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Original Article

Analytical Verification and Studies on Degradation of Voglibose Nanocrystals Formulations using the Quantitative RP-HPLC Method

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ABSTRACT

Introduction: The primary goal of the experiment was to validate a method for identifying Voglibose content in a newly developed Nano formulation specifically Nanocrystals. For estimating the content of voglibose in drug compounding, few analytical methods have been reported. This article presents a detailed validation of an RP-HPLC assay design for the quantification of Voglibose nanocrystals. **Materials and Methods:** In this study, a 250 x 4.6 mm, 5 µm RP-C18 column was employed for the separation. The mobile phase was laid a flow scale of 1 mL/min and expressed a combination of acetonitrile together with potassium dihydrogen phosphate buffer at pH 5.0 in the course of 40-60% (v/v) at 282 nm, the detection was completed. Over the analytical range of 50-170 µg/mL, a linear relationship (r^2=0.99) was seen with the standard curve. **Results:** The method for quantifying Voglibose nanocrystals underwent successful validation, exhibiting its strength, accuracy, and sensitivity while fulfilling all necessary analytical reference solutions. The method manifested linearity across the examined concentration range and showed acceptable detection and quantification limits. Tests for reproducibility verified the method's consistency when used by different analysts and on various instruments. **Conclusion:** This is the first outcome for the validation of the voglibose nanocrystal formulation. This validated assay's effectiveness supports its use in the routine analysis of voglibose nanocrystals during research and development. It enables precise assessment of drug loading, release patterns, and stability studies. This study intends to help the development and regulatory compliance of voglibose formulations in clinical applications by addressing these crucial validation elements.

Keywords: Pharmaceutical preparation, Reverse Phase-High Performance Liquid Chromatography, System suitability, Validation.

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INTRODUCTION

Voglibose, an effective α-glycosidase inhibitor, is widely used in the governance of type-2 diabetes to control postprandial blood glucose levels.[1,2] Nevertheless, voglibose has formerly been established being an essential pharmaceutical active, the already publicized narrative on voglibose illustrates this molecule distinctly.[3,4]

It is most convenient in the appearance of tablets with dosages of 0.2-0.3 mg per tablet. For estimating the content of voglibose in drug compounding, few analytical methods have been reported. Recent advancements in nanotechnology have led to the development of voglibose nanocrystals, which enhance their solubility and bioavailability, ultimately improving therapeutic outcomes. To ensure the quality and efficacy of these formulations, a reliable and validated assay method is essential.[5] High-Performance Liquid Chromatography (HPLC) becomes apparent as a preferred analytical means due to its accuracy and precision in quantifying pharmaceutical compounds.[6-8] This article presents a detailed validation of an HPLC assay design for the quantification of Voglibose nanocrystals, as shown in Figure 1.

We will explore the methodology, including parameters such as linearity, specificity, accuracy, and precision, to establish a comprehensive framework for the reliable assessment of voglibose in its nanocrystal form.[9-11] By addressing these critical validation aspects, this study aims to support the development and regulatory compliance of voglibose formulations in clinical applications. The developed method was affirmed as per International Council for Harmonization (ICH) guidelines.[12]

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MATERIALS AND METHODS

Materials

Voglibose was a gift sample from Anthem Biosciences, Bangalore. Taurine, sodium periodate, sodium sulfite, voglibose working standard, acetonitrile, and methanol were procured from Samarth Life Sciences, and Baddi (H.P) were of HPLC grade.

Method

Chromatographic separation was conducted using a Shimadzu Prominence I (2030 C plus), a programmable UV/visible detector (SPD-20A), along with a Redone (7725i) with a 20 µL full loop. Data analysis was performed employing Lab Solution software. The separation utilized an RP-C18 column (250×4.6 mm, 5 µm).[13] The mobile phase comprised a mixture of potassium dihydrogen phosphate buffer at pH i.e. 5.0, acetonitrile, and methanol in a proportion of 40:60% (v/v), delivered at a stream of 1 mL/min. Precendently for its usage, the mobile phase was filtered through a 0.2 µm membrane filter and further sonicated for 15 min. The analysis was conducted at ordinary temperature.[14] The following pattern of chromatographic conditions was by the specifications and was tabulated in Table 1.

