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RESEARCH ARTICLE

A REVIEW ARTICLE ON GLIMEPERIDE: AN ORAL HYPOGLYCAEMIC DRUG

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Abstract

Glimepiride is a second generation sulfonylurea of oral hypoglycaemic drug that stimulates the β -cells of the pancreas to secrete insulin. In this article there is full information on all the research work and development done on glimepiride drug. The main motive is to compile all the works which have done.

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Introduction:-

Glimepiride is a sulfonyl urea used to treat type –II diabetes mellitus. Molecular formula of glimepiride is $C_{24}H_{34}N_4O_5S$ with a molecular mass of about 490.617g/mol^[1]. It belongs to class-II of Biopharmaceutical classification system. It is completely insoluble in water, acidic media and slightly soluble in various buffers and organic solvents^[2]. It is administered orally; insoluble in water, slightly soluble in methylene chloride (Dichloromethane), very slightly soluble in methanol and soluble in Dimethyl Sulfoxide (DMSO)^[1, 3]. Glimepiride shows low pH dependent solubility. In acidic and neutral aqueous media, glimepiride exhibits very poor solubility at 37°C (<0.004 mg/ml). In media pH>7, solubility of drug is slightly increased to 0.02 mg/ml. These poorly water soluble drugs provide challenges to deliver them in an active and absorbable form to the desired absorption site using physiologically safe excipients^[4-6]. This poor solubility may cause poor dissolution and unpredicted bioavailability. It is practically insoluble in water and other aqueous media. However, the drawback of this potentially useful hypoglycemic agent is that it is highly hydrophobic and practically insoluble in water^[7,8].

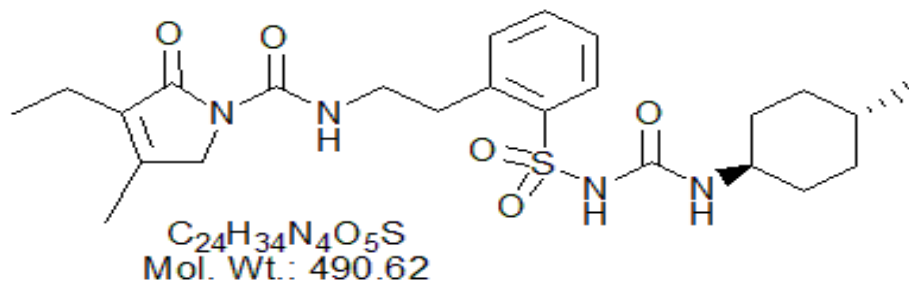


Fig 1:-Structure of Glimepiride

Mechanism of action:-

The primary mechanism of action of glimepiride for lowering blood glucose levels seems to be dependent on stimulating the release of insulin from the functioning pancreatic cells. Glimepiride acts by binding to ATP sensitive potassium channel receptors on the pancreatic cell surface, which reduces potassium conductance causing

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depolarization of the membrane. Calcium ion reflux is stimulated by the membrane depolarization through voltage-sensitive calcium channels. This increased intracellular calcium ion concentration induces the secretion of insulin. It can be employed for concomitant use with metformin, thiazolidinedione, insulin and alpha-glucosidase inhibitors for treatment of type-2 (noninsulin dependent) diabetes mellitus. It is completely absorbed from the gastrointestinal tract when it is administered orally. The possible side effects are severe hypoglycemic reactions with coma, seizure, or other neurological impairment. The other reported side effects of sulfonylureas includes clostatic jaundice, nausea and vomiting, aplastic and hemolytic anemias, agranulocytosis, generalized hypersensitivity reactions, and rashes^[1,9].

Extra-pancreatic action:-

After chronic administration, the insulinaemic action of sulfonylureas declines probably due to down regulation of sulfonylurea receptors on β -cells, but improvement in glucose tolerance is maintained. In this phase, they sensitize the target tissues (especially liver) to the action of insulin. This is due to increase in number of insulin receptors and/or a postreceptor action-improving translation of receptor activation. It is hypothesized that long term improvement in carbohydrate tolerance leads to a decreased insulin concentration in blood which reverses the down regulation of insulin receptors-apparent increase in their number. A direct extra-pancreatic action of sulfonylureas to increase insulin receptors on target cells and to inhibit gluconeogenesis in liver has been suggested, but appears to have little clinical relevance^[10].

