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QBD-Driven RP-HPLC Method Development and Validation for Ipragliflozin and Saxagliptin in Pharmaceutical Dosage Forms Following ICH Guidelines

Bidlan Komal*, Dr. K. Chaitanya Prasad, Dr. K. Nagasree, Dr. K. Shravan Kumar

Samskruti College of Pharmacy, Kondapur, Ghatkesar, Medchal, Hyderabad-501301, Telangana, India

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Abstract:
A robust and validated Reverse Phase High-Performance Liquid Chromatography (RP-HPLC) method was developed for the simultaneous estimation of Ipragliflozin and Saxagliptin in pharmaceutical dosage forms. Method optimization was achieved using a Box-Behnken Design, evaluating the influence of key chromatographic parameters such as buffer pH and flow rate. Optimal separation was accomplished using an Inspire C18-EP column (4.6 × 250 mm, 5 µm) with a mobile phase of methanol and phosphate buffer (pH 6.0) in a 70:30 ratio, at a flow rate of 1 mL/min and UV detection at 254 nm. The method demonstrated excellent resolution (3.52), acceptable tailing factors (<1.2), and high theoretical plate counts, confirming efficient peak performance. ANOVA results validated the statistical significance of the model, and all system suitability parameters met regulatory standards. The method was thoroughly validated in accordance with ICH guidelines, showing excellent linearity for Ipragliflozin (30–150 µg/mL, R^2 = 0.9993) and Saxagliptin (3–15 µg/mL, R^2 = 0.9994). Assay results confirmed high accuracy with recoveries of 99.7% and 99.6% respectively. Precision studies yielded %RSD values below 2%, indicating strong repeatability and intermediate precision. Sensitivity was established through low LOD and LOQ values, while robustness was confirmed under deliberate variations in chromatographic conditions. Overall, the developed RP-HPLC method is simple, precise, accurate, and reliable, making it highly suitable for routine quality control of Ipragliflozin and Saxagliptin in bulk and formulated pharmaceutical products.

Keywords: buffer pH, flow rate, Inspire C18-EP column, methanol, phosphate buffer, resolution, tailing factor, theoretical plate count, ANOVA, system suitability, ICH guidelines, linearity, precision, accuracy, %RSD, recovery, limit of detection (LOD), limit of quantification (LOQ)

Introduction

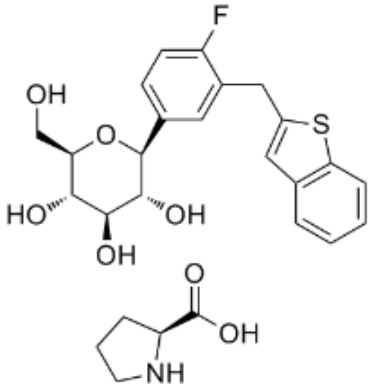

Fig.1: Ipragliflozin structure

Basic Information
IUPAC Name: (1S)-1,5-Anhydro-1-[3-(1-benzothiophen-2-ylmethyl)-4-fluorophenyl]-D-glucitol
Molecular Formula: $C_{21}H_{21}FO_5S$
Molecular Weight: 404.45 g/mol
Melting Point: Approximately 110 °C
pKa: Approximately 7.51
Category: Antidiabetic (SGLT2 inhibitor)
Solubility: Poorly soluble in water

Description: Ipragliflozin is an oral antidiabetic medication used to treat type-2 diabetes mellitus. It works by inhibiting the sodium-glucose co-transporter 2 (SGLT2) in the kidneys, which reduces glucose reabsorption and increases glucose excretion in the urine.

Mechanism of Action:
Ipragliflozin selectively inhibits SGLT2, a protein responsible for glucose reabsorption in the kidneys. By blocking this protein, it reduces blood glucose levels by promoting the excretion of glucose through urine.

Pharmacodynamics
Ipragliflozin lowers blood glucose levels by increasing urinary glucose excretion. This action helps to improve glycemic control in patients with type 2 diabetes.