Due to the lack of chromophore or/and fluorophore groups in most carbohydrates, their analysis via liquid chromatography often necessitates derivatization. Voglibose, in particular, exhibits UV absorption only in the low wavelength region, which limits its direct detection sensitivity.[15] For its derivatization, taurine, sodium periodate were employed. A taurine solution was prepared at a level based on 10 mg/mL in water, while a sodium periodate solution was formulated at 5 mg/mL in distilled water. The voglibose and taurine solutions were mixed in a 1:1 proportion and incubated for 30 min. Subsequently, an equal volume of sodium periodate mixture was added to the taurine-voglibose mixture. The reaction was then quenched with sodium sulfite, and the solution was expurgated utilizing a 0.2 µm nylon filter.[16] The mobile phase used to be a diluent.

Standard injection

Weighed as well as transferred 10 mg of the working standard into a 10 mL volumetric flask. 5 mL of diluent was added, then the mixture was subjected to sonication to dissolve the contents.[17] From this solution, pipette out 1 mL into a separate 10 mL volumetric flask, and the bulk was made up with diluent. The solution was there upon filtered through a 0.2 µm filter, resulting in a strength value of 100 µg/mL.

Sample Solution Preparation

Weighed as well as transferred voglibose nanocrystals proportionate to 10 mg within a 50 mL volumetric flask. Added 10 mL of Dichloromethane (DCM) and sonicated for 10 min. Then, 10 mL buffer solution and sonicated for an additional 10 min. Using a separating funnel, the solution was shaken for 15 min, and the aqueous phase was collected. From this, 1 mL of the solution was withdrawn into a 10 mL volumetric flask, and 1 mL taurine solution (10 mg/mL) was added. The mixture was incubated for 30 min at ambient temperature, followed by the addition of 1 mL of sodium periodate (5 mg/mL), furthermore incubation for 30 min at ambient temperature. The counteraction

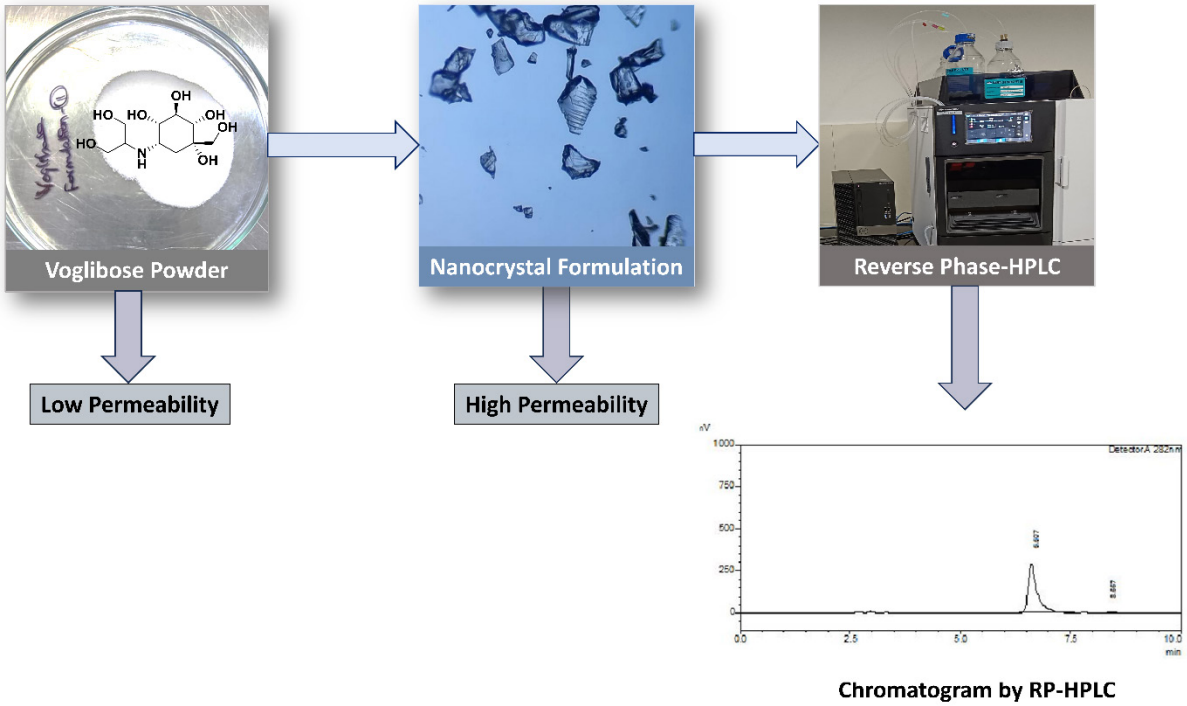

Figure 1: Schematic of quantification for Voglibose nanocrystals by RP-HPLC.

obtained was quenched by adding 1.0 mL of sodium sulfite, and the bulk was made up to 10 mL in the presence of a diluent. The solution was then filtered using a 0.2 µm nylon filter.[18]

Method validation

As an intrinsic part of analytical method progression is validation. The proposed practice was validated and contained as per ICH guidelines. After completing the HPLC method development, the method underwent validation based on several parameters, including specificity, precision, intermediate precision, linearity, accuracy, robustness together with stability.[19] The percentage relative standard deviation was computed for each parameter. The proposed HPLC system was ratified by ICH standards.

