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Development and Validation of a Uv Spectrophotometric Method for The Estimation of Sodium Picosulfate.

J Humbal, V Kapadia, M Kakadiya,L. Vekariya
School of Pharmacy, R.K. University, Rajkot, Gujarat
**Address of Correspondence*
J. Humbal, V Kapadia, M Kakadiya
Student at R.K University, Rajkot, Gujarat

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ABSTRACT :
Constipation is a common gastrointestinal disorder that significantly affects the quality of life and requires effective pharmacological management. Sodium picosulfate, a widely used stimulant laxative, plays an important role in the treatment of constipation by enhancing intestinal motility. The present study focuses on the development and validation of a simple, rapid, accurate, and cost-effective UV spectrophotometric method for the quantitative estimation of sodium picosulfate in bulk and pharmaceutical dosage forms. The method is based on the principle of UV–Visible spectroscopy, where the drug exhibits maximum absorbance (λmax) at 263 nm. A series of standard solutions in the concentration range of 5–25 µg/mL were prepared, and a calibration curve was constructed, showing excellent linearity with a correlation coefficient (R^2 = 0.9997), confirming adherence to Beer–Lambert's law. The developed method was validated according to ICH guidelines for various parameters. The accuracy of the method was confirmed by recovery studies, with mean recovery values close to 100% (99.88%), indicating high reliability. Precision studies showed %RSD values less than 2% for both intra-day and inter-day analysis, demonstrating excellent reproducibility. The method exhibited good sensitivity with low limit of detection (LOD = 0.05593 µg/mL) and limit of quantitation (LOQ = 0.16949 µg/mL). Robustness studies indicated that small variations in experimental conditions did not significantly affect the results. The assay of the pharmaceutical formulation showed a mean value of 99.27%, which is within acceptable limits.

KEY WORD: Sodium Picosulphate, UV-Visible spectroscopy, Method Validation

I. INTRODUCTION:

➢ INTRODUCTION TO DISEASE:

Constipation is a common gastrointestinal disorder characterized by infrequent bowel movements, difficulty in defecation, incomplete evacuation. It may result from low dietary fibers intake, inadequate hydration and lack of physical activity, delayed intestinal transit, medication or another physiological factors. If untreated, chronic constipation may lead to complication such as hemorrhoids and anal fissures. [8,22]

➢ INTRODUCTION OF UV-VISIBLE SPECTROSCOPY:

UV- Visible spectroscopy is an analytical technique widely used in pharmaceutical analysis to determine drug concentration by measuring the absorption of ultraviolet or visible radiation. It is based on the Beer-Lambert law (A=εcl) which establishes a relationship between absorbance and concentration. Due to its simplicity, Speed and cost-effectiveness, it is commonly used in drug analysis and analytical method validation. [4,7]

➢ INTRODUCTION TO DRUG SODIUM PICOSULFATE:

Sodium Picosulfate is a stimulant laxative used for the short-term treatment of constipation. It is activated by intestinal bacterial in the colon, stimulating intestinal movement and increasing water content of the bowel facilitates defecation. Accurate and validated analytical methods are essential for determining its concentration and ensuring the quality and stability of the pharmaceutical formulation.

International Journal of Pharmaceutical research and Applications
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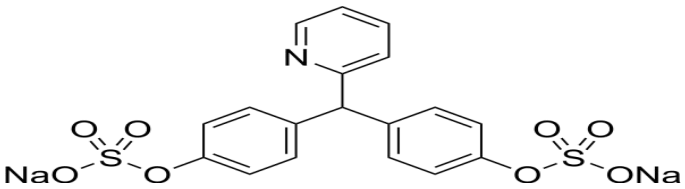
➢ MARKETED PRODUCTS:

Fig. No : 01 Marketed Product of Sodium Picosulfate

➢ DRUG PROFILE:

Sr. No.	Parameters	Description
1.	Chemicalformula	$C_{18}H_{13}NNa_2O_8S_2$
2.	IUPACname	Disodium 4,4′-(2-pyridylmethylene) diphenyl bis(hydrogen sulfate)
3.	Chemical Structure	 Fig. 01 : Structure of Sodium Picosulfate
4.	Molecular weight	481.41 gm/mol
5.	Therapeutic category	Stimulant Laxative
6.	Melting point	272–286 °C
7.	Color of drug	White to off-white crystalline powder
8.	λmax	263 nm
9.	pH	5.0 – 6.5
10.	Solubility ofdrug	Freely soluble in water, slightly soluble in ethanol andmethanol

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11.	Solubility of drug	Freely soluble in water, slightly soluble in ethanol and methanol
12.	Uses	Treatment of constipation and bowel preparation before diagnostic procedures such as colonoscopy
13.	Brand name	Picolax, Laxoberon, Guttalax

Table1: Drug Profile of Sodium Picosulfate

➢ **INTRODUCTION TO ANALYTICAL METHOD OF VALIDATION:**

Analytical method validation is a systemic process used to confirm that an analytical procedure is suitable for its intended purpose and produce accurate, reliable and reproducible result. It involves evaluating parameters such as accuracy, precision, specificity, linearity, range, detection limit, quantitation limit and robustness. Method validation is essential in pharmaceutical analysis to ensure the quality, safety and efficacy of pharmaceutical product and to comply with regulatory requirements. [7,13]

II. MATERIALS & METHODS:

- **INSTRUMENTS AND EQUIPMENT:**
  - Sodium Picosulphate (API) (Obtain gift from SNJ Pharmaceutical, Rajkot)
  - Distilled Water

UV spectrophotometry was selected for the quantitative estimation of sodium picosulfate due to its simplicity, rapid analysis, and cost-effectiveness. The method is based on the UV radiation absorption, where absorbance is proportional to drug contamination according to beer-lambert's law. Compared with properties make it suitable for routine pharmaceutical analysis without complex derivatization. [4,13]

- **INSTRUMENTS AND EQUIPMENT:**
  - UV-Visible Spectrophotometer (UV-1900, Shimadzu, Japan)
  - Quartz Cuvettes (1 cm path length)
  - Volumetric Glassware

The analysis was performed using a calibrated UV-visible double–beam spectrophotometer with matched 1cm quart cuvettes. An analytical balance (± 0.1mg) was used for accurate weighing, while a sonicator ensured complete dissolution. Glassware was clean and dry before use to prevent contamination and errors. Proper instrument calibration and maintenance were ensure to obtain reliable and reproducible result [13].

Fig.No : 02 UV – Spectrophotometer Instrument

➢ **METHOD:**

- **UV-VISIBLE SPECTROSCOPY METHOD:**

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➢ **PROCEDURE :**

- **PREPARATION OF STANDARD STOCK SOLUTION (100 µG/ML):**

The preparation of a standard stock solution is a critical step in analytical method development as it serves as the primary reference for all subsequent dilutions and measurements. In this study, accurately weighed 10 mg of sodium picosulfate was transferred into a 100 mL volumetric flask using an analytical balance. A small volume of distilled water was added initially to dissolve the drug completely. The solution was subjected to sonication for a few minutes to ensure complete solubilization and to remove any undissolved particles that might otherwise affect absorbance readings. After complete dissolution, the volume was made up to the mark with distilled water, resulting in a solution of concentration 100 µg/mL. The solution was mixed thoroughly to ensure uniform distribution of the drug throughout the solvent. Proper preparation and handling of the stock solution are essential to avoid concentration errors, which may propagate during subsequent dilutions and affect the final analytical results [4].

- **PREPARATION OF WORKING STANDARD SOLUTION (10 µG/ML):**

The working standard solution was prepared by appropriate dilution of the standard stock solution to obtain a concentration suitable for spectrophotometric analysis. Precisely 1 mL of the stock solution (100 µg/mL) was pipetted using a calibrated pipette and transferred into a 10 mL volumetric flask. The volume was then made up to the mark with distilled water to obtain a working solution of concentration 10 µg/mL. This dilution step must be performed carefully to maintain accuracy and reproducibility. The prepared working solution was mixed thoroughly and used immediately for scanning and further analysis to prevent any possible degradation or changes in concentration over time. Fresh preparation of working solutions is recommended in UV analysis to ensure consistency in absorbance values [13].