Pharmacokinetics
Absorption: Well absorbed from the gastrointestinal tract.
Distribution: Widely distributed in body tissues1.
Metabolism: Metabolized primarily by UGT2B7, with minor contributions from UGT2B4, UGT1A8, and UGT1A91.
Route of Elimination: Primarily excreted in the urine (67.9%) and feces (32.7%).
Protein Binding: Approximately 94.6-96.5%.
Half-Life: Around 14.97 ± 4.58 hours.

Uses:
Primary Use: Treatment of type 2 diabetes mellitus.

Dosage
Adults: Typically 50 mg once daily, which may be increased to 100 mg once daily if needed.
Children: Not typically used in pediatric patients

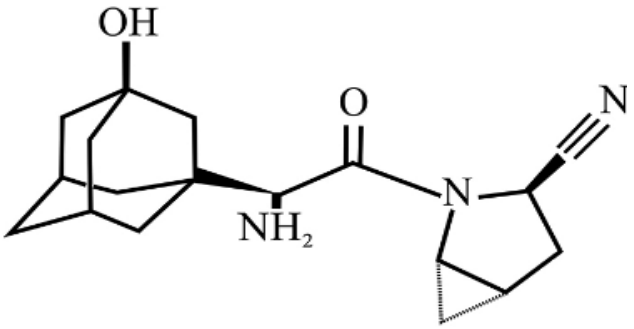

Fig.2: Saxagliptin Structure

Basic Information

IUPAC Name: (1S,3S,5S)-2-[(2S)-2-amino-2-(3-hydroxyadamantan-1-yl)acetyl]-2-azabicyclo[3.1.0]hexane-3-carbonitrile

Molecular Formula: $C_{18}H_{25}N_3O_2$

Molecular Weight: 315.41 g/mol1

Melting Point: Approximately 222-225 °C

pKa: Approximately 8.71

Category: Antidiabetic (DPP-4 inhibitor)

Solubility: Poorly soluble in water

Description

Saxagliptin is an oral antidiabetic medication used to improve blood sugar control in adults with type 2 diabetes mellitus. It is not used for treating type 1diabetes.

Mechanism of Action

Saxagliptin works by inhibiting the enzyme dipeptidyl peptidase-4 (DPP-4). This inhibition increases the levels of in cretin hormones, which help to regulate blood sugar by increasing insulin release and decreasing glucagon levels.

Pharmacodynamics

Saxagliptin helps to lower blood sugar levels by enhancing the body's natural ability to control blood sugar levels, especially after meals1.

Pharmacokinetics

Absorption: Well absorbed from the gastrointestinal tract.

Distribution: Widely distributed in body tissues.

Metabolism: Metabolized primarily by the liver.

Route of Elimination: Primarily excreted in the urine.

Protein Binding: Approximately 70%.

Half-Life: Around 2.5 hours.

Uses

Primary Use: Treatment of type 2 diabetes mellitus.

Materials and Methods

Table 1: List of Proposed Materials

S.No.	Chemicals/standards and reagents	Make
1	Trifluoro acetic acid	Qualigens
2	Formic acid	Qualigens
3	Water	Qualigens
4	Acetonitrile	Qualigens
5	Methanol	Rankem

Table 2: List of **Equipment's**

S.No.	Equipment	Model/Type
1	Electronic Balance	SAB2032
2	Ultra-Sonicator	SE60US
3	Thermal Oven	i-THERM A17782
4	pH Meter	ORION STAR A111
5	Filter Paper	0.45 microns
6	HPLC System	Waters 2690 Separation Module

Optimization of Column:

InspireC18-EP (4.6 x 250mm, 5µm) was found to be ideal as it gave good peak shape and resolution at 1.0 ml/min flow.

Optimized Chromatographic Conditions

Instrument used : High performance liquid chromatography equipped With Auto Sampler and PDA detector

Temperature : Ambient

Column : Inspire C18-EP (4.6 x 250mm, 5µm)

Mobile phase : MEOH: NAH2PO4 PH 6 (70:30ml)

Flow rate : 1ml/min

Wavelength : 254 nm

Injection volume : 10 µl

Run time : 8 min.

