesity, high cholesterol, or a family history of diabetes.

If you have been diagnosed with prediabetes — high blood sugar that doesn't reach the threshold of a diabetes diagnosis — lifestyle changes can prevent or delay the onset of disease.

Making a few changes in your lifestyle now may help you avoid the serious health complications of diabetes in the future, such as nerve, kidney and heart damage. It's never too late to start.

□ **Lose extra weight**

- Losing weight reduces the risk of diabetes. People in one large study reducedtheir risk of developing diabetes by almost 60% after losing approximately 7% of their body weight with changes in exercise and diet.
- The American Diabetes Association recommends that people with prediabetes lose at least 7% to 10% of their body weight to prevent diseaseprogression. More weight loss will translate into even greater benefits.

- Set a weight-loss goal based on your current body weight. Talk to your doctor about reasonable short-term goals and expectations, such as a losing 1to 2 pounds a week.

Be more physically active

There are many benefits to regular physical activity. Exercise can help you:

- Lose weight
- Lower your blood sugar
- Boost your sensitivity to insulin — which helps keep your blood sugarwithin a normal range

Goals for most adults to promote weight loss and maintain a healthy weightinclude:

- **Aerobic exercise.** Aim for 30 minutes or more of moderate to vigorous aerobic exercise — such as brisk walking, swimming, biking or running
  — on most days for a total of at least 150 minutes a week.
- **Resistance exercise.** Resistance exercise — at least 2 to 3 times a week
  — increases your strength, balance and ability to maintain an active life.Resistance training includes weightlifting, yoga and calisthenics.
- **Limited inactivity.** Breaking up long bouts of inactivity, such as sitting at the computer, can help control blood sugar levels. Take a few minutesto stand, walk around or do some light activity every 30 minutes.

Eat healthy plant foods

- Plants provide vitamins, minerals and carbohydrates in your diet. Carbohydratesinclude sugars and starches — the energy sources for your body — and fiber.
- Dietary fiber, also known as roughage or bulk, is the part of plant foods yourbody can't digest or absorb.
- Fiber-rich foods promote weight loss and lower the risk of diabetes. Eat avariety of healthy, fiber-rich foods, which include:

- Fruits, such as tomatoes, peppers and fruit from trees
- Nonstarchy vegetables, such as leafy greens, broccoli and cauliflower
- Legumes, such as beans, chickpeas and lentils
- Whole grains, such as whole-wheat pasta and bread, whole-grain rice,whole oats, and quinoa

➢ **The benefits of fiber include:**

- Slowing the absorption of sugars and lowering blood sugar levels
- Interfering with the absorption of dietary fat and cholesterol
- Managing other risk factors that affect heart health, such as bloodpressure and inflammation
- Helping you eat less because fiber-rich foods are more filling and energyrich
- Avoid foods that are "bad carbohydrates" — high in sugar with little fiberor nutrients: white bread and pastries, pasta from white flour, fruit juices, and processed foods with sugar or high-fructose corn syrup.

➢ **Eat healthy fats**

- Fatty foods are high in calories and should be eaten in moderation. To help lose and manage weight, your diet should include a variety of foods with unsaturated fats, sometimes called "good fats."
- Unsaturated fats — both monounsaturated and polyunsaturated fats —promote healthy blood cholesterol levels and good heart and vascular health. Sources of good fats include:
- Olive, sunflower, safflower, cottonseed and canola oils
- Nuts and seeds, such as almonds, peanuts, flaxseed and pumpkin seeds
- Fatty fish, such as salmon, mackerel, sardines, tuna and cod.