- **DETERMINATION OF λMAX:**

The determination of the wavelength of maximum absorbance (λmax) is a fundamental step in UV spectrophotometric analysis, as it ensures maximum sensitivity and accuracy of the method. The prepared working standard solution(10 µg/mL) was scanned over a wavelength range of 200–400 nm using distilled water as a blank. The scanning process allows identification of the wavelength at which the drug exhibits maximum absorbance. This wavelength was recorded as λmax and was used for all subsequent measurements. Selection of λmax minimizes errors due to slight wavelength variations and enhances the reliability of the analytical method. Additionally, measuring absorbance at λmax improves the signal-to-noise ratio, thereby increasing the precision of the method [4,13].

- **PREPARATION OF CALIBRATION CURVE (LINEARITY STUDY):**

To evaluate the linearity of the method, a series of standard solutions were prepared by diluting the stock solution to obtain concentrations in the range of 5–25 µg/mL. Each solution was prepared carefully using calibrated glassware to ensure accuracy. The absorbance of these solutions was measured at the selected λmax against distilled water as a blank. A calibration curve was constructed by plotting concentration on the x-axis and absorbance on the y-axis. The linear relationship between concentration and absorbance was assessed by calculating the regression equation and correlation coefficient (R^2). A value of R^2 close to 1 indicates excellent linearity and confirms adherence to Beer-Lambert's law within the specified concentration range. The calibration curve serves as the basis for determining the concentration of unknown samples [13].

- **METHOD VALIDATION:**

Validation of the developed analytical method was performed in accordance with ICH Q2(R2) guidelines to establish its suitability for intended use. The validation parameters included linearity, accuracy, precision, limit of detection (LOD), limit of quantitation (LOQ), and robustness. Linearity confirms the proportional relationship between concentration and absorbance, while accuracy determines the closeness of measured values to the true value. Precision evaluates the reproducibility of the method under the same and varying conditions. LOD and LOQ indicate the sensitivity of the method, representing the smallest detectable and quantifiable concentrations, respectively. Robustness assesses the effect of small deliberate

International Journal of Pharmaceutical research and Applications
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variations in experimental conditions such as wavelength or solvent composition. The validation study ensures that the method is reliable, reproducible, and suitable for routine quality control analysis of sodium picosulfate in bulk form [4,13].

➢ RESULTS AND DISCUSSION:

• RESULT:

The developed UV spectrophotometric method for the estimation of Sodium Picosulfate exhibited satisfactory analytical performance throughout the study. The experimental results obtained during method development and analysis are presented below with appropriate interpretation and graphical representation.

• ABSORPTION SPECTRUM (λMAX DETERMINATION):

The standard solution of Sodium Picosulfate was scanned in the UV region between 200–400 nm to determine its maximum absorbance. The spectrum revealed a sharp and prominent peak at 263 nm, indicating significant absorbance of the drug at this wavelength. The peak was well-defined without any interference, suggesting good spectral purity of the drug in the selected solvent system. Hence, 263 nm was selected as the analytical wavelength for further quantitative analysis.

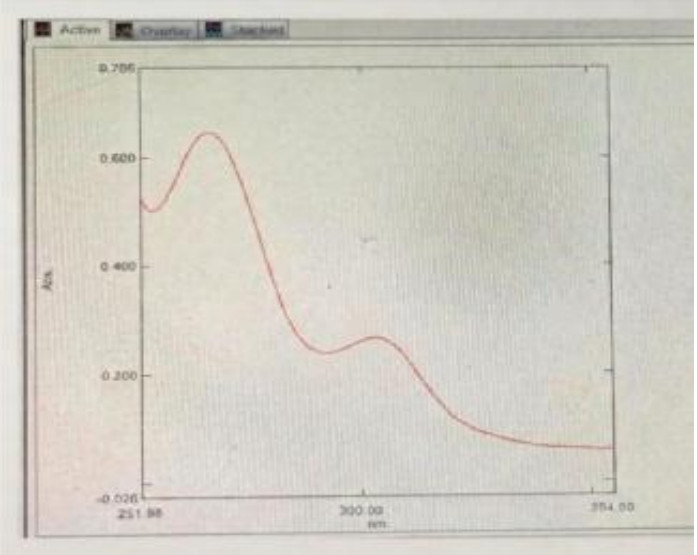

Fig. 3: Absorbance maxima of Sodium Picosulfate at 25 µg/Ml

➢ CALIBRATION CURVE AND LINEARITY:

A series of standard solutions in the concentration range of 5–25 µg/mL were prepared and their absorbance was measured at 263 nm. The absorbance values increased proportionally with increase in concentration, indicating compliance with Beer-Lambert's law.