Preparation of Buffer and Mobile Phase

Preparation of Phosphate buffer pH 5:

To prepare Sodium phosphate buffer solution, by adding 6.4gm of sodium buffer in 1000ml water. Adjust this solution to ph 6 by using NAOH.

Preparation of mobile phase:

Mix a mixture of above 300 ml NAH2PO4 (30%) and MEOH 700ml (70%) and degas in ultrasonic water bath for 5 minutes. Filter through 0.45 µ filter under vacuum filtration.

Diluent Preparation: MEOH: NAH2PO4 buffer PH 6 (70:30) ratio.

System Suitability:

Tailing factor for the peaks due to Ipraglifozine and saxagliptin in Standard solution should not be more than 2.0**.** Theoretical plates for the Ipraglifozine and saxagliptin peaks in Standard solution should not be less than 2000

Calculation: (For Ipraglifozine and saxagliptin)

Where:

$$\%\,Assay = \frac{AT}{AS} * \frac{WS}{DS} * \frac{DT}{WT} * \frac{Average\,weight}{Label\,Claim} * \frac{P}{100} * 100$$

AT= average area counts of sample preparation.

AS= average area counts of standard preparation.

WS= Weight of working standard taken in mg.

P= Percentage purity of working standard

LC= Label Claim mg/ml.

Acceptance criteria of System Suitability:

1) Tailing factor should be less than 2

2) Theoretical Plates should be above 2000

Assay:

Standard Solution Preparation:

Accurately weigh and transfer 20mg of Ipragliflozine and 2mg Saxagliptin working standard into a 20ml clean dry volumetric flask add Diluents and sonicate to dissolve it completely and make volume up to the mark with the same solvent. (Stock solution). Further pipette 0.9ml of the above stock solution into a 10ml volumetric flask and dilute up to the mark with Diluents (90ppm Ipragliflozine, 9ppm Saxagliptin).

Sample Solution Preparation:

Accurately weigh and transfer equivalent to 20mg of Ipragliflozine and 2mg Saxagliptin equivalent weight of the sample into a 20ml clean dry volumetric flask add Diluents and sonicate to dissolve it completely and make volume up to the mark with the same solvent. (Stock solution). Further pipette

0.9ml of the above stock solution into a 10ml volumetric flask and dilute up to the mark with Diluents (90ppm Ipragliflozine, 9ppm Saxagliptin).

Procedure:

Inject 10 µL of the standard, sample into the chromatographic system and measure the areas for the Ipragliflozine and Saxagliptin peaks.