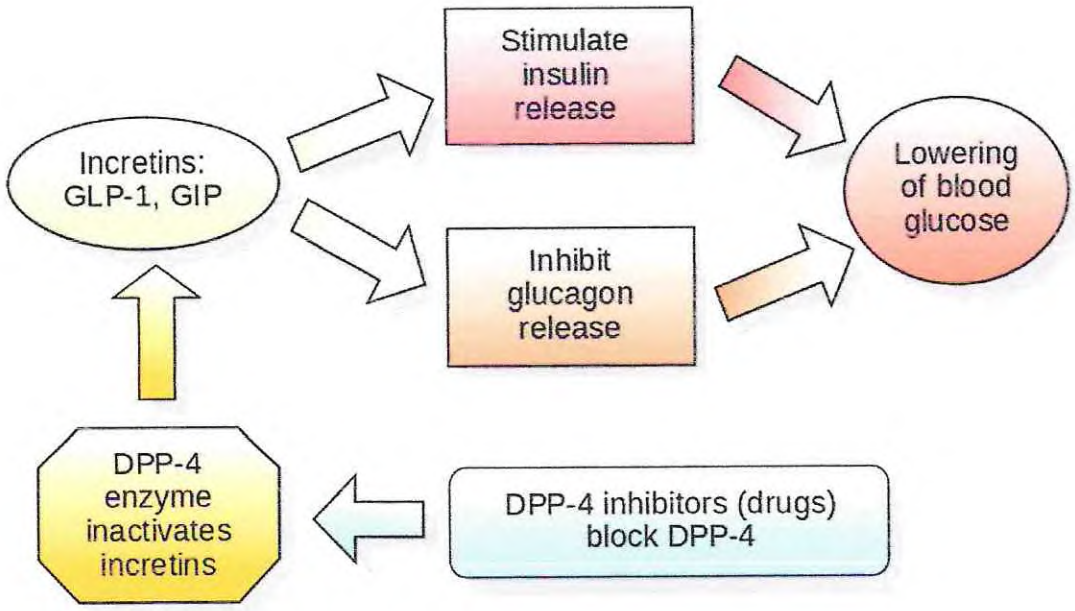
❖ Dipeptidyl peptidase 4 (DPP-4) inhibitors as a Diabetes:

- Dipeptidyl peptidase 4 (DPP-4) inhibitors are a group of antihyperglycemic medications used to manage type 2 diabetes mellitus, which is a significant risk factor for coronary disease, heart failure, stroke, and many other cardiovascular conditions.
- This activity reviews the various drugs in this group, indications, contraindications, activity, adverse events, and other key elements of DPP-4 inhibitors therapy in the clinical setting.
- It also elaborates on the essential information needed by any interprofessional team member managing the care of patients withdiabetes.
- DPP-4 inhibitors, known as gliptins, are a class of oral

  diabetic medications approved by the Food and Drug Administration(FDA) to treat type 2 diabetes mellitus in adults.
- DPP-4 inhibitors that have FDA approval include sitagliptin, saxagliptin,linagliptin, and alogliptin. Vildagliptin has approval from the European Medicines Agency (EMA), but not by the FDA.
- These drugs act through incretin hormones, which are gut hormonesresponsible for glucose homeostasis after oral food intake.

➢ Pharmacology:

- Inhibitors of dipeptidyl peptidase 4 (DPP-4 inhibitors or gliptins) are a class of oral hypoglycemics that block the enzyme dipeptidyl peptidase-4 (DPP-4). They can be used to treat diabetes mellitus type 2.
- The first agent of the class – sitagliptin – was approved by the FDA in2006. Glucagon increases blood glucose levels, and DPP-4 inhibitors reduce glucagon and blood glucose levels.
- The mechanism of DPP-4 inhibitors is to increase incretin levels (GLP- 1 and GIP) which inhibit glucagon release, which in turn increases insulin secretion, decreases gastric emptying, anddecreases blood glucose levels.



Origin of Different DPP – 4 inhibitors

Generic Name	Country	Brand Name
Sitagliptin	Europe, US, Japan	Januvia
Vildagliptin	Europe, US, Japan	Galvus, Equa
Saxagliptin	Europe, Japan	Onglyza
Linagliptin	Europe, US	Trajentra, Tradjenta, Tra-zenta
Alogliptin	Europe, US, Japan	Vipidia, Nesina
Anagliptin	Japan	Suiny
Teneligliptin	Japan	Tenelia
Gemigliptin	Korea	Zemiglo
Omarigliptin	Japan	Marizev
Gosogliptin	Russia	Pfizer
Denagliptin	USA, Finland	Glaxo
Melogliptin	Europe, US, Japan	Glenmark
Trelagliptin	Europe, US	Takeda
Retagliptin	China	---------