The calibration curve was constructed by plotting concentration versus absorbance, which resulted in a straight line. The linear regression analysis showed a strong relationship between the two variables.

The correlation coefficient (R^2 = 0.999) confirmed excellent linearity of the method over the selected concentration range. The linear nature of the graph indicates that the method is suitable for accurate quantification of the drug.

International Journal of Pharmaceutical research and Applications
Volume 11, Issue 5, Sep.-Oct.2026,pp:1129-1141 www.ijprajournal.com ISSN:2456-4494

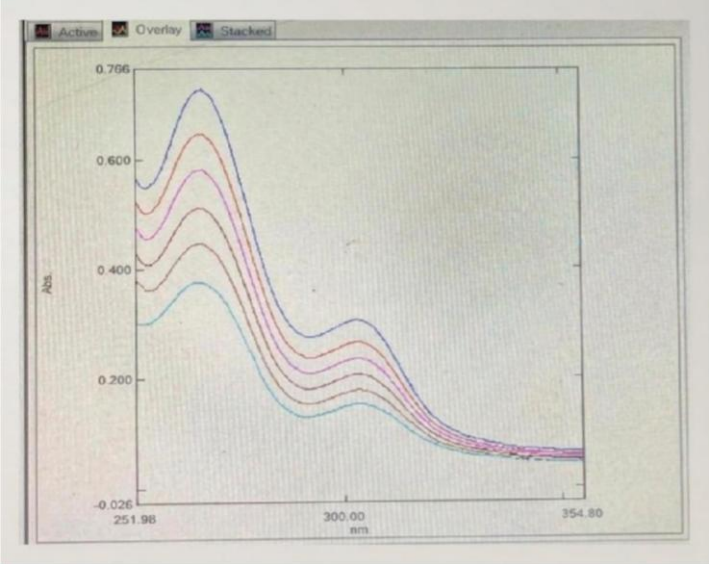

Fig. 4 : Overlay of sodium Picosulfate spectra at different Concentration

- **OBSERVATIONS OF ABSORBANCE VALUES:**

The absorbance readings obtained for different concentrations were consistent and reproducible. A gradual and uniform increase in absorbance with concentration was observed, which confirms the reliability of the analytical method. No significant deviation from linearity was observed within the studied range.

- **OVERALL ANALYTICAL FINDINGS:**

The results obtained from the study clearly indicate that the developed method provides reliable and consistent absorbance measurements. The sharp absorption peak, linear calibration curve, and accurate assay values collectively demonstrate the suitability of the method for quantitative estimation of Sodium Picosulfate.

The graphical representations further support the analytical performance by showing clear peak identification and linear response, which are essential for a validated analytical method.

- **Evalution of validation Parameters**
  - **ACCURACY:**

Accuracy represents the closeness between the experimental value obtained and the true value. It is commonly determined by performing recovery studies at different concentration levels to assess the correctness of the method [13]. High accuracyindicatesthatthemethodisfreefromi nterferenceandproducesreliable results [4]. The study was carried out at three differentconcentrationlevels,namely**80%,1 00%,and120%**,byspikingknown quantities of standard drug into the pre-analyzed sample.