Specificity

Specificity in HPLC pertains to the method's capability to extricate the target analyte from other substances present inside the sample matrix, such as impurities, degradation products, and potential interferences. Validating this specificity is crucial for ensuring the accuracy and reliability of analytical results. This validation process is confirmed by injecting a placebo, a spiked sample, and a blank to confirm that the analyte is pure and does not co-elute with other components.[20]

Accuracy and Precision

Precision was assessed by conducting three independent sampling preparations from a single lot of the formulation. The sample solution was prepared following the equivalent procedure outlined for sample preparation. The percentage assay results demonstrated variations of less than 2% for both in-day and constant assessments, indicating that the mode is precise. A known quantity of pure drug was incorporated into the placebo at levels of 50%, 100%, and 150%. Specifically, 5 mg of voglibose was measured and transferred for the 50% concentration, 10 mg for the 100% concentration, and 15 mg for the 150% concentration into a 10 mL volumetric flask.[21] Equivalent weight of the placebo was then added, followed by 5 mL of DCM to facilitate dissolution. Subsequently, 5 mL of diluents was added to adjust the volume. The solution was then placed in a separating funnel and shaken for 15 min.[22] From this mixture, 0.5 mL was pipette into a 10 mL volumetric flask, to which 1 mL of taurine solution (10 mg/mL) was added. This mixture was incubated in furtherance of 30 min at ambient temperature. Afterwards, 1 mL of sodium periodate (5 mg/mL) was introduced, and the incubation continued for

Table 1: Chromatographic conditions.

Chromatograph	HPLC (Shimadzu with 2030 PDA)
Column	RP-C 18 column (250×4.6 mm 5 µ)
Mobile Phase	Potassium phosphate monobasic pH 5.0 : acetonitrile (40:60% v/v)
Flow rate	1 mL per minute
Detection	282 nm
Injection volume	20 µL
Column Temperature	25°C

Table 2(a): Values of precision of technique imparted in the quantification.

Name appertaining the sample	Area	Mean	%RSD	Assay%
Reference solution-1/1	181412	182706	0.6	98.9
Reference solution-1/2	182132			
Reference solution-1/3	184342			
Reference solution-1/4	183464			
Reference solution-1/5	183232			
Reference solution-1/6	181657			
Sample solution- 1/1	180124	180683	0.4	
Sample solution -1/2	180124			

Table 2(b): Values of Intermediate precision.

Name of the sample	Area	Mean	%RSD	Assay%
Reference solution-1/1	176500	176390	0.9	98.1
Reference solution-1/2	174564			
Reference solution-1/3	174989			
Reference solution-1/4	175867			
Reference solution-1/5	178657			
Reference solution-1/6	177768			
Sample solution- 1/1	173145	173078	0.05	
Sample solution - 1/2	173012			

an additional 30 min at room temperature. The reaction was cut short by adding 1.0 mL of sodium sulfite, and the total volume was adjusted to 10 mL with diluent. The solution was filtered using a 0.2 µm nylon strain.[23]

Linearity

The linearity of the assessment was weighted by analyzing distinct concentrations concerning reference solutions of Voglibose. The concentrations tested were 50%, 75%, 100%, 125%, and 150% (100 µg/mL).

Filter Compatibility

This process assesses whether the selected filters affect the analyte's concentration or introduce contaminants that could compromise the analysis. The primary goal of filter compatibility testing is to evaluate the potential impact of diverse filters on the analyte's integrity.[24] This includes assessing the recovery rates and identifying any interference or changes in the chemical composition of the samples post-filtration. Overall, nylon filters are a suitable choice for HPLC applications, provided that they have been validated for compatibility with the specific method and analytes being tested.

Limit of Quantification and Limit of Detection

The Limit of Quantification (LOQ) and Limit of Detection (LOD) for the developed method were intended by injecting a progressively lower range of standard solutions using the RP-HPLC technique.[25] The LOD refers to the lowest range of analyte that produces a discrete response, defined by a signal-to-noise ratio equivalent to 3.