Works done on glimeperide:-

There are a number of works done on drug glimepiride. Following are the works done on glimeperide drug:

- ❖ Glimepiride (GMP) was selected as a model drug for dissolution enhancement studies in the present investigation. Attempts were made to enhance the dissolution of GMP using a solid dispersion (SD) technique. SDs of GMP-PXM 188 (Poloxamer 188) were prepared in different ratios using the melting method, and then tablets of best formulation of SD were formulated by using direct compression method. SDs were evaluated for XRD, SEM, *In-vitro* dissolution profiles, and dissolution efficiency, and developed tablet formulations were evaluated for various pharmaceutical characteristics viz. hardness, % friability, weight variation, drug content, disintegration time, *In-vitro* dissolution profiles, and dissolution efficiency. Among different formulations of SDs, SD containing drug is to polymer ratio 1 : 4 gives best dissolution profile and dissolution efficiency and among tablet formulations, formulations containing 5% croscarmellose sodium gives best disintegration and dissolution profiles compared with other formulations. Results showed that poloxamer is a promising polymer for enhancing the solubility of GMP^[11].
- ❖ Solid dispersion (SD) of Glimepiride is prepared by dissolving drug and polyvinyl pyrrolidone K30 in Dichloromethane and the solvent is removed by rotary evaporator under reduced pressure. The solubility increased around twenty times greater when drug and carrier is used in 1:10 ratios. The Oro dispersible tablets were prepared by using Sodium starch glycolate, cross carmellose sodium, pre-gelatinized starch and polacrillin potassium as super disintegrants. The rapid disintegration (24 sec) is obtained to polacrillin potassium (10%) and maximum drug release (85.6%) obtained in 10 min. From these results it is concluded that solubility of glimepiride is increased by preparing solid dispersion and rapid bioavailability is observed by preparing orodispersible tablets^[2].
- ❖ The SDs of Glimepiride with PEG 20000 were prepared with 1:1, 1:3 and 1:5 (Glimepiride:PEG 20000) ratio by melting method. The primary objective of the present study was to investigate the physicochemical properties of glimepiride in SDs with PEG 20000. The possible interactions between glimepiride and PEG 20000 in both solid state and liquid states were investigated. Interaction in the solid state was investigated by FTIR and XRD. Interaction in solution was studied by phase solubility analysis and dissolution experiments. The SDs of glimepiride with PEG 20000 exhibited enhanced dissolution rate of glimepiride, and the rate increased with increasing concentration of PEG 20000 in SDs. Mean dissolution time (MDT) of glimepiride decreased significantly after preparation of SDs and physical mixture with PEG 20000. The FTIR spectroscopic studies showed the stability of glimepiride and absence of well-defined glimepiride-PEG 20000 interaction. The XRD studies indicated the amorphous state of glimepiride with PEG 20000^[12].
- ❖ Glimepiride (GMP) was selected as a model drug for dissolution enhancement studies in the present investigation. Attempts were made to enhance the dissolution of GMP using a SD technique. SDs of GMP with polyvinylpyrrolidone (PVP K 30) was prepared in different ratios using solvent evaporation method and then tablets of best formulation of SD were formulated by using direct compression method. Tablet formulations were prepared by direct compression technique using super-disintegrants; crospovidone in different

concentrations. SDs were evaluated for FTIR, XRD, SEM, *In-vitro* dissolution profiles, and developed tablet formulations were evaluated for various pharmaceutical characteristics viz. hardness, % friability, weight variation, drug content, disintegration time, *In-vitro* dissolution profiles^[4].

