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Stability indicating UV spectrophotometric method development, validation and estimation of inosine pranobex in bulk and tablet dosage form

Geetha V, Vetrichelvan T and Murugan S

Abstract
Novelty: The present study reports, for the first time, the development of three simple, rapid, and eco-friendly UV spectrophotometric methods for the quantitative estimation of Inosine Pranobex using distilled water as solvent and cost-effective analytical method for routine quality control, as no UV spectrophotometric methods have been previously documented.
Materials and Methods: Three methods Zero-order (259 nm), First-order derivative (213 nm), and Area under the Curve (269-249 nm) were developed and validated in accordance with ICH guidelines. Linearity was established within 2-10 µg/ml and 10-50 µg/ml concentration ranges.
Results and Discussion: All methods exhibited excellent linearity, accuracy, and precision (% RSD < 2%), with satisfactory LOD and LOQ values. Forced degradation studies confirmed the drug's stability under various stress conditions.
Conclusion: The developed methods are novel, accurate, precise, sensitive, and economical, making them highly suitable for routine analysis of Inosine Pranobex in bulk and pharmaceutical formulations.

Keywords: Inosine pranobex, UV visible spectrophotometric methods, three methods, forced degradation studies

Introduction
Inosine pranobex also referred to as inosine acedoben dimepranol (INN), methisoprinol, inosiplex, or Isoprinosine is a synthetic antiviral drug composed of inosine and dimepranol acedoben (a salt of acetamidobenzoic acid and dimethylaminoisopropanol) in a fixed 1:3:3 molar ratio [1-4]. Widely prescribed in several European countries, it is primarily indicated for the treatment of acute viral infections [5][7], including the common cold and HIV infections to overt AIDS.[6] This medication used to treat the various virus related conditions like rheumatoid arthritis, multiple sclerosis and alopecia.[8] The compound is chemically defined as 4-acetamidobenzoic acid, 9-[(2R,3R,4S,5R)-3,4-dihydroxy-5-(hydroxymethyl)oxolan-2-yl]-1H-purin-6-one,1 (dimethylamino) propan-2-ol.[9-11] (Fig. 1).

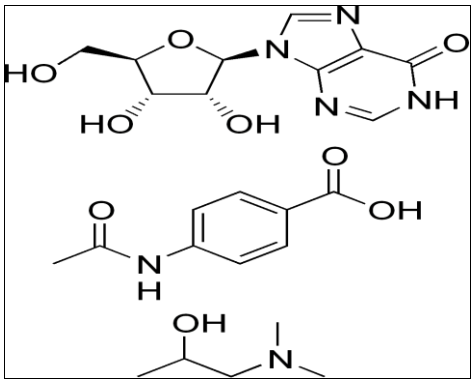

Fig 1: Chemical structure of Inosine Pranobex

Since no UV spectrophotometric method has been reported in inosine Pranobex drug. In the present study, a simple, economical, and rapid UV spectrophotometric method was developed for the quantification of Inosine Pranobex in both bulk material and tablet formulation.

The proposed method was validated in accordance with ICH guidelines, evaluating parameters such as accuracy, precision, limit of detection (LOD), limit of quantitation (LOQ), and ruggedness. The primary objective of this research was to establish a reliable and cost-effective spectrophotometric approach for routine quality control analysis of Inosine Pranobex**.**

- **Drug profile of Inosine Pranobex:** [13]
- **Generic Name:** Inosine Pranobex
  Synonyms: Isoprinosine, Methisoprinol
  Category: Immunomodulatory and Antiviral Agent
- **Chemical Name:** 4-acetamidobenzoic acid 9-[(2R,3R,4S,5R)-3,4-dihydroxy-5-(hydroxymethyl) oxolan-2-yl]-1H-purin-6-one, 1-(dimethyl amino) propan-2-ol (Inosine Pranobex)
- **Molecular Formula:** $C_{52}H_{78}N_{10}O_{17}$
- **Molecular Weight:** 1,115.23 g/mol

Description: Inosine Pranobex is a synthetic purine derivative that exhibits both immunostimulant and antiviral properties. It enhances the immune response by stimulating lymphocyte proliferation, promoting cytokine synthesis, and increasing macrophage and natural killer (NK) cell activity.

- **Therapeutic uses:** It is used for the management of viral infections such as herpes simplex, influenza, and subacute sclerosing panencephalitis (SSPE).
- **Appearance:** White to off-white crystalline powder.
- **Storage:** Store in a cool, dry place, away from light and moisture.