Results and Discussion

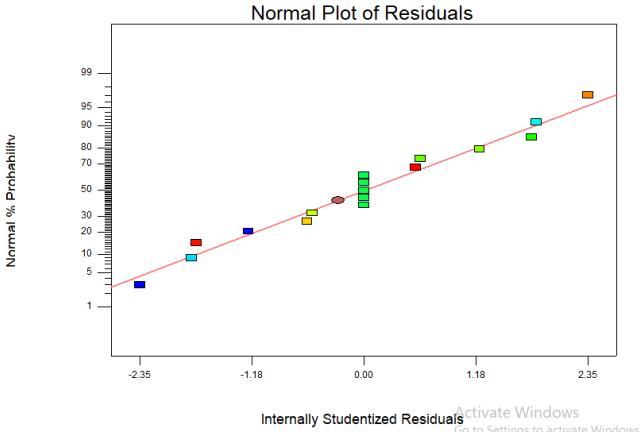

Fig.3: Normal plot of Residuals for Ipragliflozin & Saxagliptin

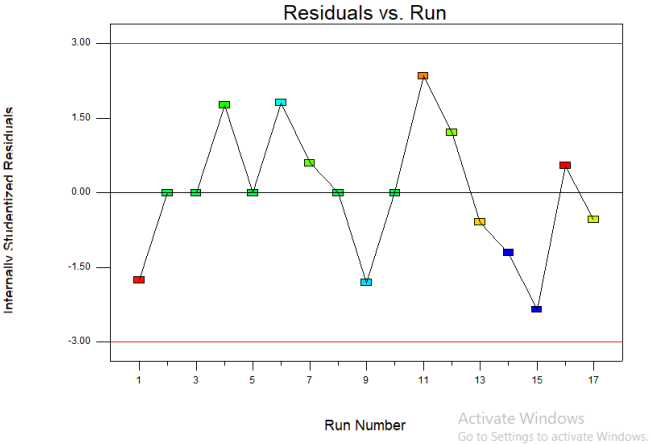

Fig.4: Residuals vs. Run for Ipragliflozin and Saxagliptin

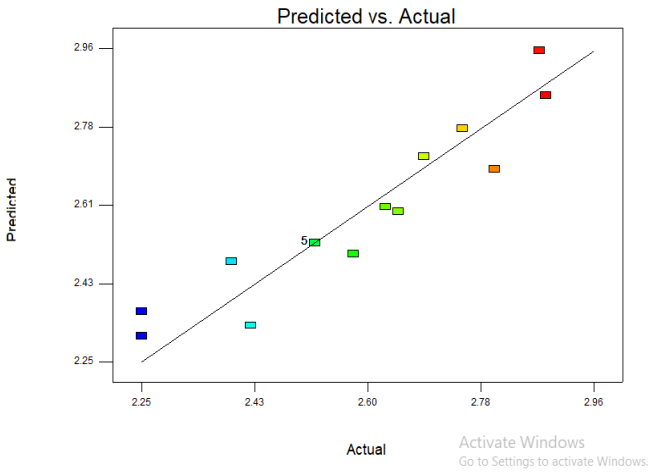

Fig.5: Predicted vs. Actual for Ipragliflozin and Saxagliptin

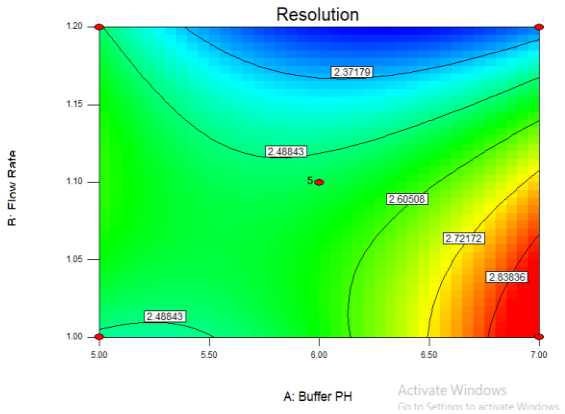

Fig.6: Resolution for Ipragliflozin and Saxagliptin

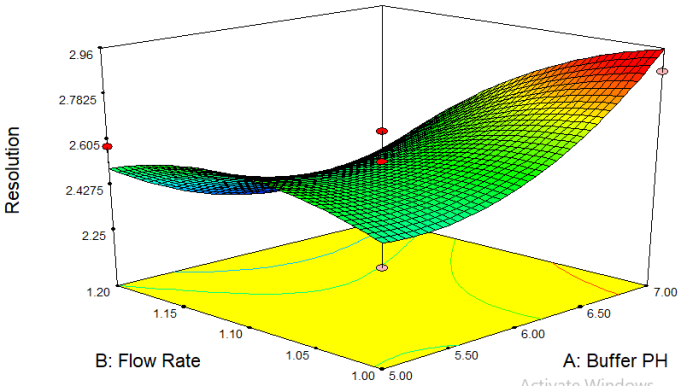

Fig.7: 3D Surface for Ipragliflozin and Saxagliptin

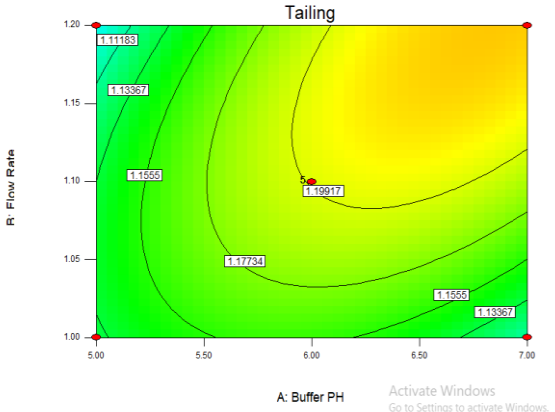

Fig.8: Tailing factor for Ipragliflozin and Saxagliptin

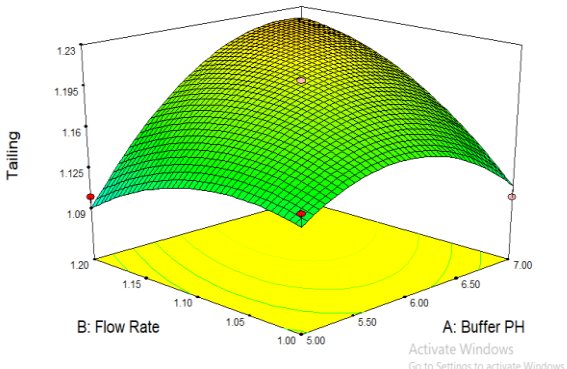

Fig.9: 3D 3D Surface for Ipragliflozin and Saxagliptin

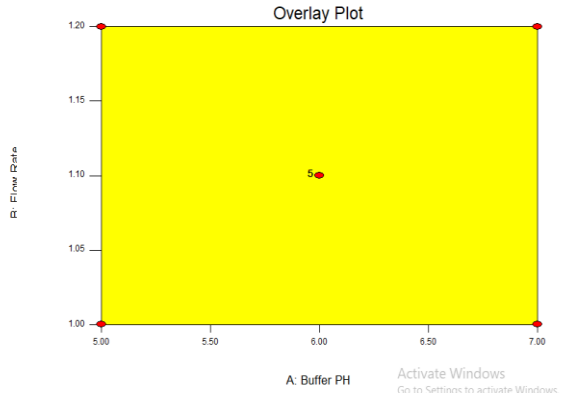

Fig.8: Overlay plot for Ipragliflozin and Saxagliptin

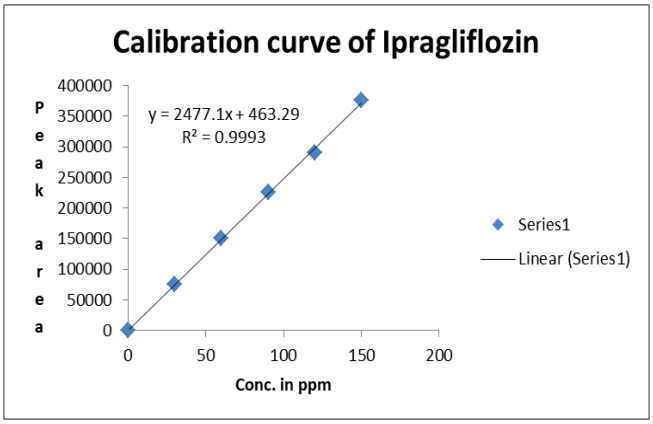

Fig.12: Calibration graph for Ipraglifozine

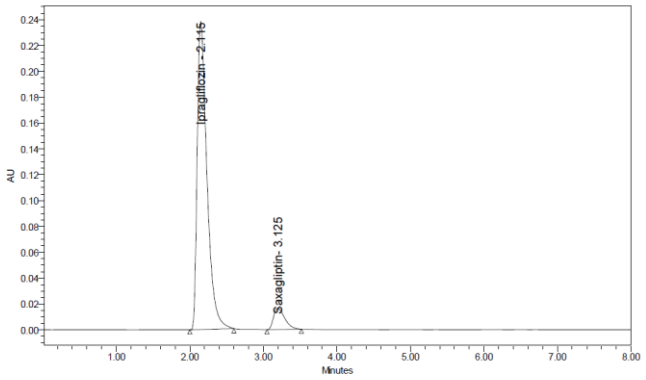

Fig.9: Chromatogram for system suitability

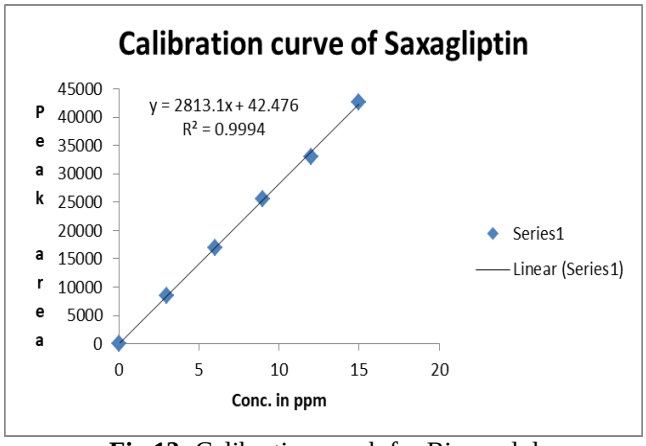

Fig.13: Calibration graph for Bisoprolol

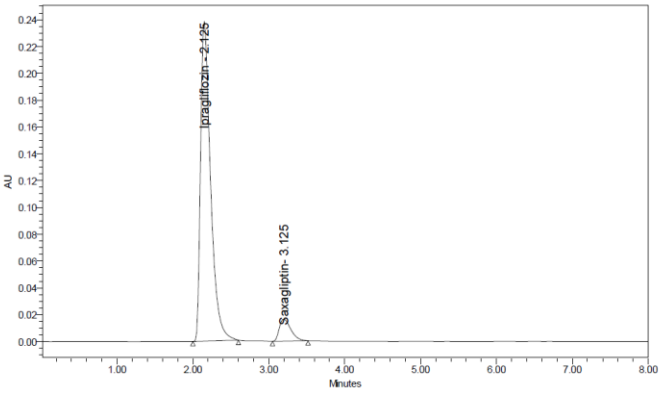

Fig.10: Chromatogram for Standard

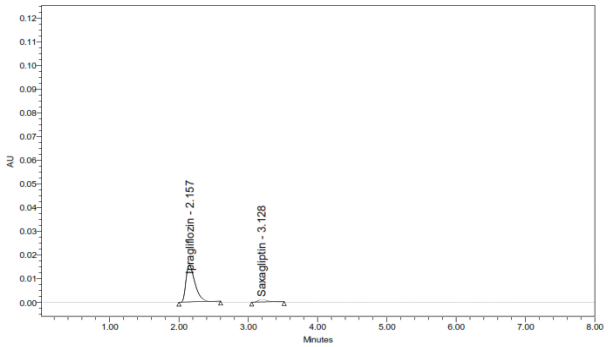

Fig.14: Ipraglifozine and saxagliptin showing LOD