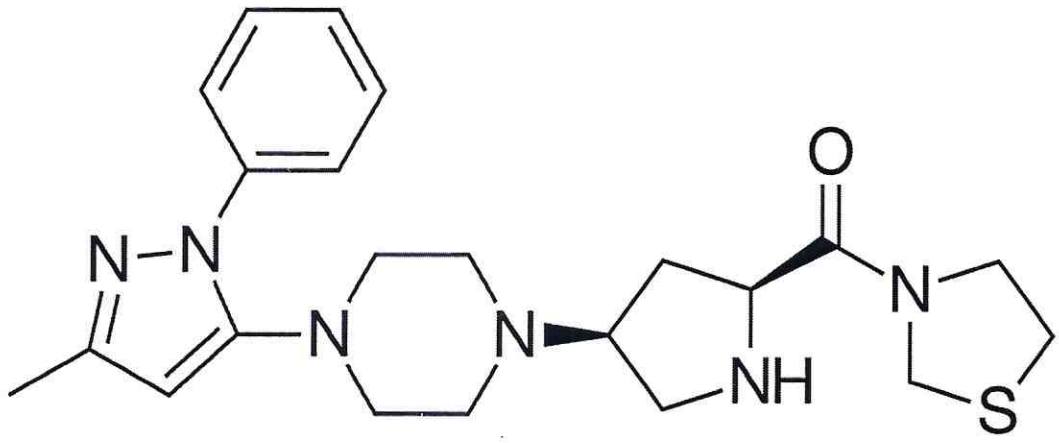
❖ Drug Profile:

Teneligliptin was originally synthesized by Mitsubishi Tanabe Pharma Corporation (Osaka, Japan) and was the first drug of its kind to be synthesized in Japan. Mitsubishi Tanabe Pharma Corporation and Daiichi Sankyo Co, Ltd, (Tokyo, Japan) jointly sell the drug under the brand name TENELIA®.

Incretin hormones,1–3 namely glucagon-like peptide-1 (GLP-1) and glucose dependent insulinotropic polypeptide (GIP), are released from enteroendocrine cells and enhance insulin secretion.1,2,4–6 Incretins are rapidly inactivated by the enzyme dipeptidyl peptidase-4 (DPP-4), and have a very short half-life (t1/2) as a result. DPP-4 inhibitors increase the levels of active GLP-1 and GIP by inhibiting DPP-4 enzymatic activity; thus, in patients with diabetes, these inhibitors improve hyperglycemia in a glucose-dependent manner by increasing serum insulin levels and decreasing serum glucagon levels.7–13 Therefore, incretin-related agents such as DPP-4 inhibitors are promising drugs that can decrease glucose fluctuations in diabetic patients and have emerged as a new class of antidiabetic. The effect of these inhibitors on glycemic control when administered as monotherapy or in combination with other drugs has been investigated in multiple trials.7,8,11,12 Moreover, DPP-4 inhibitors have shown favourable results in improving glycemic control with a minimal risk of hypoglycemia and weight gain.

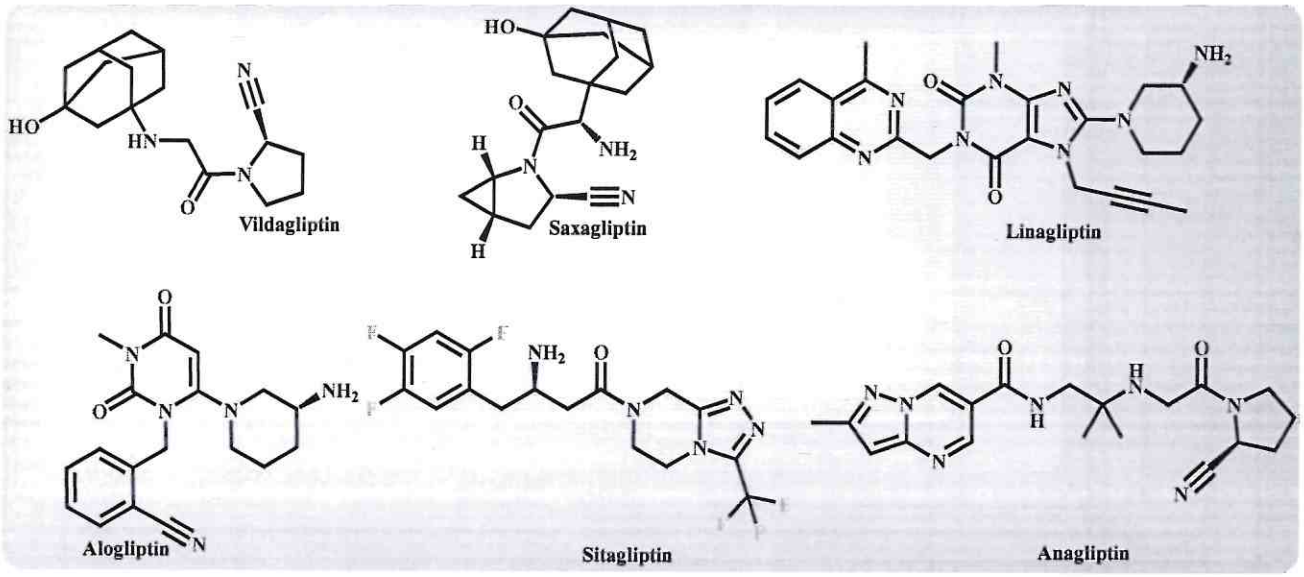
Chemistry of Teneligliptin

Structure:



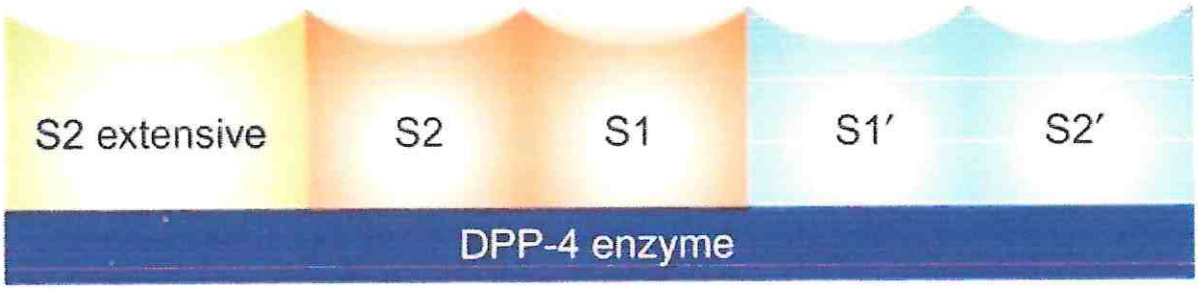
- Teneligliptin is a recently developed oral dipeptidyl peptidase 4 inhibitor indicated for the management of type 2 diabetes mellitus (T2DM) in adults along with diet and exercise.
- Teneligliptin has been recently available in Japan (Teneria®), Argentina (Teneglucon®), and India (Tenepure; Teneza) at relatively affordable price. This is a positive step toward the management of T2DM in developing countries, where the cost of medicine is out-of-pocket expenditure and is a limiting factor for health care.
- This review evaluates the efficacy and safety of teneligliptin in the management of T2DM. Teneligliptin has been systematically evaluated inT2DM as monotherapy with diet and exercise and in combination with metformin, glimepiride, pioglitazone, and insulin in short-term (12 weeks)and long-term (52 weeks) studies.

➢ **Other Molecule:**



❖ Are all DPP-4 inhibitors same?

- All DPP-4 inhibitors have the same mechanism of action and safety profile, but there are some important differences not only in the pharmacokinetic and pharmacodynamic properties but also in the potencyof DPP-4 enzyme inhibition.
- Comparative studies have determined binding modes of DPP-4 inhibitors with the active site of DPP-4 enzyme. DPP-4 enzyme has five binding sites (subsites), namely, S1, S2, S1′, S2′, and S2 extensive
- An interaction of DPP-4 inhibitors with S1 and S2 is considered to be the fundamental interaction that is required for DPP-4 inhibition.
- Additional interaction with S1′, S2′, and S2 extensive site may further increase the DPP-4 inhibition.
- DPP-4 inhibitors are classified according to their interactions with a DPP-4 enzyme Classification of DPP-4 inhibitors is based on their selectivity for enzyme and are Class 1, Class 2, and Class 3.
- Class 1 inhibitors (eg, vildagliptin and saxagliptin) bind with S1 and S2 and are considered as fundamental/basic inhibitors.
- Class 2 inhibitors (alogliptin and linagliptin) bind with additional sites ofS1′ and S2′ and may produce more DPP-4 inhibition than Class 1.
- Class 3 inhibitors (sitagliptin and teneligliptin) bind additional site of S2 extensive and produce more extensive DPP-4 inhibition. Teneligliptin, a Class 3 inhibitor, reported fivefold higher activity than sitagliptin.



❖ Metabolism & Excretion:

Reported evidence suggests that with teneligliptin 20 mg therapy, Tmax was 1 hour and t 1/2 was 18.9 hours. Maximum (89.7%) inhibition in plasma DPP-4 activity was noted within 2 hours and maintained >60% at 24 hours. Compared to placebo, active plasma GLP-1 concentration was higher throughout the day and even at 24 hours after administration of teneligliptin 20 mg. Metabolism of teneligliptin was majorly mediatedthrough CYP3A4.