Materials and Method

Instrumentation

The instrument used in the present study was Shimadzu double beam UV/Visible spectrophotometer (Model UV-1700) with spectral band width of 1 nm and Lab india 3000 double beam Ultra-visible spectrophotometer. All weighing was done on electronic balance (Model Shimadzu AUX-220), Sonicator was used for sonication of the sample solution, Hot air oven InfraDIGI-250℃.

Materials and chemicals

A Pure Inosine Pranobex was received from pharmaceutical company in Mumbai, India. Distilled water was used as a solvent throughout the experimentation. A pharmaceutical preparation was purchased from the local pharmacy.
In stability studies used to chemical such as 0.1N H_2SO_4, 0.1N KOH, HPLC grade water, 0.3% hydrogen peroxide, 10% sodium bisulfate.

Method Optimization

Selection and optimization of solvent

Several solvents, including methanol, ethanol, and distilled water, were evaluated to identify the most suitable diluent for UV spectrophotometric analysis of inosine pranobex. These solvents were assessed based on their ability to dissolve inosine pranobex, the absence of spectral interference, and the clarity of the baseline. Distilled water demonstrated superior solubility and minimal interference, providing consistent and reproducible absorbance measurements across the calibration range. Therefore, distilled water was selected as the solvent for all further studies.

Selection of wavelength

The UV absorption spectrum of inosine pranobex was analyzed using zero-order, first-order derivative, and area under the curve (AUC) methods to optimize sensitivity and specificity. The zero-order spectrum showed a maximum absorbance at 259 nm, while the first-order derivative spectrum exhibited a peak at 213 nm. Additionally, the AUC method was applied by measuring the absorbance between 269 nm to 249 nm to improve accuracy. These wavelengths were selected to ensure precise and reliable quantification of inosine pranobex in the study.

Preparation of standard stock solution

A standard stock solution was prepared by dissolving 500 mg of Inosine pranobex was weighed accurately and transferred in a 100 ml volumetric flask and dissolved in distilled water to get concentration 5,000 µg/ml.

Preparation of working standard solution

From 2 ml was pipetted in above solution dissolved in 100 ml volumetric flask by using distilled water to get concentration as 100 µg/ml.

Experimental

Method A: Zero order Method

To select the analytical wavelength, a 10 µg/ml solution of Inosine Pranobex was scanned in spectrum mode from 200 nm to 400 nm, using distilled water as the blank. The zero-order spectrum was recorded using a UV spectrophotometer. From the spectrum, the wavelength corresponding to maximum absorbance was found to be 259 nm (Fig. 2).
A series of solutions was prepared in 100 ml graduated flasks by pipetting varying volumes of standard Inosine Pranobex solution and making up the volume with distilled water as the solvent. The solutions were scanned in spectrum mode over the range of 200 nm-400 nm. Zero-order data were obtained, and a calibration curve for Inosine Pranobex was constructed for the concentration range of 2-10 µg/ml (Fig. 3).

Method B: First order derivative method

To select the analytical wavelength, a 10 µg/ml solution of Inosine Pranobex was scanned in spectrum mode from 200 nm to 400 nm, using distilled water as the blank. The first-order derivative spectrum was recorded using a UV spectrophotometer. From the spectrum, the wavelength corresponding to the maximum amplitude was observed at 213 nm (Fig. 4).
A series of solutions was prepared in 10 ml graduated flasks by pipetting varying volumes of standard Inosine Pranobex solution and making up the volume with distilled water as the solvent. The solutions were scanned in spectrum mode over the range of 200-400 nm. First-order derivative spectra were obtained in derivative mode, and the absorbance of the resulting solutions was measured at 213 nm using distilled water as the blank. A calibration curve was constructed for the concentration range of 10-50 µg/ml (Fig. 5).

Method C: Area under curve (AUC) Method

The Area under Curve (AUC) method involves calculating the integrated absorbance values with respect to wavelength between two selected wavelengths. The AUC between the chosen wavelength limits was determined using UV

spectrophotometry. In this method, a 10 µg/ml solution was scanned in spectrum mode over the range of 400-200 nm, and the AUC was measured between 269 nm and 249 nm (Fig. 6).

A series of solutions was prepared in 100 ml graduated flasks by pipetting varying volumes of standard Inosine Pranobex solution and making up the volume with distilled water as the solvent. The solutions were scanned in spectrum mode over the range of 200-400 nm. AUC values were calculated, and a calibration curve for Inosine Pranobex was constructed for the concentration range of 2-10 µg/ml (Fig. 7).