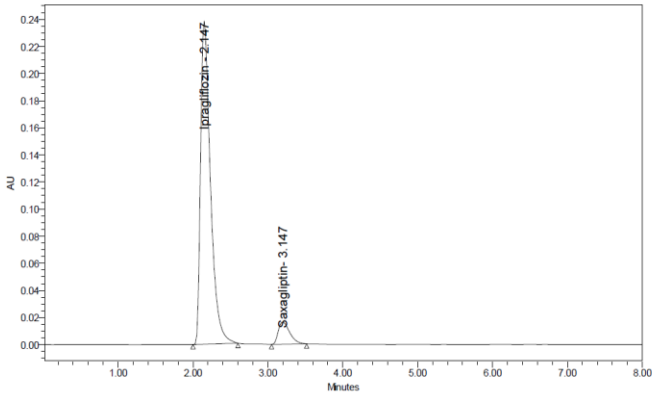

Fig.11: Chromatogram for Sample

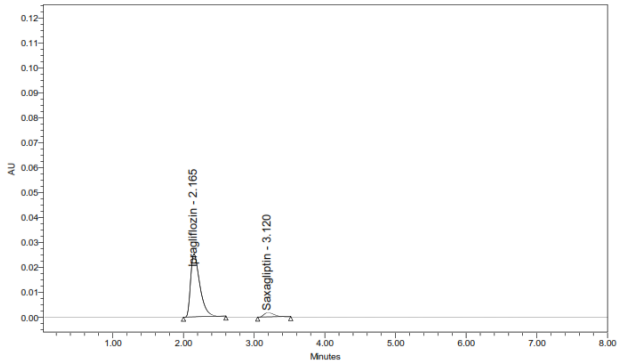

Fig.15: Ipraglifozine and saxagliptin showing LOQ

Table 3: ANOVA for Response Surface Quadratic Model

Source	Sum of square	df	Mean square	F value	P value Prob>f	
Model	0.50	9	0.056	5.96	0.0141	significant
A-Buffer PH	0.050	1	0.050	5.30	0.0549	
B-Flow Rate	0.18	1	0.18	19.54	0.0031	
C-Organic ratio in MP	8.000E-004	1	8.000E-004	19.54	0.7786	
Residual	0.066	7	9.368E-003			
Lack of Fit	0.066	3	0.022			
Pure Error	0.000	4	0.000			

Table 4: Results of system suitability parameters

Name	Rt	Area	Height	Resolution	Tailing factor	Plate count
Ipragliflozin	**2.115**	**224851**	**745172**	**3.52**	**1.02**	**6810**
Saxagliptin	**3.125**	**25724**	**74451**		**1.15**	**2572**

Table 5: Accuracy (recovery) data for Ipraglifozine and saxagliptin

% Concentration Ipraglifozine	Area*	Amount Added (mg)	Amount Found (mg)	% Recovery	Mean Recovery
50%	112281	10	9.9	99.5	98.9
100%	218547	20	19.6	98.1	
150%	330952	30	29.3	99.1	

%Concentration saxagliptin	Area*	Amount Added (mg)	Amount Found (mg)	% Recovery	Mean Recovery
50%	12701	1	0.98	98.5	98.6
100%	25296	2	1.96	98.1	
150%	38340	3	2.97	99.1	

Table 6: Results of LOD