Solution Stability

Solution stability is a critical aspect of HPLC method validation. It ensures that the analytes remain unchanged over time under specified conditions, which is essential for generating reliable and reproducible results.[26] Assessing solution stability involves evaluating how various determinants, such as light, temperature, and time, affect the integrity of the analytes inside the solution.

Robustness

The robustness of the schema has been assessed by making minor adjustments to the chromatographic conditions, including variations within the mobile phase together with column temperature.[27]

Degradation studies

A study was conducted to elicit the effective segregation of degradants in nanocrystal forms by assay method in different environments.[28]

Statistical Analysis

The approach validation parameters were assessed using descriptive statistical analysis. To evaluate the consistency and dependability of the RP-HPLC method in accordance with ICH criteria, the mean, Standard Deviation (SD), and percentage Relative Standard Deviation (%RSD) were computed for precision, accuracy, linearity, robustness, and system appropriateness.

RESULTS

Specificity

The data eliciting specificity for which chromatograms are obtained is shown in Figure 2.

Precision

The percentage assay results demonstrated variations of less than 2% for both in day and constant assessments, indicating that the mode was precise. The results are presented in Tables 2a and 2b.

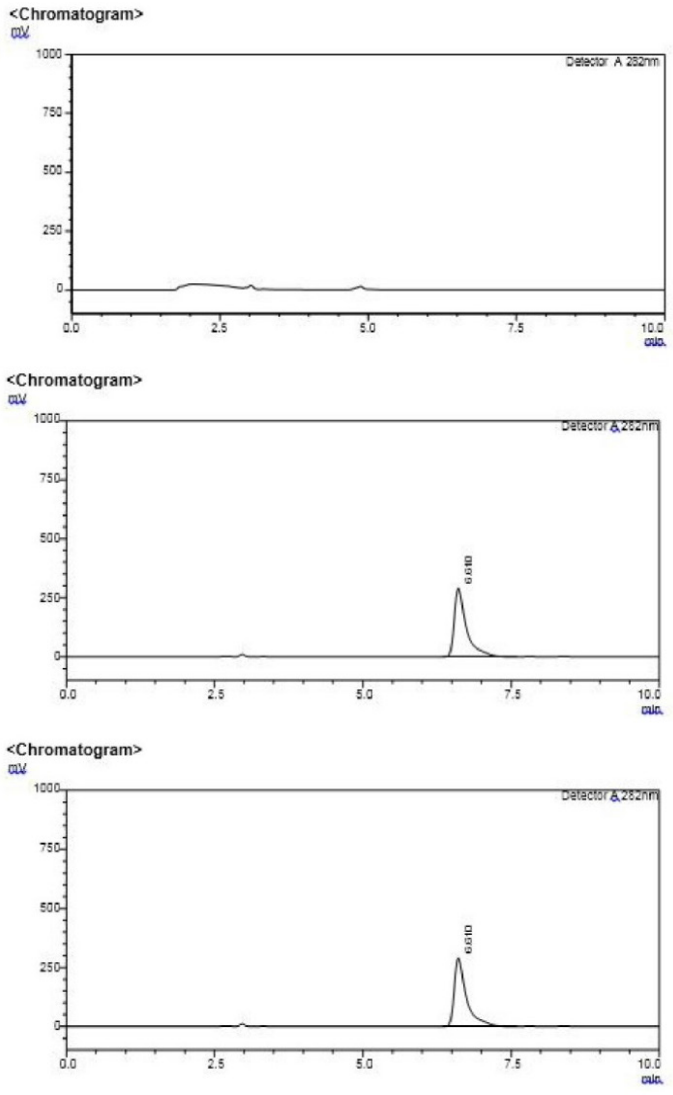

Figure 2: (a-c) Displayed the chromatogram of a placebo, standard, sample solution of Voglibose nanocrystals.

Table 3: % Recovery of Voglibose samples.