Estimation of tablets

Twenty tablets were accurately weighed, and their average weight was calculated. Powder equivalent to 500 mg of Inosine Pranobex was accurately weighed and transferred into a 100 ml volumetric flask. The powder was dissolved in distilled water and subjected to sonication for 15 minutes to ensure complete dissolution. The flask was shaken thoroughly, and the volume was adjusted to the mark with the same solvent. The resulting solution was filtered through Whatman filter paper to remove any insoluble excipients. From the filtered solution, 2 ml was precisely pipetted and diluted to 100 ml with distilled water to get concentration 100 µg/ml. Subsequently, 4 ml of this dilution was further diluted to 100 ml with distilled water to prepare a final solution with a concentration of 4 µg/ml, which was used for zero-order and area under curve (AUC) analyses. For the first-order derivative method, subsequently 2 ml of the solution was withdrawn and diluted to 10 ml with distilled water to obtain a 20 µg/ml solution. The absorbance of all prepared solutions was measured at their respective wavelengths, and the sample concentrations were calculated by applying the corresponding linear regression equations obtained from calibration curves.

Validation of the method [12]

The aim of the method was validated with regards to various parameters i.e. linearity, precision, accuracy, repeatability limit of detection, limit of quantification and ruggedness as per ICH guidelines.

Linearity studies

Aliquots of working standard solution (100 µg/ml) of Inosine Pranobex 2, 4. 6. 8 and10 were transferred into 100 ml volumetric flask. The volume was adjusted to the mark with the distilled water to get concentrations (2, 4, 6, 8 and 10 µg/ml). The absorbance of each solution was measured at wavelength 259 nm for zero order and 269 - 249 nm for AUC using blank as distilled water

Aliquots of working standard solution (100 µg/ml) of Inosine Pranobex 1, 2. 3. 4 and 5 were transferred into 10 ml volumetric flask. The volume was adjusted to the mark with the distilled water to get concentrations (10, 20, 30, 40 and 50 µg/ml). The absorbance of each solution was measured at wavelength 259 nm for first order derivative method using blank as distilled water

Precision

Precision is determined by intraday and interday precision. Intra-day precision was determined by analysing the 4 µg/ml (zero order and AUC) and 20 µg/ml (first order) for six times in the same day. Inter-day precision was determined by analysing the same concentration of the solutions daily for six days.

Accuracy

Accuracy was determined by calculating recovery of inosine pranobex by the standard addition methods. Known amounts of standard solutions inosine pranobex 2, 4, 6 µg/ml (Zero - order and AUC) 10, 20, 30 µg/ml (First order method). Were added to a prequalified test solution of inosine Pranobex (4µg/ml) for zero and AUC and (20µg/ml) for first order. Each solution was measure in triplicate, and the recovery was calculated by measuring absorbance.

LOD and LOQ

Several approaches for determining the LOD & LOQ are possible depending on whether the procedure is non-instrumental or instrumental. The LOD and LOQ were calculated using equation LOD=3.3*Avg. S.D/S. and LOQ= 10*Avg. S.D/S. where, "Avg. S. D/S is the average of standard deviation of absorbance, and "S" is the slope of the corresponding calibration curve.

Ruggedness

Ruggedness of the proposed method was determined by analysis the aliquots for 4 µg/ml (Zero-order and AUC) and 20 µg/ml (First order) concentration of Inosine Pranobex from sample solution by two analysts using the same operational and environmental conditions.

Stability Studies [14-17]

A stability-indicating method is an essential tool in pharmaceutical analysis to ensure that a drug product remains safe and effective throughout its shelf life. Such methods are capable of distinguishing the active drug from any degradation products formed under stress conditions like acid, base, oxidative, hydrolysis, reduction, photolytic, thermal and UV degradation. UV-degradation spectrophotometry is widely used for this purpose due to its simplicity, cost-effectiveness, and ability to provide accurate measurements in a short time. In this study, the drug substance (API) was examined using UV spectrophotometry at its maximum absorbance wavelength (λ max) of 259 nm. The method ensures selectivity for the active ingredient complies with ICH stability testing requirements, and provides a reliable means to assess drug quality under various conditions.

Acid degradation

From 100 µg/ml inosine pranobex working standard solution 0.4 ml was pipetted out in to a 10 ml volumetric flask. To this 1ml of 0.1N H_2SO_4 was added and allowed to stand for 24hrs. Then the solution was neutralized by adding 1ml of 0.1 N KOH and the volume was made up to the mark using distilled water. Absorbance of the solution was measured at 259 nm.

Base degradation

From 100 µg/ml inosine pranobex working standard solution 0.4 ml was pipetted out in to a 10 ml volumetric flask. To this 1ml of 0.1N KOH was added and allowed to stand for 24hrs. Then the solution was neutralized by adding 1ml of 0.1 N H_2SO_4 and the volume was made up to the mark using distilled water. Absorbance of the solution was measured at 259 nm.