Drug name	Baseline noise(µV)	Signal obtained(µV)	S/N ratio	Conc.
Ipraglifozine	63	170	2.70	0.02
saxagliptin	63	186	2.95	0.02

Table 7: Results of LOQ

Drug name	Baseline noise(µV)	Signal obtained(µV)	S/N ratio	CONC. In ppm
Ipraglifozine	63	615	9.76	0.07
saxagliptin	63	629	9.98	0.08

Conclusion

A robust and validated RP-HPLC method was successfully developed for the simultaneous estimation of Ipragliflozin and Saxagliptin using a Box-Behnken Design to optimize chromatographic conditions. The optimal separation was achieved on an Inspire C18-EP (4.6x250mm, 5µm) column with a mobile phase comprising methanol and phosphate buffer (pH 6.0) in a 70:30 ratio, at a flow rate of 1mL/min and detection at 254 nm. The method showed excellent resolution (3.52) between the two drugs, acceptable tailing factors (<1.2), and high theoretical plate counts, indicating good peak efficiency. ANOVA results confirmed the significance of buffer pH and flow rate on resolution and tailing factor. System suitability parameters were within the specified limits, fulfilling regulatory expectations. Validation studies as per ICH guidelines demonstrated that the method is linear, precise, accurate, and robust. The method showed excellent linearity for Ipragliflozin (30–150 µg/mL) and Saxagliptin (3–15 µg/mL), with correlation coefficients of 0.9993 and 0.9994 respectively. Assay results showed 99.7% for Ipragliflozin and 99.6% for Saxagliptin, indicating high method accuracy. Precision studies yielded %RSD values <2, confirming repeatability and intermediate precision. Recovery values in accuracy studies were within 98–102%, and LOD/LOQ values confirmed method sensitivity. Robustness was validated by deliberate variations in flow rate and mobile phase composition, with no significant changes in system suitability. Overall, the developed method is suitable for routine quality control analysis of Ipragliflozin and Saxagliptin in pharmaceutical dosage forms.

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[3] "Aspects and Implementation" (MDPI) – Also outlines the ICH Q8(R2) definition of QbD, design space, DoE, risk management, PAT, and regulatory support.

[4] Science Direct review, "Quality by design in pharmaceutical manufacturing" – Highlights QbD elements like QTPP, CQAs, CMAs, CPPs, design space, and control strategy; includes regulatory milestones such as the first QbD-based drug approval (Januvia, 2006).

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