% Accuracy = Amount Found/Amount added x 100

Sr no	Concen tration (ppm)	% of sample	Amount (con.) spiked in formulatn	Total concen tration (ppm)	Absorba nce found	Amount Recovered	% Recovery
1	10	80%	8	18	0.531	17.983051	99.905838
			8	18	0.530	17.949153	99.717514
			8	18	0.532	18.016949	100.09416

International Journal of Pharmaceutical research and Applications
Volume 11, Issue 5, Sep.-Oct.2026,pp:1129-1141 www.ijprajournal.com ISSN:2456-4494

2	10	100%	10	20	0.590	19.983051	99.915254
			10	20	0.592	20.050847	100.25424
			10	20	0.589	19.949153	99.745763
3	10	120%	12	22	0.649	21.983051	99.922958
			12	22	0.647	21.915254	99.614792
			12	22	0.648	21.949153	99.768875

Table2:ResultofAccuracyData

%of Sample	%MeanRecovery	SD	%RSD
80%	99.905838	0.188324	0.188501
100%	99.971751	0.258903	0.258976
120%	99.768875	0.154083	0.15444
Mean	**99.882155**	**0.200437**	**0.200639**

Table3:StandardDeviationofAccuracy

- **PRECISION:**

Precision describes the degree of agreement among repeated measurements of the same sample under specified conditions [13]. It is expressed in terms of repeatability and intermediate precision and is usually reported as relative standard deviation (%RSD).

% RSD = Standard deviation / mean x 100

dayprecisionwasassessedbyanalyzingthreediffe rentconcentrations(10, 15, and 20 ppm) of Sodium Picosulfate multiple times within the same day. The absorbance values obtained were consistent, and the calculated %RSD values were found to be very low.

These low %RSD values (less than 2%) indicate excellent repeatability of the method under the same operating conditions within a short time interval.

(i) Intra-day Precision:

Intra-

Srno.	Concentration (ppm)	Absorbance	Average	S.D.	%RSD
1	10	0.295	0.296	0.002082	0.7016852
		0.296			
		0.299			
2	15	0.442	0.446	0.003606	0.8084196
		0.449			
		0.447			
3	20	0.596	0.598	0.005292	0.8848667
		0.594			
		0.604			

Table4:ResultofIntra-dayPrecision

(ii) Inter-dayPrecision:

Inter-day precision was evaluated by analyzing the same concentrations on different days to assess the reproducibility of the method under varying conditions.

International Journal of Pharmaceutical research and Applications
Volume 11, Issue 5, Sep.-Oct.2026,pp:1129-1141 www.ijprajournal.com ISSN:2456-4494

Sr no.	Concentration (ppm)	Absorbance	Average	S.D.	%RSD
1	10	0.287	0.288	0.001	0.3472222
		0.288			
		0.289			
2	15	0.436	0.438	0.002	0.456621
		0.438			
		0.44			
3	20	0.584	0.584667	0.003055	0.5225286
		0.588			
		0.582			

Table5:ResultofInter-dayPrecision

- **SPECIFICITY:**

Specificity is the ability of the method to measure the analyte accurately in the presence of other components such as impurities, degradants, or excipients [13]. It ensures that the analytical response is solely due to the analyte of interest and is not affected by interfering substances [4].

- **LINEARITY:**

Linearity indicates the ability of the analytical method to produce results that are directly proportional to the concentration of analyte within a specified range [13]. It is evaluated using calibration curves and correlation coefficients [4].

In the present study, linearity was established by analyzing standard solutions of Sodium Picosulfate in the concentration range of **5–25 µg/mL**.

Theabsorbancevaluesrecordedat263nmshowedaconsistentandproportional increase with increasing concentration, indicating good adherence to Beer-Lambert's law. A calibration curve was constructed by plotting concentration against absorbance, which resulted in a straight line with minimal deviation.

Y=mx+c

Sr.No.	CONCENTRATION	ABSORPTION
1	5	0.148
2	10	0.295
3	15	0.442
4	20	0.598
5	25	0.735

Table6: Result of Linearity data

International Journal of Pharmaceutical research and Applications
Volume 11, Issue 5, Sep.-Oct.2026,pp:1129-1141 www.ijprajournal.com ISSN:2456-4494