Hydrolytic degradation
From 100 µg/ml inosine pranobex working standard solution 0.4 ml was pipetted out in to a 10 ml volumetric flask. Then, 3 ml of HPLC-grade water was added to induce forced degradation, and the mixture was allowed to stand for 24 hours. The solution was diluted to volume with the distilled water in 10 ml volumetric flask and analysed by measuring UV absorbance at 259 nm.

Oxidative degradation
From 100 µg/ml inosine Pranobex working standard solution 0.4 ml was pipetted out in to a 10 ml volumetric flask. To this 1ml of 0.3% hydrogen peroxide was added and allowed to stand for 24 hrs. Then the volume was made up to mark using distilled water. Absorbance of the solution was measured at 259 nm

Reduction degradation
From 100 µg/ml inosine pranobex working standard solution 0.4 ml was pipetted out in to a 10 ml volumetric flask. Forced degradation was induced by adding 1 ml of 10% sodium bisulfate, and the solution was allowed to stand undisturbed for 24 hours. The volume was then adjusted to the mark with distilled water and analysed by measuring UV absorbance at 259 nm.

Thermal degradation: The standard inosine pranobex was accurately weighed and subjected to thermal degradation by placing it in an oven maintained at 70°C for 24 hours. From this 100 µg/ml inosine pranobex solution was prepared and 0.4 ml was pipetted out in to a 10 ml volumetric flask, diluted to volume with the distilled water, and the UV absorbance was measured at 259 nm.

Photolytic degradation: The standard inosine pranobex was weighed and exposed to sunlight for 4 hrs. From this 100 µg/ml inosine pranobex solution was prepared and 0.4 ml was pipetted out in to a 10 ml volumetric flask, diluted to volume with the distilled water. Then the UV absorbance was then recorded at 259 nm.

UV degradation: The standard inosine pranobex was weighed and exposed to UV light for 24 hrs. From this 100 µg/ml inosine Pranobex solution was prepared and 0.4 ml was pipetted out in to a 10 ml volumetric flask, diluted to volume with the distilled water, and the UV absorbance was measured at 259 nm.

Results and Discussion
Spectrum and Calibration Curve Diagram of Method A, B and C
Method A: Zero order method

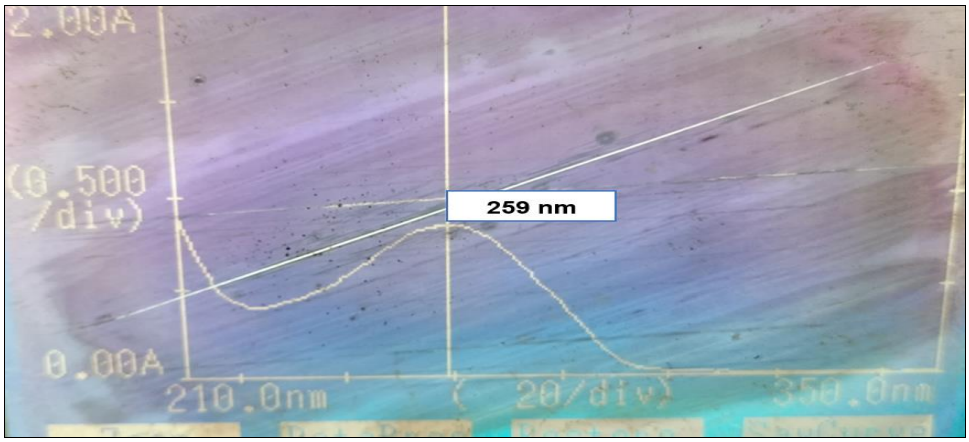

Fig 2: Zero order method spectrum of Inosine Pranobex (10 µg/ml) showing absorbance at 259 nm

