



**INTERNATIONAL JOURNAL OF
PHARMACEUTICAL SCIENCES**
[ISSN: 0975-4725; CODEN(USA): IJPS00]
Journal Homepage: <https://www.ijpsjournal.com>



Review Article

A Review on Analytical Methods for Determination of Lobeglitazone Sulfate in Pharmaceutical and Biological Matrices

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ARTICLE INFO

Published: 11 Sept. 2025

Keywords:

diverse matrices,
medications, U.V. Visible
Spectrophotometry

DOI:

10.5281/zenodo.17100041

ABSTRACT

A key factor in the safety and effectiveness of pharmaceutical products is the qualitative and quantitative assessment of the medicine. In India, a novel thiazolidinedione called lobeglitazone (LGZ) has been approved to treat type 2 diabetes (T2D). It is believed to have less adverse effects than pioglitazone (PGZ). Since an attempt has been made in this study to compile all pertinent research for the estimation of Lobeglitazone in diverse matrices, both as a single drug and in combination with other medications, published in a variety of pharmaceutical journals. This review paper provided an overview of the fundamental and sophisticated methods for estimating the Lobeglitazone. The three methods that researchers employ the most frequently are U.V. Visible Spectrophotometry, High Performance Liquid Chromatography and High performance liquid chromatography. The approaches also provide comprehensive validation parameters, which help the researchers choose an analytical approach depending on the data they are looking for.

INTRODUCTION

Chronic metabolic disease known as diabetes mellitus (DM) is typified by ongoing hyperglycaemia. It could be brought on by decreased insulin secretion, resistance to insulin's peripheral effects, or both. The International Diabetes Federation (IDF) estimates that in 2015, 415 million adults in the 20–79 age range had diabetes mellitus.[1] As this number is predicted to

increase to an additional 200 million by 2040, diabetes is proving to be a global public health burden.[1] In individuals with diabetes mellitus, chronic hyperglycaemia can exacerbate other metabolic abnormalities and harm multiple organ systems. This can result in life-threatening and incapacitating health complications, the most common being microvascular (retinopathy, nephropathy, and neuropathy) and macrovascular (a 2- to 4-fold increased risk of cardiovascular

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Relevant conflicts of interest/financial disclosures: The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.



diseases). Based on its origin and clinical manifestation, diabetes mellitus is categorized into three main types: type 1 diabetes, type 2 diabetes, and gestational diabetes (GDM). Secondary diabetes and monogenic diabetes are two other, less prevalent forms of the disease.[2][3][4][5]

Diabetes Mellitus Type 1 (T1DM)

5% to 10% of people with diabetes have type 1 diabetes mellitus (T1DM), which is defined by the autoimmune destruction of the beta cells in the pancreatic islets that produce insulin. Consequently, there is a complete lack of insulin. Autoimmunity has been linked to a mix of genetic predisposition and environmental influences, including viruses, poisons, and certain food items. T1DM can occur at any age, however it is more frequently observed in children and adolescents.

Diabetes Mellitus Type 2 (T2DM)

Roughly 90% of all instances of diabetes are type 2 diabetic mellitus (T2DM). Insulin resistance is the term used to describe the reduced response to insulin in type 2 diabetes. In order to maintain glucose homeostasis during this condition, insulin is ineffective and is initially countered by an increase in insulin production. However, over time, insulin production diminishes, leading to type 2 diabetes. Adults over 45 are most typically diagnosed with type 2 diabetes. However, because obesity, physical inactivity, and energy-dense diets are on the rise, it is becoming more common among kids, teens, and young adults.

Gestational diabetes mellitus

Gestational diabetes mellitus, or hyperglycemia in pregnancy, is the term used to describe hyperglycemia that is initially discovered during pregnancy. Though it can happen at any point during pregnancy, pregnant women are most likely

to experience GDM in the second and third trimesters. The American Diabetes Association (ADA) states that 7% of pregnancies end in complications due to GDM. Future type 2 diabetes mellitus is more likely to occur in children born to women with GDM. Hypertension, preeclampsia, hydramnios, and GDM can all exacerbate the condition and increase the need for surgical treatments. The fetus may be larger and heavier than usual (macrosomia) or it may have congenital abnormalities. These newborns may experience respiratory distress syndrome even after delivery, which increases the risk of childhood and teenage obesity. Risk factors for gestational diabetes mellitus include advanced age, obesity, high gestational weight gain, a family history of diabetes, and a history of congenital abnormalities in prior children.