- ❖ Glimepiride (GMP) is poorly water soluble drug, so solubility is the main constraint for its oral bioavailability. The objective of the research project is to enhance of the solubility of Glimepiride by using solid dispersion technique. The polymers used were Poloxamer 188 and Poloxamer 407 and solid dispersions were prepared by kneading method. The solubility study was carried out to study the effect of polymers on solubility of Glimepiride. The prepared solid dispersions were characterized by *In-vitro* solubility Study, % drug content; Fourier transforms spectroscopy (FTIR), *In-vitro* drug dissolution to identify the physicochemical interaction between drug and excipients. The dissolution studies of solid dispersion were performed by using USP II apparatus. The solid dispersion prepared with Poloxamer 188 showed better drug release as compared to solid dispersion prepared with Poloxamer 407^[7].
- ❖ The rationale of this study was to improve the solubility, dissolution rate and sustained release of the drug. Glimepiride cubosomes were prepared by Top down approach employing Glycerylmonooleate (GMO) as lipid phase vehicle, Poloxamer 407 as stabilizer and distilled water as aqueous phase. The resultant cubosome dispersion were characterized by encapsulation efficiency, *In-vitro* drug release, particle size, zeta potential, FTIR and SEM. Optimized formulation (F5) showed a maximum drug release of 71 % in 6 hours, particle size of 88.7nm and zeta potential of 43.6 mV. Glimepiride cubosomal Capsules were prepared with the optimized cubosomal dispersion, by using a new technique starch and aerosil were used as granulating agents to obtain a wet mass. Then the wet mass was passed through sieve no. 16 to form granules. Then the granules were dried in hot air oven. The dried granules were filled into capsules. The granules were evaluated for SEM, zeta potential, flow properties and *In-vitro* drug release. Optimized capsule formulation (C2) contains starch showed a maximum drug release of 49 % in 6 hours, particle size of 213nm and zeta potential of -159 mV. *In-vitro* release kinetics exhibited sustained release up to 6 hours and followed non-Fickian diffusion. Results suggest that GMO cubosomes, as lipid nanovectors, could significantly enhance oral efficacy when compared to Glimepiride powder^[13].
- ❖ The main objective of the study was to increase the amount of dissolved drug molecules at the absorption site by increasing the dissolution rate, since for class II drugs like glimepiride, *In-vivo* dissolution rate is rate limiting step in drug absorption. Surface solid dispersion (SSD) was selected as the method of choice since it would be easier in subsequent formulating and processing of tablets. The carriers used were croscopovidone, croscarmellose, sodium starch glycolate, pre-gelatinized starch, Avicel PH 101 and potato starch. The SSDs were prepared at various drug-to-carrier weight ratios by solvent evaporation method. The optimized SSD was characterized and formulated into tablets^[14].
- ❖ A novel matrix controlled transdermal systems of anti-diabetic drug glimepiride were prepared using natural polymer chitosan for the extended and controlled delivery of the drug. Characterization was done by physicochemical studies. Optimization of the system was done using *In-vitro* drug permeation studies through rat skin. Skin irritation tests and pharmacokinetic evaluations were carried out in healthy rats. Blood glucose reducing hypoglycemic activity of the systems was studied in diabetic rats^[15].
- ❖ Glimepiride is an oral hypoglycaemic agent and is completely absorbed after oral administration but it is subjected to liver metabolism which contributes to its efficacy with single oral administration. To increase the patient compliance and to have convenience of administration, nasal gel of Glimepiride was prepared using mucoadhesive polymers which may increase its residence time there by subsequent bioavailability. Nasal formulation with the controlled action of drug is a good alternative. Challenges in the development of nasal formulation include low residence time. Mucociliary clearance can be overcome by developing a mucoadhesive formulation^[16].
- ❖ The main objective of this present research work is to achieve sustained release of Glimepiride and to enhance the gastrointestinal residence time, for this purpose mucoadhesive microbeads were formulated by employing Ionic gelation method with HPMC and Na-CMC as coating polymers. Formulated mucoadhesive microbeads were properly evaluated for size distribution, tapped density entrapment efficiency, wall thickness, drug release studies, SEM and GI residence time. In this present research influence of polymer on rate of drug release and concentration of polymer coat on rate of drug release from the Glimepiride mucoadhesive microbeads were studied. The rate of drug release was found to be decreased by increasing the concentration of the coat polymer^[17].
- ❖ The objective of this study was to develop sustained release tablets of glimepiride by wet granulation method based on combination of hydrophilic (HPMC15cps, HPC) and hydrophobic (Ethyl cellulose) polymers. The

drug excipient mixtures were subjected to preformulation studies. The tablets were subjected to physicochemical studies, *In-vitro* drug release, kinetic studies and stability studies^[18].