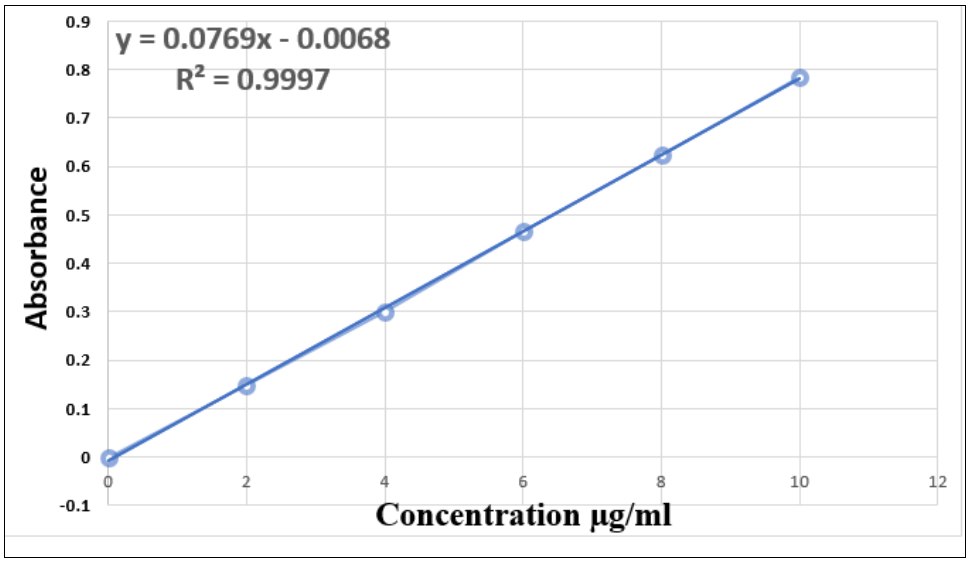

Fig 3: Calibration curve for Inosine pranobex at 259 nm by Zero - order spectroscopy

Method B: First order derivative Method

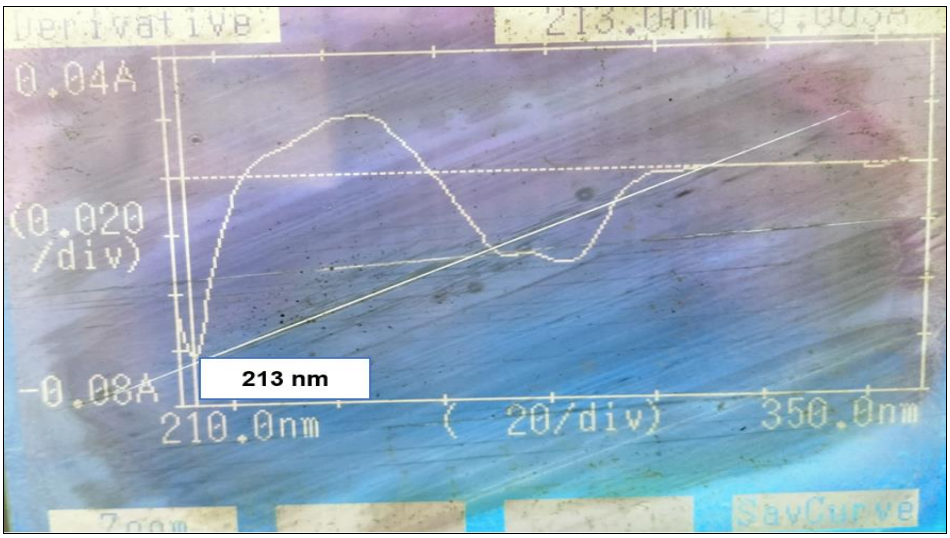

Fig 4: First order derivative spectrum of Inosine pranobex (10 µg/ml) showing absorbance at 213 nm

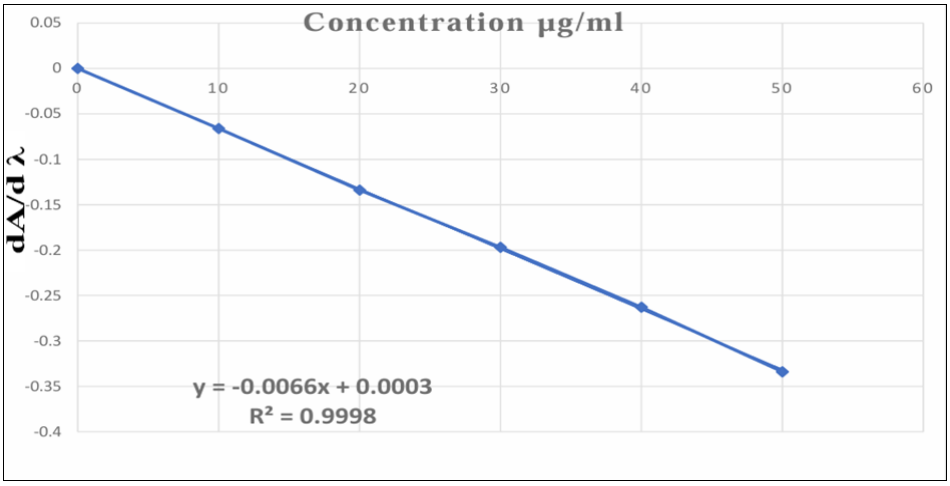

Fig 5: Calibration curve for Inosine pranobex at 213 nm by first order derivative Spectroscopy