Name of the sample	Area	Mean	Amount Added (mg/mL)	Amount Recovery (mg/mL)
Standard Solution 1/1	175645	175623.7	50	
Standard Solution 1/2	174564		50	
Standard Solution 1/3	175467		50	
Standard Solution 1/4	176475		50	
Standard Solution 1/5	175468		50	
Standard Solution 1/6	176123		50	
Sample Solution 50%-1/1	87435	87544.5	50	49.86
Sample Solution 50%-1/2	87657			
Sample Solution 50%-2/1 Sample solution 50%-2/2	87213 87211	87100	50	49.6
Sample Solution 50%-3/1	87191	87053	50	49.6
Sample Solution 50%-3/2	86915		50	49.6
Sample Solution 100%- 1/1	174987	175120.5	100	99.7
Sample Solution100%- 1/2	175254	175120.5	100	99.7
Sample Solution 100%- 2/1	175173	175077	100	99.6
Sample Solution 100%- 2/2	174981	175077	100	99.6
Sample Solution 100%- 3/1	173292	173291.5	100	98.8
Sample Solution 100%- 3/2	173291	173291.5	100	98.8
Sample Solution 150%- 1/1	261243	261208	150	148.7
Sample Solution 150%- 1/2	261173	261208	150	148.7
Sample Solution 150%- 2/1	258893	261634.5	150	149
Sample Solution 150%- 2/2	264376	261634.5	150	149
Sample Solution 50%-2/1	263844	261294.5	150	148.8
Sample Solution 150%- 3/1	263844	261294.5	150	148.8
Sample Solution 150%- 3/2	258745	261294.5	150	148.8

Table 4: Recovery and interference data for determining the changes.

Name of the sample	Area	Mean	%RSD	Assay%
Reference solution-1/1	175573	176768.67	0.6	
Reference solution-1/2	178766			
Reference solution-1/3	176768			
Reference solution-1/4	176977			
Reference solution-1/5	175651			
Reference solution-1/6	176877			
Sample solution 0.2 µ NF- 1/1	175345	175112	0.1	99.0
Sample solution 0.2 µ NF- 1/2	174879			
Sample solution 0.2 µ PVDF - 1/1	172546	172166	0.3	97.3
Sample solution 0.2 µ PVDF-1/2	171786			
Samplesolution0.2 µ PTFE - 1/1	172777			

Table 5(a): Temperature showing the Column Oven temperature at 38°C.

Name of the sample	Area	Mean	%RSD	Assay%
Reference solution-1/1	177257	176479	0.3	99.1
Reference solution-1/2	176764			
Reference solution-1/3	175776			
Reference solution-1/4	176975			
Reference solution-1/5	175656			
Sample solution- 1/1	175114	174883	0.1	
Sample solution-1/2	174653			

Table 5(b): Column Oven temperature 42°C.

Name of the sample	Scope of the surface	Mean	Assay%	
Reference solution-1/1	176234	1759810.3		99.0
Reference solution-1/2	176787			
Reference solution-1/3	175787			99.0
Reference solution-1/4	174965			
Reference solution-1/5	175666			
Reference solution-1/6	176449			
Sample solution- 1/1	174556	174215 0.2		
Sample solution-1/2	173875			

Table 5(c): Mobile Phase pH-5.8.

Name of the sample	Area	Mean	%RSD	Assay%
Reference solution-1/1	174564	174932.17	0.5	98.9
Reference solution-1/2	176745			
Reference solution-1/3	174387			
Reference solution-1/4	174686			
Reference solution-1/5	174536			
Reference solution-1/6	174675			
Sample solution-1/1	172335	173001	0.4	
Sample solution-1/2	173667			

Table 5(d): Mobile Phase pH-6.2.

Name of the sample	Area	Mean	%RSD	Assay%
Reference solution-1/1	173686	173830.33	0.20	
Reference solution-1/2	173897			
Reference solution-1/3	174368			
Reference solution-1/4	173168			
Reference solution-1/5	173876			
Reference solution-1/6	173987			
Sample solution-1/2	170143	170070.5	0.1	97.8

Table 6: Data showing degradation studies of Voglibose nanocrystals.

Stress Condition	Quantity of drug (Final concentration of the drug)	Incubation time	Volume of Stress agents	Volume of Neutralizing agent	%Assay of active substances±SD	%Assay of degraded product	Mass balance
Acid Hydrolysis (0.1N HCl)	100 µg/mL	24 hr	Acid Hydrolysis (0.1N HCl) 5 mL	Basic Hydrolysis (0.1NaOH) 5 mL	90.15±0.77%	9.85%	100%
Basic Hydrolysis (0.1NaOH)	100 µg/mL	24 hr	Basic Hydrolysis (0.1NaOH) 5 mL	Acid Hydrolysis (0.1N HCl) 5 mL	89.46±4.22%	10.54%	100%
Thermal Degradation (50°C)	100 µg/mL	24 hr	Sample introduced into thermal degradation (50°C)	-	97.37±0.55%	2.63%	100%
3% Hydrogen peroxide	100 µg/mL	24 hr	3% Hydrogen peroxide 5 mL	5 mL (3% sodium metabisulphite	91.94±1.91%	8.06%	100%
UV	100 µg/mL	24 hr	200 nm to 400 nm	-	98.66±0.50%	1.4%	100%