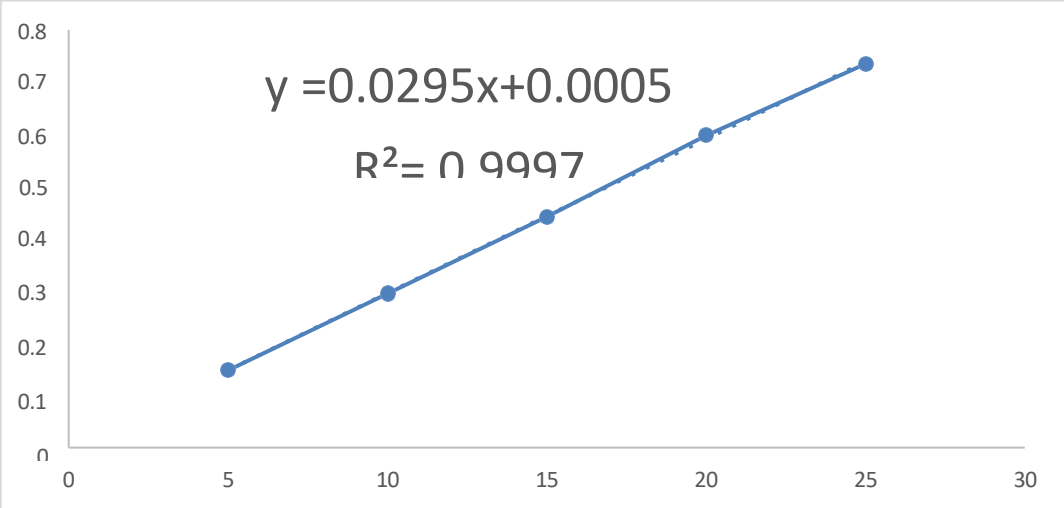

Fig. 5 : CalibrationcurveforSodiumPicosulfateat263nm

Theregressioncoefficient(R^2=0.9997)wasfoundtobeveryclosetounity,which clearly indicates excellent linearity of the method. The low intercept value and uniformdistributionofdatapointsfurtherconfirmthereliabilityofthecalibration model. These results demonstrate that the method is highly suitable for quantitative estimation of Sodium Picosulfate over the selected concentration range.

- **LIMIT OF DETECTION (LOD):**

LOD is the lowest amount of analyte that can be detected but not necessarily quantified under the stated conditions [13]. It reflects the sensitivity of the method [4].

LOD = 3.3 × σ/S

= 3.3 × 0.0005/0.0295

LOD=0.05593µg/ml

ThelowLODvalue(0.05593µg/mL)indicatesthatthedevelopedmethodishighly sensitive and capable of detecting very small amounts of Sodium Picosulfate.

- **LIMIT OF QUANTITATION (LOQ):**

LOQ represents the lowest concentration of analyte that can be quantified with acceptable accuracy and precision [13]. It defines the minimum level for reliable quantification [4].

LOQ= 10 × σ/S

= 10 × 0.0005/0.0295

LOQ=0.169491µg/ml

TheobtainedLOQvalue(**0.16949µg/mL**)indicatesthatthemethodiscapableof accurately quantifying the drug even at very low concentrations, demonstrating good sensitivity and reliability.

- **ROBUSTNESS:**

Robustness indicates the capacity of the analytical method to remain unaffected by small, deliberate variations in experimental conditions such as pH, temperature, or wavelength [13]. It demonstrates the reliability and stability of the method during routine use [4].

The absorbance values were recorded at **261 nm,263 nm, and 265 nm**, andthe results showed minimal variation. The %RSD value for wavelength variation was found to be **0.3639**, which is well within acceptable limits (<2%).

Concentration (ppm)	composition wavelength(nm)	Ab.1	Ab.2	Ab.3	mean	SD	%RSD
10	316	0.152	0.153	0.152	0.152333	0.00083	0.547486181
	318	0.155	0.151	0.154	0.153333		
	320	0.154	0.153	0.155	0.154000		
					0.153222		
	(Apparatus)						
	ChangeinGlass	0.162	0.165	0.162	0.163		

International Journal of Pharmaceutical research and Applications
Volume 11, Issue 5, Sep.-Oct.2026,pp:1129-1141 www.ijprajournal.com ISSN:2456-4494

10	Apparatus	0.165	0.164	0.166	0.165	0.001	0.609756098
		0.163	0.163	0.166	0.164		
					0.164		

Table7:ResultofRobustnessstudy

Additionally, robustness was also evaluated by slight changes in apparatus conditions. The %RSD obtained in this case was **0.0646**, indicating very low variability.