Method C: Area under curve method (AUC)

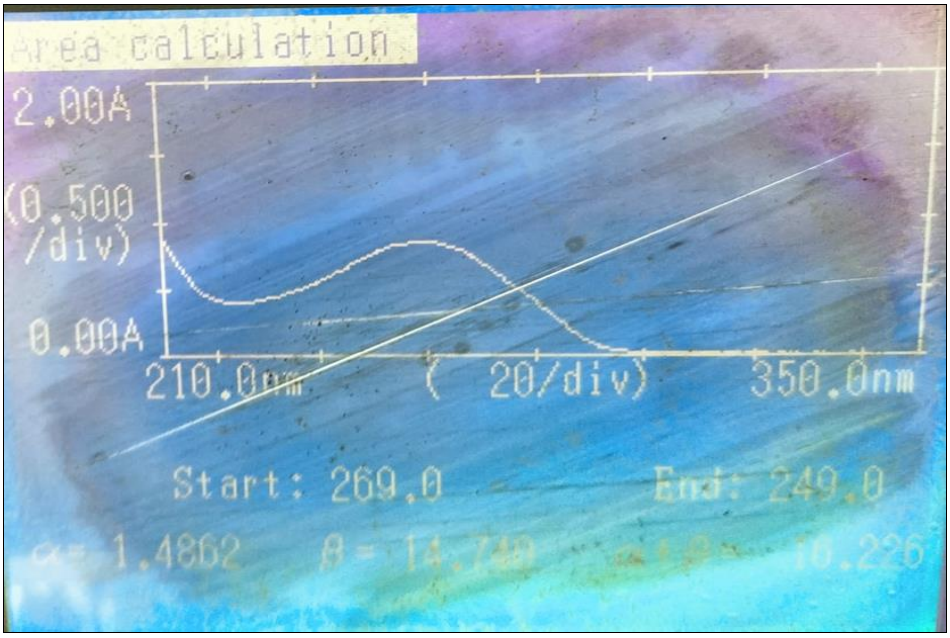

Fig 6: Area under curve spectrum of Inosine pranobex (10 µg/ml) showing area from 269 nm to 249 nm

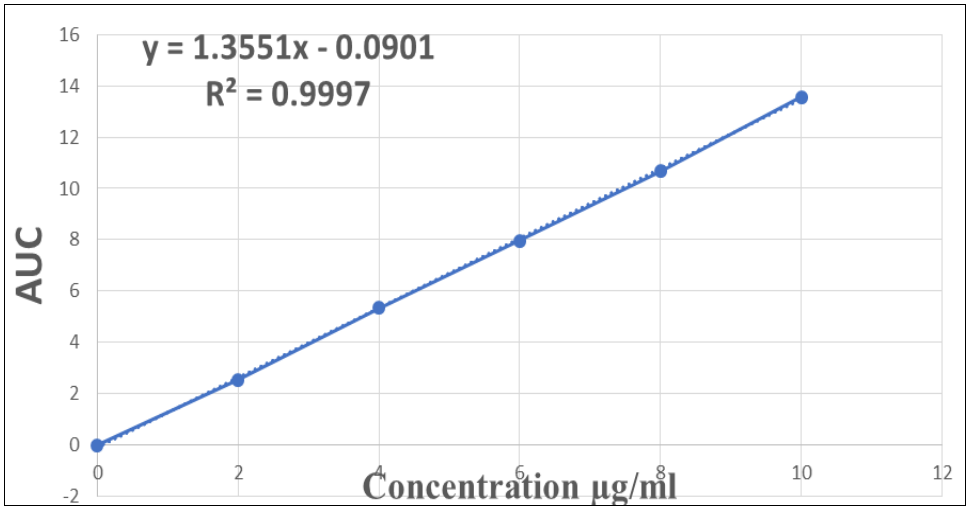

Fig 7: Calibration curve for Inosine Pranobex by Area under curve Spectroscopy

System validation

Inosine Pranobex has been tested for linearity, precision, accuracy, LOD, LOQ and ruggedness of the following parameters. As per the guidelines, the results were found to be acceptable. The regression analysis data shown in Tab-1

Table 1: Optical characteristics and linearity data of Inosine pranobex

Parameters	Method A	Method B	Method C
Beer lambert's (µg/ml)	02-10	10-50	02-10
Measured wavelength (nm)	259	213	269-249
Slope (m)	0.0769	0.0066	1.3551
Intercept (c)	0.0068	0.0003	0.0901
Correlation coefficient (r^2)	0.9997	0.9998	0.9997

Linearity: From the linear regression data, the calibration curves shown in (Fig. 3,5,7) linear relationship over the 02 - 10 µg/ml (zero-order and AUC) and 10 - 50 µg/ml (First order) concentration range of Inosine Pranobex were cleared for "methods A, B and C.