CYP3A4, a cytochrome P450 isozyme and flavin-containing monooxygenases (FMO1 and FMO3) play major roles in the metabolism of teneligliptin. In vitro, teneligliptin exhibits a weak inhibitory effect for CYP2D6, CYP3A4, and FMO; however, it demonstrates no inhibitory effect for CYP1A2, CYP2A6, CYP2B6, CYP2C8, CYP2C8/9, CYP2C19,
and CYP2E1. In addition, teneligliptin does not induce the expression of CYP1A2 or CYP3A4. About 34.4% of teneligliptin is excreted unchanged via the kidney and the remaining 65.6% teneligliptin is metabolized and eliminated via renal and hepatic excretion; 216 hours after the administration of 14C-labeled teneligliptin (20 mg), the cumulative excretion percentages of radioactive teneligliptin in urine and faeces were 45.4% and 46.5%, respectively.

❖ Different Brands of Teneligliptin

Sr. No.	Marketed Name	Company Name
01	Dynaglipt	Mankind pharmaceuticals pvt. ltd.
02	Tenlison-20	Unison pharmaceuticals pvt. ltd.
03	Tenlimac	MacLeod's pharmaceuticals ltd.
04	Tenespec-20	Spectra Therapeutics pvt. ltd.

❖ Observation Table

MANKIND

Sr. No.	Concentration (µg/ml)	Wavelength (nm)	Absorbance
01	3	246	0.349
02	6	246	0.568
03	9	246	0.776
04	12	246	1.030
05	15	246	1.223

UNISON

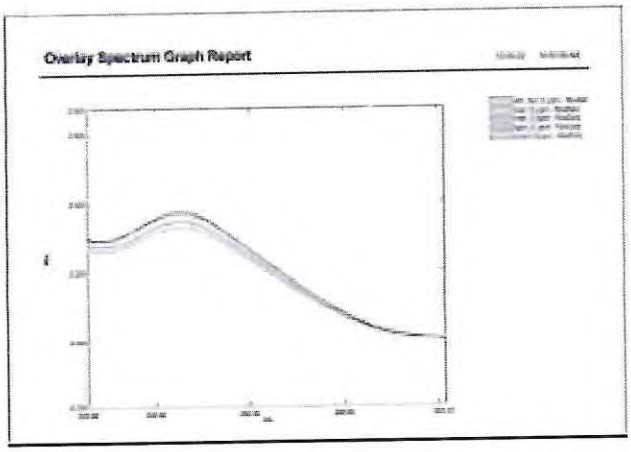
Sr. No.	Concentration (µg/ml)	Wavelength (nm)	Absorbance
01	3	246	0.376
02	6	246	0.562
03	9	246	0.811
04	12	246	1.044
05	15	246	1.258

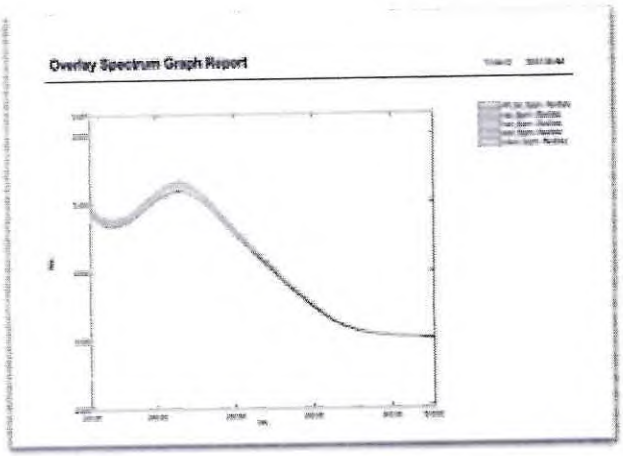
MACLEODS

Sr. No.	Concentration (µg/ml)	Wavelength (nm)	Absorbance
01	3	246	0.332
02	6	246	0.434
03	9	246	0.699
04	12	246	0.993
05	15	246	1.222

SPECTRA

Sr. No.	Concentration (µg/ml)	Wavelength (nm)	Absorbance
01	3	246	0.348
02	6	246	0.436
03	9	246	0.683
04	12	246	0.982
05	15	246	1.299