- ❖ Glimepiride acts as an insulin secretagogue. To provide the patients with the most convenient mode of administration, there was a need to develop immediate release dosage form, particularly one that disintegrates rapidly and disperses and helps in enhancing the Bioavailability of the drug. Glimepiride immediate release tablets were formulated by using wet granulation method and povidone k30, starch as binders, croscarmellose sodium, sodium starch glycolate, crospovidone as disintegrants, lactose monohydrate as diluent and magnesium stearate as lubricant. The tablets were evaluated for pre-compression and post-compression parameters after conducting preformulation studies. All the parameters were within the pharmacopoeial limits and the drug disintegrate on time was less and the *In-vitro* dissolution studies showed that the drug release was fast^[19].
- ❖ The main objective of the research was to formulate directly compressible fast disintegrating tablets of glimepiride by using different super disintegrants such as crospovidone, croscarmellose sodium, sodium starch glycolate and L-HPC in various concentrations^[20].
- ❖ The purpose of the present study was to design an inlayered tablet consisting of glimepiride core tablet for immediate release to produce immediate therapeutic effect, which was inserted inside the cup of metformin hydrochloride for sustained deliver of metformin hydrochloride. The inner core portion was design using superdisintegrants for immediate release and the outer cup portion was designed as matrix formulations using polymers such as Hydroxypropyl methyl cellulose (HPMC) and Poly vinyl pyrrolidone (PVP) to modulate the drug release^[21].
- ❖ The purpose of preparing self microemulsifying drug delivery system in this work is to enhance the solubility and oral bioavailability of poorly water soluble drug, Glimepiride. Self-micro emulsifying drug delivery system (SMEDDS) are the isotropic mixture of surfactant, co-surfactant and oil incorporated with drug. In the aqueous media, gastro intestinal motility emulsification takes place. Glimepiride was undergone solubility studies in various surfactants, co-surfactants and oils^[22].
- ❖ The present study reveals the formulation and evaluation method of glimepiride loaded liposomes. The liposomal formulations of glimepiride were prepared by using phosphatidylcholine (lecithin) and cholesterol by using thin film hydration method^[23].
- ❖ The aim of the present study was to design and develop the best sustained release formulations of glimepiride tablets, to evaluate the release pattern and to compare it with that of immediate release tablets. The study was designed to achieve maximum efficacy for the treatment of type-2 diabetes mellitus. Glimepiride sustained release tablets were prepared by direct compression method using different ratios of various release retarding polymers such as carbopol, ethyl cellulose, methocel K4 MCR, methocel K15 MCR, methocel K100 MCR and xanthum gum. These formulations were also compared with glimepiride immediate release tablets. The prepared tablets were subjected to various physical parameter tests including weight variation, friability, hardness, thickness, diameter, etc. *In-vitro* dissolution studies of the formulations were done at pH 6.8 in phosphate buffer using USP apparatus 2 (paddle method) at 50 rpm^[24].
- ❖ The present research work is an attempt to develop and evaluate Nanosuspension of Glimepiride in order to improve the solubility and bioavailability of poorly water soluble drugs. Nanosuspensions of Glimepiride were developed with different ratios of Urea and poly vinyl pyrrolidone (PVP) combinations by nanoprecipitation technique. Nanoprecipitation method being simple and less sophisticated was optimized for the preparation of nanosuspension^[25].
- ❖ The objective of this work was to prepare Glimepiride (1mg) fast dissolving tablets by wet granulation method. Glimepiride was the drug of choice because of its low dose. The prepared Glimepiride fast dissolving tablet (FDT) were found to have faster onset of action than the conventional Glimepiride tablets. Also, they were effective in lowering fasting blood glucose levels. Glimepiride fast dissolving tablets were prepared using super disintegrants like Croscarmellose sodium, cross povidone, sodium starch glycollate by employing wet granulation technique. Prepared tablets were evaluated for angle of repose, hardness, friability, disintegration, *In-vitro* dissolution studies. Dissolution was performed using USP type II apparatus at a temperature of $37 \pm 0.5^\circ\text{C}$, 50 RPM, 900 ml pH 6.8 phosphate buffer and samples were estimated spectrophotometrically at 228nm. The *In-vitro* dissolution studies shown that tablets prepared using cross povidone superdisintegrant showed better drug release when compared to other super disintegrants^[26].