Table 2: Linearity data for Inosine Pranobex

Method	Concentration	Wavelength	R^2
A. Zero order method	2 - 10 µg/ml	259 nm	0.9997
B. First order derivative method	10 - 50 µg/ml	213 nm	0.9998
C.AUC method	2 - 10 µg/ml	269 - 249 nm	0.9997

Precision: The results of repeatability in terms of% RSD for methods A, B, and C were observed less 2 that shows precise nature of developed methods. Results are shown in (Table 3).

Table 3: Quantification of Inosine Pranobex

Sample	Methods	Sample number(n=6)	Label claim (mg/tab)	Amount present (mg/tab)	% purity	Mean purity% w/v	S. D	% RSD
Inosine Pranobex	Zero order method	1	500	505.70	101.14	100.06	0.8336	0.8331
		2	500	495.40	99.08			
		3	500	502.50	100.50			
		4	500	495.40	99.08			
		5	500	502.50	100.50			
		6	500	500.40	100.08			
	First order derivative method	1	500	503.20	100.64	101.56	0.4733	0.4660
		2	500	508.40	101.68			
		3	500	509.30	101.86			
		4	500	509.20	101.84			
		5	500	509.30	101.86			
		6	500	507.60	101.52			
	AUC	1	500	498.92	99.78	100.24	0.3677	0.3668
		2	500	503.50	100.70			
		3	500	502.03	100.40			
		4	500	500.47	100.09			
		5	500	502.81	100.56			
		6	500	499.60	99.92			

Intra-day: For intraday precision studies replicates of concentration 4 µg/ml (zero-order and AUC) and 20 µg/ml (First order) was analyzed at different times in same day. The% RSD and data disclose in (Table 4).

Inter-day: For interday precision studies replicates of concentration 4 µg/ml (zero-order and AUC) and 20 µg/ml (First order) was analyzed at different times in different days subsequently. The% RSD and data disclose in (Table 4).

Table 4: Precision of intraday and interday studies:

Sample	Methods	Sample number (n=6)	Label claim (mg/tab)	% purity		S. D		% RSD	
				Intra day	Inter day	Intra day	Inter day	Inter day	Intra day
Inosine Pranobex	Zero order	1	500	100.18	99.40	0.6870	0.7019	0.6840	0.7025
		2	500	101.30	99.94				
		3	500	100.64	100.69				
		4	500	100.68	99.55				
		5	500	99.25	100.80				
		6	500	100.64	99.09				
	First order derivative method	1	500	101.84	99.90	0.9953	0.9667	0.9860	0.9629
		2	500	100.64	101.68				
		3	500	99.58	99.50				
		4	500	101.86	100.18				
		5	500	101.68	101.52				
		6	500	100.04	99.58				
	AUC	1	500	99.84	99.94	0.3593	0.3627	0.3586	0.3616
		2	500	100.15	100.41				
		3	500	100.31	99.78				
		4	500	100.46	100.56				
		5	500	100.62	100.71				
		6	500	99.69	100.40				

Accuracy: Accuracy determined from the pretested sample solution at three different concentration i.e, 50%, 100%, 150%. The% recovery values showed that the accuracy of the methods was found to be satisfactory (Table 5).

Table 5: Accuracy studies of Inosine Pranobex

Sample	Methods	Conc (%)	Amount spiked (µg/ml)	Amount spiked (µg/ml)	Estimated Amount (µg/ml)	Recovered Amount (µg/ml)	Average% Recovery (n=3)	S. D	% RSD
IP	Zero order method	50	4	2	6.01	2.01	100.50	1.0000	0.9950
		100	4	4	7.99	3.99	99.75	0.5204	0.5217
		150	4	6	9.97	5.97	99.50	0.7514	0.7551
	First order derivative method	50	20	10	29.96	9.96	99.60	1.5176	1.5232
		100	20	20	40.10	20.10	100.50	0.7500	0.7462
		150	20	30	49.92	29,92	99.73	0.3605	0.3615
	AUC	50	4	2	5.98	1.98	99.00	0.2886	0.2915
		100	4	4	7.96	3.96	99.00	0.1443	0.1457
		150	4	6	10.003	6.003	100.05	0.3868	0.3866

n-mean of 3 observations, IP= Inosine pranobex

LOD and LOQ: To calculate the average of standard deviation of absorbance, and "S" is the slope of the corresponding calibration curve. The data given as (Table 6).