Overlay Spectrum Graph Report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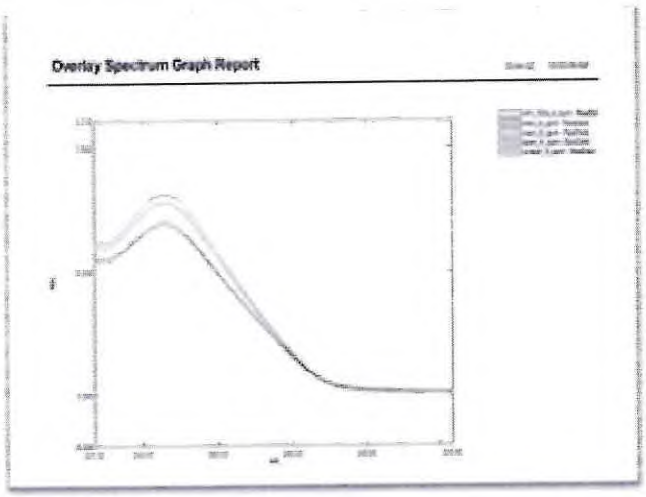
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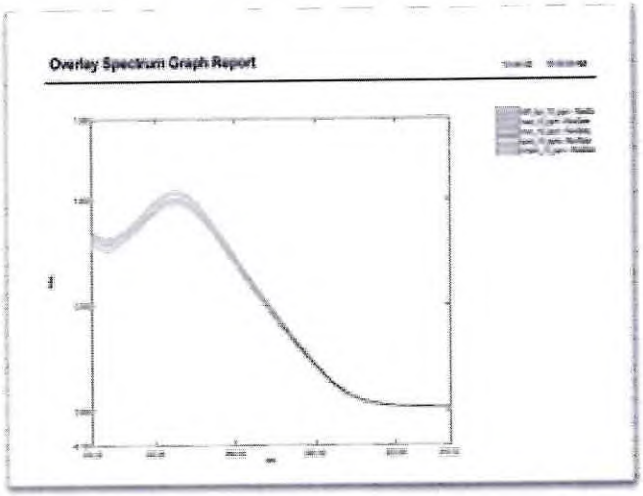
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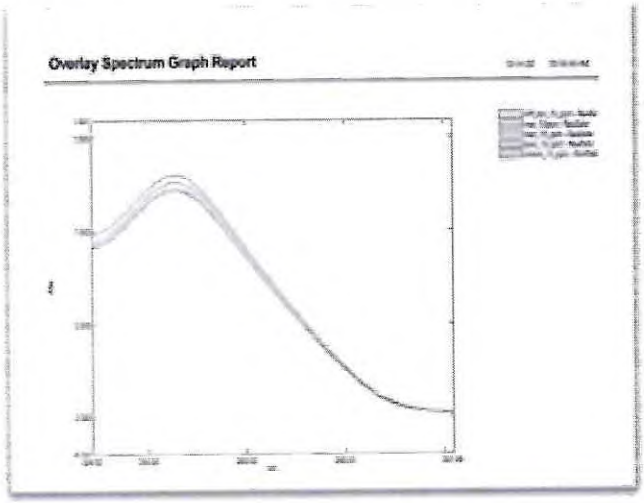
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❖ Different Brands of Anti-diabetic drugs and its percentage purity

Sr. No.	Marketed Name	Company Name	Percentage purity %
01	Dynaglipt	Mankind pharmaceuticals pvt ltd	95.3 %
02	Tenlison-20	Unison pharmaceuticals pvt ltd	97.2 %
03	Tenlimac	Macleods pharmaceuticals ltd	96 %
04	Tenespec-20	Spectra Therapeutics pvt ltd	97.6 %

❖ CONCLUSION

The statement suggests that a comparative analysis was conducted on various drugs, and after the analysis, it was concluded that Dynaglipt from Mankind Pharmaceutical Pvt. Ltd., Tenlison-20 from Unison Pharmaceutical Pvt. Ltd., Tenlimac from Macleods Pharmaceutical Ltd., and Tenespec-20 from Spectra therapeutics Pvt Ltd have an equal percentage of purity. This implies that these drugs are of high quality and are expected to exhibit a uniform efficacy rate. It is important to note that purity is a critical factor when it comes to drug efficacy. A higher purity percentage indicates that the drug is free from impurities and contaminants that could affect its efficacy or cause adverse effects. Therefore, drugs with equal purity percentage, such as the ones mentioned in the statement, are likely to have a consistent effect on patients, making them more reliable and effective in treating the intended medical condition. Overall, the statement suggests that the comparative analysis has provided valuable insights into the quality and efficacy of various drugs. The finding that Dynaglipt, Tenlison-20, Tenlimac, and Tenespec-20 exhibit equal percentage of purity is a significant observation that could help healthcare providers and patients make informed decisions about the drugs they use.

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