Diabetes monogenic

This kind of diabetes is brought on by a single genetic mutation in an autosomal dominant gene. Neonatal diabetes mellitus and maturity-onset diabetes of the young (MODY) are two instances of monogenic diabetes. Monogenic diabetes accounts for 1% to 5% of all instances of diabetes. A hereditary condition, MODY typically manifests in people under the age of 25.

Diabetes Secondary

Complications from other pancreatic disorders (like pancreatitis), hormone imbalances (like Cushing disease), or medication side effects (like corticosteroids) might result in secondary diabetes. Lobjitazone Sulphate (C₂₄H₂₄N₄O₅S) is a new drug candidate for Type2 diabetes mellitus treatment. LBG is a medication belonging to the thiazolidinedione class, serves as an antidiabetic agent (Figure 1). It is chemically known as 5-(4-(2-((6-(4-Methoxyphenoxy) pyrimidin-4-yl) (methyl)amino) ethoxy) benzyl) thiazol2,4-dione.



Molecular weight of lobeglitazone sulphate is 578.6 g/mol. Physical properties and taxonomy are mentioned in table 1 and 2, respectively. Its main mechanism involves enhancing insulin sensitivity by engaging Peroxisome Proliferator-Activated Receptors (PPAR) gamma found in adipose tissue. Through this activation, lobeglitazone facilitates insulin's binding to adipose cells, leading to decreased blood glucose levels, improved HbA1C levels, and better lipid and liver profiles. [7,8]

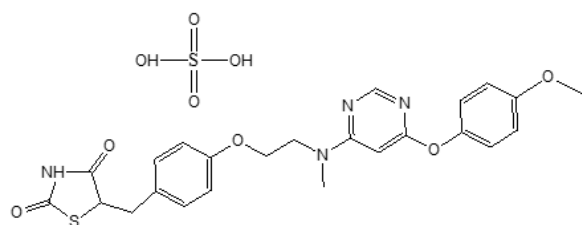


Figure 1: Chemical structure of Lobeglitazone sulphate

Table 1: Physical property of Lobeglitazone sulphate ¹⁷¹

State	White or pale-yellow powder
Solubility	Dimethyl sulfoxide (DMSO)
Pka	6.35±0.50(Predicted)
Log P	4.3
Melting Point	165-167 °C

Table 2: Summary of Lobeglitazone pharmacokinetic parameters after a single oral dose of 0.5 mg in health male subjects ¹⁸¹

Parameter	Value
T _{max} , hr ^a	1.00±0.50
C _{max} , µg/L	50.0±7.9
AUC _{inf} , µg/hr/L	379.0±44.6
CL/F, L/hr	1.33±0.15
t _{1/2} , hr	7.82±0.43
f _e , %	Negligible
Protein binding, %	99.3–99.9
Metabolism	CYP 3A4 (main), 2C19 and 2D6
Metabolites	M7 (O-demethylation; main), M9 (N-demethylation)
T max, hr ^a	1.00±0.50

Values are presented as mean±standard deviation unless indicated otherwise. T_{max}, time to C_{max}; C_{max}, maximum plasma concentration; AUC_{inf}, area under concentration–time curve from 0 to infinity; CL/F, oral clearance; t_{1/2}, elimination half-life; f_e, fraction excreted unchanged in urine; CYP, cytochrome P450. A Median and range are presented for T_{max}, bFraction of Lobeglitazone excreted unchanged in urine was below the lower limit of quantification (0.2 ng/mL).

Table 3: Taxonomy of Lobeglitazone sulfate ¹⁷¹

Kingdom	Organic compound
Super class	Organic oxygen compounds
Class	Thiazolidinedione
Subclass	Ethers
Direct Parent	Diarylethers
Alternative Parent	Phenoxy compounds / Methoxybenzenes / Anisoles / Dialkylarylamines / Thiazolidinediones / Alkyl aryl ethers / Aminopyrimidines and derivatives / Imidolactams / Heteroaromatic compounds / Dicarboximides
Substitutents	Alkyl aryl ether / Aminopyrimidine / Anisole / Aromatic heteromonocyclic compound / Azacycle / Benzenoid / Carbonic acid derivative / Carbonyl group / Carboxylic acid derivative / Dialkylarylamine
Molecular Framework	Aromatic heteromonocyclic compounds

Table 4: Marketed formulations of Lobeglitazone sulfate

Generic Name	Brand Name	Dosage Form	Strength	Manufacturer
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Lobeglitazone	LOBG	Tablet	0.5 mg	Glenmark Pharmaceuticals Ltd.
Lobeglitazone	Lobeglitone	Tablet	0.5 mg	Steris Healthcare Pvt Ltd
Lobeglitazone	Lobetron	Tablet	0.5mg	Zuventus Healthcare Ltd
Lobeglitazone+Glimepiride	LOBG-G1	Tablet	0.5mg/1mg	Glenmark Pharmaceuticals Ltd.
Lobeglitazone	Lobula	Tablet	0.5mg/1mg	La Renon Healthcare Pvt Ltd

Analytical Methods for Estimation of Lobeglitazone sulphate in Bulk Drug, Pharmaceutical Formulation and Biological Fluids

Many different analytical methods have been reported for the estimation of Lobeglitazone Sulfate in bulk and dosage form as well as in biological fluids.