Marketed products of glimepiride:-**Table No. 1:-**List of marketed products of Glimeperide drug

S.No	Brand Name	Manufacturers	Type	Unit	Uses
1	Amaryl (2 mg)	Sun Pharmaceutical Industries Ltd.	Tablet	2mg	Proper control of diabetes may also lessen your risk of a heart attack or stroke
2	Amaryl (3 mg)	Nicholas Piramal India Ltd.	Tablet	3mg	lower the blood sugar levels in type 2 diabetes mellitus
3	Asoride	Cipla Limited	Tablet	1mg	Type-2 diabetes mellitus
4	Bepride (4mg)	Sun Pharmaceutical Industries Ltd.	Tablet	4mg	lower the blood sugar levels in type 2 diabetes mellitus
5	Betaglim (1mg)	Panacea Biotec Ltd	Tablet	1mg	control blood sugar in people with type 2 diabetes
6	Blisto (2 mg)	Unichem Laboratories Ltd.	Tablet	2mg	lower the blood sugar levels in type 2 diabetes mellitus
7	Cgryl	Centaur Pharmaceuticals Pvt.Ltd.	Tablet	1mg	lower the blood sugar levels in type 2 diabetes mellitus
8	Diaglim	Dr Reddy Laboratories Ltd	Tablet	2mg	control blood sugar in people with type 2 diabetes.
9	Diagraph (2 mg)	BiomaxBiotechnicsPvt Ltd	Tablet	2mg	control blood sugar in people with type 2 diabetes.
10	Diapride	B & B (Micro Labs Ltd.)	Tablet	1mg	lower the blood sugar levels in type 2 diabetes mellitus
11	Diaset (1 mg)	StadmedPvt Ltd	Tablet	1mg	lower the blood sugar levels in type 2 diabetes mellitus
12	Diaswich (2 mg)	Piramal Healthcare	Tablet	2mg	lower the blood sugar levels in type 2 diabetes mellitus
13	Dibiglim	Sandoz (Novartis India Ltd)	Tablet	1mg	lower the blood sugar levels in type 2 diabetes mellitus
14	Emperide	Emcure Pharmaceuticals Ltd.	Tablet	1mg	lower the blood sugar levels in type 2 diabetes mellitus
15	Euglim (4 mg)	Indoco Remedies Ltd	Tablet	4mg	lower the blood sugar levels in type 2 diabetes mellitus
16	Flexiglim	Unichem Laboratories Ltd.	Tablet	0.5mg	lower the blood sugar levels in type 2 diabetes mellitus
17	Flexiglim (4 mg)	Otsira(Aristo Pharmaceuticals Pvt Ltd.)	Tablet	4mg	lower the blood sugar levels in type 2 diabetes mellitus
18	Gamaryl (3 mg)	Stancare (Ranbaxy Laboratories Ltd)	Tablet	3mg	lower the blood sugar levels in type 2 diabetes mellitus
19	Gemer	Xieon Lifesciences Pvt. Ltd.	Tablet	1mg	lower the blood sugar levels in type 2 diabetes mellitus
20	Gepride	Medley Pharmaceuticals Ltd.	Tablet	1mg	lower the blood sugar levels in type 2 diabetes mellitus
21	Geriglim	Alembic Limited.	Tablet	1mg	lower the blood sugar levels in type 2 diabetes mellitus
22	Geriglim (2 mg)	CND (ZydusCadila Healthcare Ltd)	Tablet	2mg	lower the blood sugar levels in type 2 diabetes mellitus
23	Gip (2 mg)	Win-Medicare Limited	Tablet	2mg	lower the blood sugar levels in type 2 diabetes mellitus
24	Glador	Lupin Laboratories Ltd.	Tablet	1mg	lower the blood sugar levels in type 2 diabetes mellitus
25	Gleam (1mg)	Franco Indian Remedies	Tablet	1mg	lower the blood sugar levels in type 2 diabetes mellitus