Accuracy and Linearity

The presence of drug product in the solution was intended to employ the assay means. The recovery scheme persisted remade by three measures; the percentage Relative Standard Deviation (%RSD) was calculated using the appropriate scheme. Mean recoveries ranged from 98.0% to 102.0%, indicating that there was by no means intervention from the excipients. The linear graphical picture is shown with an optimum R^2 value and a straight line equation in Figure 3, and the recovery of voglibose is given in Table 3.

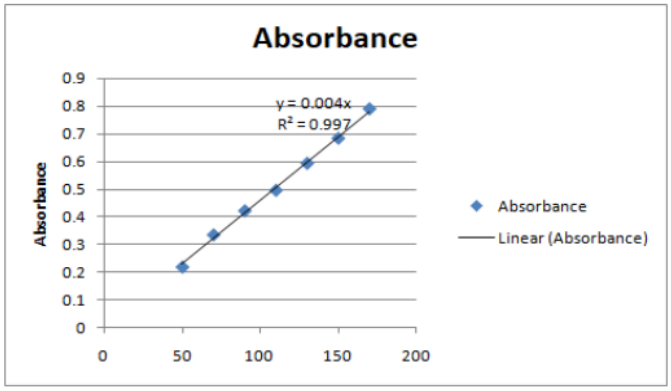

Figure 3: Linear relationship between concentration and absorbance of voglibose nanoforms.

Limit of Quantification and Limit of Detection

For voglibose, the calibration range was 50-150 µg/mL. LOD was found to be 3 µg/mL. On the other hand, the LOQ is the minimum range of analyte that perchance is reliably computed, with a signal-to-noise ratio of 10. LOQ for voglibose was determined to be 10 µg/mL. Theoretical plates were 6376, tailing factor was 1.976. These results indicated that developed method was sensitive. The results are delineated in Table 4.

Robustness

The limits for variations in the mobile phase and temperature were well within acceptable ranges, demonstrating good system suitability and precision beneath the specified conditions, with results falling within the acceptance convention of no more than 2%. The reports were tabulated in Tables 5a-5d. It was noted particularly in existence occurred no significant variance occurred in the chromatograms, indicating that such developed RP-HPLC method is robust.

Forced degradation Studies

Voglibose nanocrystals were subjected to stress conditions. According to ICH guidelines, stress conditions include hydrolysis, base, oxidative, acid, photostability, and thermal degradation. The degradation behavior was routinely observed using the suggested RP-HPLC technique. In every stressful condition examined, the peaks were pure and uniform; this elicits that the suggested method is static and specific. All of the stability findings are shown in Table 6 and Figure 4, chromatograms obtained, which

Table 7: Tabular Summary of RP-HPLC Validation Parameters for Voglibose Nanocrystals.

Validation Parameter	Acceptance Criteria	Results
Specificity	No interference from placebo or excipients; analyte peak should be pure.	No interference observed; analyte well resolved.
Linearity	Correlation coefficient (r^2) ≥ 0.999	r^2 = 0.9999 (excellent linearity over 50-150 µg/mL range).
Range	80-120% of test concentration	50-150 µg/mL confirmed
Accuracy (Recovery)	98-102% recovery at each level (50%, 100%, 150%)	49.5-150.6 mg/mL recovery (98.8-100.4%); within acceptable limits.
Precision (Repeatability)	%RSD≤2.0%	%RSD = 0.4% (standard), 0.4% (sample)-within limit.
Intermediate Precision	%RSD≤2.0%	%RSD = 0.9% (standard), 0.05% (sample)-within the limit.
Limit of Detection (LOD)	The Signal-to-noise ratio of 3	3 µg/mL
Limit of Quantification (LOQ)	The Signal-to-noise ratio of 10	10 µg/mL
Robustness	No significant change in retention time, area, or resolution with slight variations.	Robust to temperature (38°C-42°C) and pH changes (5.0±0.2).
Solution Stability	98-102% recovery over 24 hr	99.9% (12 hr), 99.0% (24 hr)-stable.
Filter Compatibility	% Recovery within 98-102%, no interference	Nylon: 99.0%; PVDF/PTFE: ~97.3%-Nylon preferred.
System Suitability	Theoretical plates>2000, Tailing factor<2,%RSD<2%	Plates=6376; Tailing=1.976; %RSD=0.6%-all parameters passed.
Slope	-	1765.7
Y-Intercept	-	580.6

showed that maximum degradation occurred in the base media. Table 7 shows a summary of validation.