- **ASSAY:**

The assay of Sodium Picosulfate in pharmaceutical formulation was carried out usingthedeveloped UVspectrophotometric methodunder optimized conditions. The analysis was performed multiple times to ensure accuracy and reproducibility.

Concentration(ppm)	Std.Absorbance	Test Absorbance	% Recovery	SD
10	0.295	0.291	98.6440678	0.0046224
	0.295	0.292	98.98305085	
	0.295	0.298	101.0169492	
	0.295	0.289	97.96610169	
	0.295	0.299	101.3559322	
	0.295	0.288	97.62711864	
		Mean	99.26553672	

Table8:ResultOfAssay study

The percentage recovery values obtained ranged from **97.62% to 101.35%**, indicating that the method provides accurate estimation of the drug content. The mean assay value was found to be: Mean % **Assay = 99.2655%**

The low standard deviation (**SD = 0.0046**) indicates high precision and consistency in the results. The assay values are within acceptable limits (98–102%),confirmingthatthemethodissuitableforroutine qualitycontrolanalysis of pharmaceutical formulations.

III. DISCUSSION:

The present study aimed to develop and validate a simple, accurate, and reliable UV spectrophotometric method for the estimation of Sodium Picosulfate. The method showed satisfactory results for all validation parameters, confirming its suitability for routine pharmaceutical analysis.

The selected wavelength of **263 nm (λmax)** showed a clear absorption peak without significant interference. The method exhibited excellent linearity over the concentration range of **5–25 µg/mL**, with an R^2 value of **0.9997**, confirming its compliance with Beer-Lambert's law.

Accuracy studies showed percentage recovery between **99.76% and 99.97%**, with a mean recovery of **99.88%**, indicating excellent accuracy. Intra-day and inter-day precision studies showed %RSD values below 2%, confirming good repeatability and reproducibility.

The method demonstrated high sensitivity, with an **LOD of 0.05593 µg/mL** and an **LOQ of 0.16949 µg/mL**. Robustness studies also showed negligible effects from small variations in wavelength and instrumental conditions, with %RSD values of **0.3639% and 0.0646%**, respectively.

The assay of the marketed formulation showed a mean content of **99.27%**, indicating satisfactory drug content and suitability for routine quality control analysis.

Overall, the developed method demonstrated excellent linearity, accuracy, precision, sensitivity, and robustness. The results support its suitability for the routine estimation of Sodium Picosulfate in pharmaceutical formulations.

International Journal of Pharmaceutical research and Applications
Volume 11, Issue 5, Sep.-Oct.2026,pp:1129-1141 www.ijprajournal.com ISSN:2456-4494

IV. SUMMARY:

Parameters	Result
Wavelength(λ)range	200-400 nm
Regressionequation	y=0.0295x+0.0005
λmaxWavelength	263 nm
Linearityrange	5-25µg/ml
Accuracy(mean% recovery)	99.360
Intercept	0.0005
LimitofDetection(LOD)	0.05593µg/ml
LimitofQuantification(LOQ)	1.169491µg/ml
Correlationcoefficient(R^2)	0.9997
Accuracy(%RSD)	0.2342
PrecisionInterday(%RSD)	0.7982
PrecisionIntraday(%RSD)	0.4421
Assay(% Recovery)	99.26%

V. CONCLUSION:

Based on the results obtained, it can be concluded that the developed UV spectrophotometric method for the estimation of Sodium Picosulfate is simple, rapid, accurate, precise, sensitive, and robust. All validation parameters were found to be within acceptable limits as per ICH guidelines, confirming the reliability and suitability of the method.

Themethodcan besuccessfullyappliedfortheroutine qualitycontrol analysis ofSodiumPicosulfateinbulkandpharmaceuticaldosag eforms.Additionally,due to its simplicity and cost-effectiveness, the method can be effectively utilized in pharmaceutical industries and research laboratories without the need for sophisticated instrumentation.

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