Table 6: LOD and LOQ of Inosine pranobex

Sample	Methods	LOD	LOQ
Inosine Pranobex	Zero order method	0.4310	1.3062
	First order derivative method	1.8021	5.4609
	AUC	0.4089	1.2393

Ruggedness: The results of ruggedness were in acceptable range that is% RSD values less than 2 for all the developed methods as shown in (Table 7). The results proved no statistical difference between different analyst using same operational and environmental conditions.

Table 7: Ruggedness studies of Inosine Pranobex

Drug	Methods	Analyst 1		Analyst 2		Instrument 1		Instrument 2	
		% Amount found ± SD (n=6)	%RSD	% Amount found ± S. D (n=6)	% RSD	% Amount found ± S. D (n=6)	% RSD	% Amount found ± S. D (n=6)	% RSD
IP	Zero order method	99.77±0.5576	0.5590	99.99±0.5406	0.5406	100.10±0.9118	0.9109	100.18±0.9738	0.9721
	First order derivative method	100.99±0.7767	0.7690	101.24±0.7692	0.7598	100.76±0.8915	0.8847	100.88±0.9081	0.9001
	AUC	100.49±0.2543	0.2531	100.06±0.3561	0.3559	100.42±0.2839	0.2827	100.16±0.3187	0.3182

n-mean of 6 observations

Table 8: Summary of validation parameters

Parameter	Zero order method	First order derivative method	Area under curve method (AUC)
Wavelength range	200-400 nm	200-400 nm	200-400 nm
Regression equation (y=mx+c)	0.0769-0.0068	-0.0066+0.0003	1.3551-0.0901
Measured wavelength	259 nm	213 nm	269-249 nm
Linearity range	02-10 µg/ml	10-50 µg/ml	02-10 µg/ml
Slope (m)	0.0769	0.0066	1.3551
Intercept (c)	0.0068	0.0003	0.0901
Correlation coefficient (r^2)	0.9997	0.9998	0.9997
(LOD) µg/ml	0.4310	1.8021	0.4089
(LOQ) µg/ml	1.3062	5.4609	1.2393
Precision - Quantification (%RSD)	0.8331	0.4660	0.3870

Table 9: Degradation data of Inosine Pranobex

Stress conditions	Typical conditions	Time interval	Degradation results
Acid degradation	0.1N H_2SO_4	24hrs	Not degraded
Base degradation	0.1 N KOH	24hrs	Not degraded
Hydrolytic degradation	HPLC grade water	24hrs	Not degraded
Oxidative degradation	0.3% H_2O_2	24hrs	Not degraded
Photolytic degradation	Sunlight	04hrs	Not degraded
Reduction degradation	10% Sodium bisulfate	24hrs	Not degraded
Thermal degradation	70℃	24hrs	Not degraded
UV - degradation	UV- light	24hrs	Not degraded

Table 10: Advantages of the developed UV spectrophotometric method

Parameters	Details / Advantages
Novelty	First UV spectrophotometric method developed for Inosine Pranobex- a novel contribution to pharmaceutical analysis
Analytical techniques	Zero order method (259 nm) First order derivative method (213 nm) Area under curve method (269-249 nm)
Solvent used	Distilled water- Ecofriendly, inexpensive, readily available and non-toxic
Cost effectiveness	No expensive reagents or solvents used; Reduced operational cost
Green chemistry compliance	Used of water avoids hazardous solvents- environmentally sustainable method
Simplicity	Easy to perform with a standard UV- spectrophotometer
Stability-indicating capability	No degradation observed under stress - confirms method is suitable for stability studies

Conclusion

A simple, accurate, precise, and cost-effective UV spectrophotometric method was developed and validated for the quantitative estimation of Inosine Pranobex in both bulk drug and tablet dosage forms. The method was validated in accordance with ICH guidelines, demonstrating acceptable results for linearity, precision, accuracy, ruggedness, LOD, and LOQ. Stress degradation studies conducted under acidic, basic, oxidative, reductive, hydrolytic, thermal, photolytic, and UV light conditions confirmed the stability-indicating nature of the method, as it effectively differentiated the drug from its degradation products. The results indicated no significant degradation of the drug under the tested conditions, confirming its stability. Furthermore, no interference from formulation excipients was observed, establishing the method's specificity and suitability for routine quality control.

The advantages of the developed method include its simplicity, rapid execution, requirement, and low operational cost, making it highly suitable for laboratories with limited resources. Its ability to accurately quantify Inosine Pranobex in both bulk and tablet forms without interference from excipients enhances its applicability in routine quality control, stability monitoring, and regulatory submissions. Therefore, this method offers a reliable, efficient, and economical approach for pharmaceutical analysis of Inosine Pranobex.

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