DISCUSSION

The comprehensive validation of the assay method for quantifying voglibose nanocrystals has unequivocally established its suitability for routine analytical applications in research and development. The validation parameters rigorously assessed and met include:

Specificity and Strength

The method successfully demonstrated its ability to specifically quantify voglibose nanocrystals, even in the presence of potential excipients or degradation products that might be present in complex nanocrystal formulations. This "strength" (often referred to as robustness or ruggedness) indicates the method's ability to remain unaffected by small, deliberate variations in method parameters, which is critical for inter-laboratory transfer and long-term consistency.

Accuracy

The high accuracy achieved, evidenced by minimal bias in recovery studies, confirms that the method consistently provides results that are close to the true concentration of voglibose within the nanocrystal formulation. This is fundamental for reliable quantitative analysis, particularly for drug loading determination.

Sensitivity

The established Limits of Detection (LOD) and Quantification (LOQ) demonstrate the method's high sensitivity, allowing for the reliable quantification of voglibose even at low concentrations. This is particularly important for analyzing drug release profiles, where the concentration of released drug can be very low, and for impurity profiling if the method were to be extended for that purpose.

Linearity

The observed linearity across the tested concentration range confirms a proportional relationship between the voglibose concentration and the analytical response. This linearity ensures that the method can accurately quantify voglibose across the