26	Gli (2 mg)	Cadila Pharmaceuticals Ltd.	Tablet	2mg	lower the blood sugar levels in type 2 diabetes mellitus
27	Glifix	Aurobindo Pharma Ltd.	Tablet	1mg	lower the blood sugar levels in type 2 diabetes mellitus
28	Glimcip	Cipla Limited	Tablet	1mg	lower the blood sugar levels in type 2 diabetes mellitus
29	Glimcom	Comed Chemicals Pvt Ltd	Tablet	1mg	lower the blood sugar levels in type 2 diabetes mellitus
30	Glime (2 mg)	Healtheon (Glenmark Pharmaceuticals Ltd.)	Tablet	2mg	lower the blood sugar levels in type 2 diabetes mellitus
31	Glimestar	Discovery (Mankind Pharmaceuticals Pvt. Ltd.)	Tablet	1mg	lower the blood sugar levels in type 2 diabetes mellitus
32	Glimfit (2 mg)	US Vitamins Limited	Tablet	2mg	lower the blood sugar levels in type 2 diabetes mellitus
33	Glimfit (4 mg)	Sun Pharmaceutical Industries Ltd.	Tablet	4mg	lower the blood sugar levels in type 2 diabetes mellitus
34	Glimitab (1mg)	Centaur Pharmaceuticals Pvt.Ltd.	Tablet	1mg	lower the blood sugar levels in type 2 diabetes mellitus
35	Glimkap	Karnataka Antibiotics & Pharmaceuticals Ltd.	Tablet	1mg	lower the blood sugar levels in type 2 diabetes mellitus
36	Glimpid (2mg)	Cardiovascular (Ranbaxy Laboratories Ltd)	Tablet	2mg	lower the blood sugar levels in type 2 diabetes mellitus
37	Glimpid (4 mg)	Intas Laboratories Pvt Ltd	Tablet	4mg	lower the blood sugar levels in type 2 diabetes mellitus
38	Glimser (2 mg)	Alembic Chemical Works Co Ltd	Capsule	2mg	lower the blood sugar levels in type 2 diabetes mellitus
39	Glimulin (4 mg)	Piramal Healthcare	Tablet	4mg	lower the blood sugar levels in type 2 diabetes mellitus
40	Glimy	Dr Reddy Laboratories Ltd	Tablet	1mg	lower the blood sugar levels in type 2 diabetes mellitus
41	Glimy (4 mg)	Intas Laboratories Pvt Ltd	Tablet	4mg	lower the blood sugar levels in type 2 diabetes mellitus
42	Glimz	Wallace Pharmaceuticals Ltd.	Tablet	1mg	lower the blood sugar levels in type 2 diabetes mellitus
43	Glista -OD	Cadila Pharmaceuticals Ltd.	Tablet	1mg	lower the blood sugar levels in type 2 diabetes mellitus
44	Glista -OD (2 mg)	Unichem Laboratories Ltd.	Tablet	2mg	lower the blood sugar levels in type 2 diabetes mellitus
45	Glp (2 mg)	IPCA Laboratories Ltd.	Tablet	2mg	lower the blood sugar levels in type 2 diabetes mellitus
46	Glucoryl	Alkem Laboratories Ltd	Tablet	1mg	lower the blood sugar levels in type 2 diabetes mellitus
47	Glycirid	Indi Pharma Pvt Ltd	Tablet	1mg	lower the blood sugar levels in type 2 diabetes mellitus
48	Grilde	Unichem Laboratories Ltd.	Tablet	3mg	lower the blood sugar levels in type 2 diabetes mellitus
49	Isryl (2 mg)	Systopic Laboratories (P) Ltd.	Tablet	2mg	lower the blood sugar levels in type 2 diabetes mellitus
50	K -Glim (2 mg)	Blue Cross Laboratories Ltd.	Tablet	2mg	lower the blood sugar levels in type 2 diabetes mellitus
51	Leride	Tablets (India) Limited	Tablet	1mg	lower the blood sugar levels in type 2 diabetes mellitus
52	Nabal	Win-Medicare Limited	Tablet	2mg	lower the blood sugar levels in type 2 diabetes mellitus
53	Novaride (4 mg)	Alembic Limited.	Tablet	4mg	lower the blood sugar levels

					in type 2 diabetes mellitus
54	Zoryl	Intas Laboratories Pvt Ltd	Tablet	1mg	lower the blood sugar levels in type 2 diabetes mellitus
55	Zoryl (3 mg)	US Vitamins Limited	Tablet	3mg	lower the blood sugar levels in type 2 diabetes mellitus
56	Zoryl (4 mg)	B & B (Micro Labs Ltd.)	Tablet	4mg	lower the blood sugar levels in type 2 diabetes mellitus

Conclusion:-

The main purpose of writing this review was to collect all relevant data in an article about glimeperide. In this different types of formulation of glimepiride are made which is provided in summarized and concised way for a better knowledge and future formulated approach.

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