High Performance Liquid Chromatography (HPLC) methods

A simple, precise, and accurate reverse-phase high-performance liquid chromatography

approach is described by Kalepu Eswar Krishna Sai et al. to determine the amount of Lobeglitazone in both bulk and pharmaceutical dose forms. A 250 cm×4.6 mm×5 µm Phenomenex Luna column was used for the chromatographic separation. The mobile phase consisted of acetonitrile and potassium dihydrogen orthophosphate in a 70:30 V/V ratio and a pH of 4.0 that was adjusted using orthophosphoric acid. The effluents were detected at a wavelength of 250 nm, with a flow rate of 1.0 mL/min. Lobeglitazone was shown to have a retention period of 2.157 minutes. In accordance with ICH criteria, the HPLC technique was designed and verified satisfactorily. (Table 5).

Table 5: Validation parameters reported by Kalepu Eswar Krishna Sai et al ^[9]

Parameter	Result
Stationary Phase	Phenomenex Luna column with dimensions of 250 cm×4.6 mm×5 µm
Mobile phase	Potassium dihydrogen orthophosphate: acetonitrile in a 70:30 V/V ratio
Detection wavelength	250 nm
Linearity	10-60 µg/mL
Correlation coefficient	0.9996
Flow rate	1.0 mL/min
Retention time	2.157 min
LOD	0.8 µg/mL
LOQ	2.5 µg/mL
Precision(%RSD)	0.228-0.335
Accuracy	80%
	100%
	120%
99.78%-101.31%	
% Assay	99%

Bioanalytical Method:

Piyusha D. Gulhane et al developed a simple, rapid, reliable, precise, accurate, sensitive and

selective analytical method for the estimation of Lobeglitazone in human plasma using as an internal standard (IS). The method was developed using acetonitrile-methanol-water (6:3:1, v/v) 10



μL of supernatant was injected into the HPLC system. The method showed good linearity. Subsequently, serial dilutions of five different concentrations ranging between 3.12–50 ppm were made, ultrasonicated and then analysed as per the chromatographic condition for Plasma ($r^2 \geq 0.9996$). The mean percent extraction recovery of Lobjeglitazone was 90.8 % for plasma. The intra-day precision of plasma ranged from 0.233, 0.290, 1% (RSD), respectively, and the inter-day precision of plasma ranged from 1.5 to 0.115 and 0.99, 1%, respectively. The method was validated with respect to accuracy, precision, linearity and robustness.

Table 6: Validation parameters reported by Piyusha D. Gulhane et al ^[10]

Parameter		Result
Mobile phase		Acetonitrile-methanol-water (6:3:1, v/v) 10 μL
Concentration range(ppm)		3.12-50 ppm
Correlation Coefficient(r^2)		0.9996
LOD (ng/band)		1.05
LOQ(nr/band)		3.04
Precision	Intra-day %RSD	0.233-0.290

	Inter-day %RSD	1.5-0.115
Accuracy	80%	98.23 %-100.73%
	100%	
	120%	

High Performance Thin Layer Liquid Chromatography (HPTLC) methods

The HPTLC technique was developed by Asim Kumar Sen et al. to accurately quantify glimepiride and lobjeglitazone sulfate in tablet formulations. Aluminum plates coated with silica gel 60F254 were used for the HPTLC examination. The solvent solution comprised ethyl acetate, benzene, and hexane (4:3:1 v/v/v), which was followed by densitometric scanning at 238 nm. It was determined that the Rf value for GLM was 0.48 ± 0.002 and for LBZ it was 0.68 ± 0.001 . With correlation values of 0.9988 and 0.9981 for LBZ and 200–4000 ng/band for GLM, respectively, the approach demonstrated linearity in these ranges. With quantification limits of 72.32 ng/band for LBZ and 176.55 ng/band for GLM, and detection limits of 23.86 ng/band for LBZ and 58.26 ng/band for GLM, exceptional sensitivity was noted (Table 7).