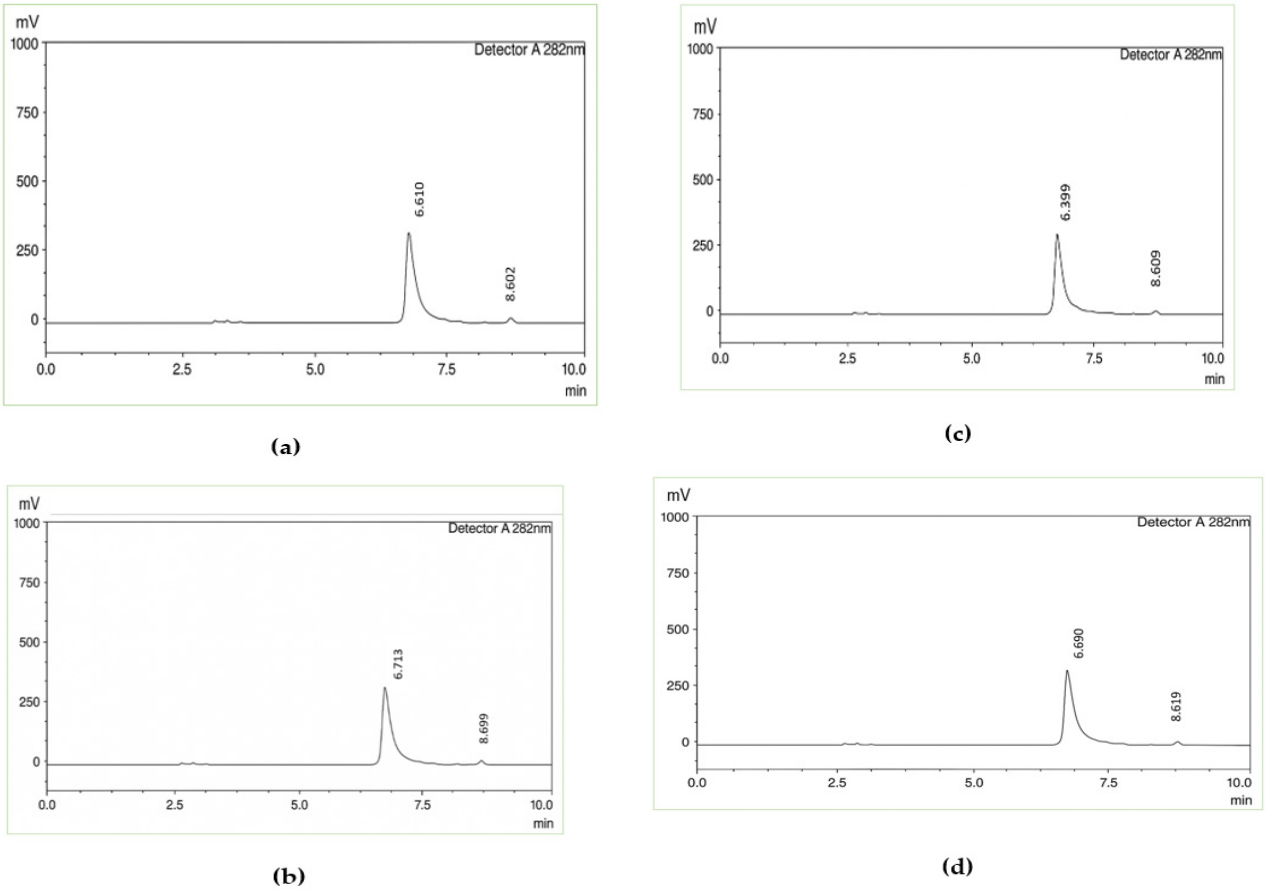

Figure 4: (a) Chromatogram showing acid hydrolysis, (b) Showing basic hydrolysis, (c) Showing per oxidation degradation (d) Showing thermal degradation of Voglibose nanocrystals.

expected range of concentrations encountered in various stages of research and development, from initial formulation screening to stability studies.

Reproducibility

The successful reproducibility tests, involving different analysts and instruments, are a strong indicator of the method's transferability and robustness. This inter-analyst and inter-instrument consistency minimizes variability and ensures that the data generated across different experimental setups or laboratories will be comparable and reliable.

The validated method's effectiveness in supporting routine analysis stems directly from these demonstrated analytical attributes. Its utility in precisely assessing drug loading ensures accurate determination of the amount of therapeutic agent incorporated within the nanocrystal matrix, a critical parameter for dose control and efficacy. Furthermore, its application in characterizing drug release patterns will provide crucial insights into the *in vitro* and potentially *in vivo* performance of the nanocrystal formulations, guiding optimization for desired pharmacokinetic profiles. Finally, the method's robustness and accuracy make it an indispensable tool for stability studies, enabling the monitoring of voglibose content and integrity over time under various storage conditions, which is paramount for shelf-life determination and regulatory submissions. The comprehensive validation provides a high degree of confidence in the analytical results generated, making this method a cornerstone for the continued investigation and advancement of voglibose-based nanocrystal formulations towards clinical application.

CONCLUSION

A robust and highly effective assay method for the quantitative analysis of voglibose nanocrystals has been successfully developed and comprehensively validated. This validated method consistently demonstrates exceptional strength, accuracy, sensitivity, linearity, and reproducibility, fulfilling all requisite analytical criteria. Its proven effectiveness makes it an invaluable and dependable tool for the routine analysis of voglibose nanocrystals throughout all phases of pharmaceutical research and development. Specifically, this method enables the precise and reliable assessment of critical formulation attributes, including drug loading, *in vitro* release kinetics, and long-term stability. The successful validation of this analytical assay significantly contributes to the scientific rigor and advancement of voglibose-based nanocrystal formulations, providing essential data for optimizing their design, ensuring

quality control, and facilitating compliance with future regulatory requirements for clinical translation.

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ABBREVIATIONS

HPLC: High Performance Liquid Chromatography; **RPC:** Reversed Phase Chromatography; **UV:** Ultraviolet; **DCM:** Dichloromethane; **LOD:** Limit of Detection; **LOQ:** Limit of Quantification; **RSD:** Relative Standard Deviation; **NF:** National Formulary; **PVDF:** Polyvinylidene Fluoride; **PTFE:** Polytetrafluoroethylene; **RP:** Reverse Phase; **ICH:** International Council for Harmonization; **SD:** Standard Deviation; **r^2:** Correlation coefficient; **%RSD:** Percentage Relative Standard Deviation.

CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

AUTHOR CONTRIBUTIONS

Concept-P.A.; Supervision-R.G.; Materials-M.S; Literature Search: P.A.; Analysis or Interpretation-P.A.; Writing-P.A.; Critical Review-R. G and D.P.D.

SUMMARY

This study focused on comprehensive validation of a Reverse Phase High-Performance Liquid Chromatography (RP-HPLC) method developed for the quantification of Voglibose nanocrystals.The process utilized for quantifying Voglibose nanocrystals has been successfully validated, demonstrating its robustness, precision, and sensitivity, while meeting all required analytical reference standards. This aims to facilitate the advancement and regulatory adherence of voglibose formulations in clinical settings by addressing these essential validation aspects.

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