Table 7: Validation parameters reported by Asim Kumar Sen et al ^[11]

Parameters		Method I	
		LBG	GLM
Densitometric scanning wavelength (nm)		238 nm	
Stationary Phase		Aluminium plates layered with silica gel 60F ₂₅₄	
Mobile Phase		Ethyl acetate, benzene, and hexane (4:3:1 v/v/v)	
Rf Value		0.68 ± 0.001	0.48 ± 0.002
Concentration range (ng/band)		100–2000	6-26
Correlation Coefficient (r^2)		0.9988	0.999
LOD (ng/band)		23.86	58.26
LOQ(ng/band)		72.32	176.55
Precision	Repeatability (n=6) %RSD	Less than 2	
	Intraday (n=3) %RSD		
	Interday (n=3) %RSD		
Accuracy (%)	80%	97% -102%	
	100%		
	120%		
% Label claim Assay \pm SD (n=3)		100.33 ± 1.00	100.66 ± 1.28

UV Spectrophotometric methods

Jeel Dobariya et al., developed two UV spectrophotometric methods for accurately analyzing Lobeglitazone Sulfate and Glimepiride in combined dosage form, used in the treatment of type 2 Diabetes Mellitus. Method I, known as the simultaneous equation method (Vierodt's Method), relies on measuring the absorption at 250 nm for Lobeglitazone Sulfate and 227 nm for Glimepiride, their respective λ_{max} values. Method II involves the second order derivative method, where the absorbance of Lobeglitazone Sulfate is

measured at 297 nm (zero-crossing point of Glimepiride), and that of Glimepiride is measured at 259 nm (zero-crossing point of Lobeglitazone Sulfate). Both methods exhibit linearity within specified concentration ranges: 3-13 $\mu\text{g}\cdot\text{mL}^{-1}$ for Lobeglitazone Sulfate and 6-26 $\mu\text{g}\cdot\text{mL}^{-1}$ for Glimepiride, using methanol as the solvent. The accuracy of these methods was confirmed through recovery studies, yielding results within the range of 98-102% for both drugs. Precision was evaluated through repeatability and intermediate precision studies, demonstrating % RSD values below 2%, indicating high precision (Table 8).

Table 8: Validation parameters reported by Jeel Dobariya et al^[12]

Parameters		Method I		Method II	
		LBG	GLM	LBG	GLM
Working wavelength (nm)		250 nm	227 nm	297 nm	259 nm
Concentration range ($\mu\text{g}/\text{ml}$)		3-13	6-26	3-13	6-26
Slope		0.055	0.065	0.050	0.0952
Intercept		0.020	0.021	0.007	0.0358
Correlation Coefficient (r^2)		0.997	0.999	0.999	0.999
LOD ($\mu\text{g}/\text{ml}$)		0.401	0.104	0.066	0.084
LOQ ($\mu\text{g}/\text{ml}$)		1.217	0.316	0.201	0.257
Precision	Repeatability (n=6) %RSD	1.72	0.73	0.70	1.05
	Intraday (n=3) %RSD	0.78-1.25	0.53-0.69	0.44 - 0.78	0.35 - 1.04
	Interday (n=3) %RSD	0.87-1.56	0.72-0.94	1.45 - 1.69	0.53 - 1.11
Accuracy (%)	80%	98.50 \pm 1.18	99.50 \pm 1.25	100.50 \pm 1.06	100.75 \pm 0.61
	100%	98.80 \pm 1.00	100.60 \pm 1.06	98.80 \pm 1.46	100.20 \pm 1.09
	120%	99.66 \pm 0.80	100.50 \pm 0.67	100.66 \pm 1.04	100.50 \pm 0.32
% Label claim Assay \pm SD (n=3)		100.33 \pm 1.00	100.66 \pm 1.28	100.53 \pm 0.77	100.12 \pm 0.42

CONCLUSION

Several approaches have been published for the measurement of the anti-diabetic medication Lobeglitazone sulfate in pharmaceutical formulations and biological matrices. The most used techniques for estimating Lobeglitazone sulfate in bulk, formulations, and biological matrices are RP-HPLC, HPTLC, and UV

Spectrophotometry. As a result, the current review aids researchers in expanding their perspectives on several enhanced features for upcoming research on medication evaluation.

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HOW TO CITE: Dr. Dhara Patel*, Shaili Patel, Sujan Ghanchi, Surbhi Raval, Dhananjay Meshram, A Review on Analytical Methods for Determination of Lobeglitazone Sulfate in Pharmaceutical and Biological Matrices, *Int. J. of Pharm. Sci.*, 2025, Vol 3, Issue 9, 1207-1213 <https://doi.org/10.5281/zenodo.17100041>

