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Research Article

Stability Indicating UV Spectrophotometric Methods for the Determination of Nateglinide in Pharmaceuticals

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Abstract

Two methods which are simple, rapid and cost-effective are presented for determination of NTG in bulk and tablets using uv-spectrophotometry. Methods are based on measurement of absorbance of drug solution either in 0.1M NaOH at 210 nm (NaOH method) or in 0.1 M HCl at 270nm (HCl method). Beer's law is obeyed over concentration ranges of 3-54 and 4-72 µg/mL for NaOH method and HCl method, respectively; and corresponding molar absorptivity values are 4.09 $\times 10^3$ and 3.04 $\times 10^3$ L/mol/cm. Calculated Sandell sensitivities are 0.0776 and 0.0995 $\mu g cm^{-2}$ with NaOH and HCl as diluents, respectively. Limits of detection (LOD) and quantification (LOQ), calculated according to the ICH guidelines are: 0.91 and 2.73µg/mL (NaOH method) and 0.72 and 2.16 µg/mL (HCl method). Intra-day and inter-day accuracy and precision, determined by replicate analyses at three concentration levels, were ≤2% (%RE) and ≤1.63% (%RSD), respectively. Method robustness was assessed by making small changes in the measurement wavelength whereas the ruggedness was tested by inter-analysts and inter-cuvettes variations. Validated methods were applied to the determination of active ingredient in tablets. Drug was subjected to forced degradation *via* acid and alkali hydrolysis, oxidation, thermolysis and photolysis.

Keywords: Nateglinide; Determination; UV Spectrophotometry; Pharmaceuticals; Stability-Indicating

Introduction

Nateglinide (NTG) is chemically known as [N-(trans-4-isopropylcyclohexyl carbonyl)-D-phenylalanine] (Figure 1) [1]. It is a D-phenylalanine derivative lacking either a sulphonylurea orbenzamido moiety and is a novel oral meal-time glucose regulator and has been approved for the treatment of diabetes mellitus [2,3]. This meglitinide derivative works by stimulating the pancreas to release insulin by closing the ATP-dependent potassium channels. The resulting influx of calcium induces insulin secretion. It is rapidly and completely absorbed from the gastrointestinal tract and peak plasma concentration reaches at 0.5-1.0 h. It is metabolized by cytochrome P-450 system to inactive metabolite and eliminated with half-life of 1.4h [4].

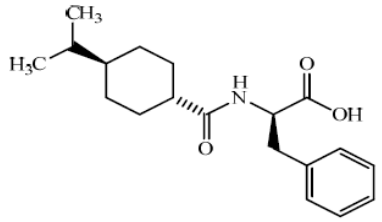

Figure 1: Structure of NTG.

Due to its therapeutic importance, many methods based on diverse techniques, such as high-performance liquid chromatography [5-15], liquid-chromatography-tandem mass spectrometry [16-19] and micellarel ectrokinetic chromatography [20] have been reported for the determination of drug in body fluids. NTG is official in British Pharmacopoeia [21], Indian Pharmacopoeia [22], the United States Pharmacopoeia [23] and European Pharmacopoeia [24]. These pharmacopoeias describe liquid chromatographic method for assay of pure drug, but no method for dosage form. In addition to the pharmacopoeial methods, a number of spectrophotometric and chromatographic methods have been reported for the determination of NTG in pharmaceuticals, and include, visible spectrophotometry [25-30], high-performance thin layer chromatography [31,32] and HPLC [33-42].

Considering several advantageous aspects like simplicity, speed, ease of performance, sensitivity and cost-effectiveness, uv-spectrophotometry is perhaps the most widely used technique in the field of pharmaceutical analysis [43-48], and quite a few workers have applied this technique to the determination of NTG in pharmaceuticals. Rajasekaran *et al* [25] have reported a method in which the absorbance of pure drug and tablet extract in 95% ethanol was measured at 210nm. By measuring the absorbance in methanol, NTG in bulk form and tablets was assayed by Rastogi *et al* [49]. Jain *et al* [50] have developed two methods in which the absorbance of the drug solution or the tablet extract in methanol was measured at 216nm or in a mixture of methanol and 10% NaOH (3N) at 225.4nm. Recording the absorbance of the bulk drug and tablet extract in phosphate buffer of pH 6.8, Babu *et al* [51] have devised three procedures in which the measurements were made at 217, 239 and 248 nm. A stability-indicating method has been reported by Rahul and Vinod [52], where a mixture of 0.1N HCl and 0.5% sodium laurylsulphate was used as the medium and absorbance measured at 212nm. Thomas and Patil [53] have reported two methods for the simultaneous determination of NTG and metformin hydrochloride

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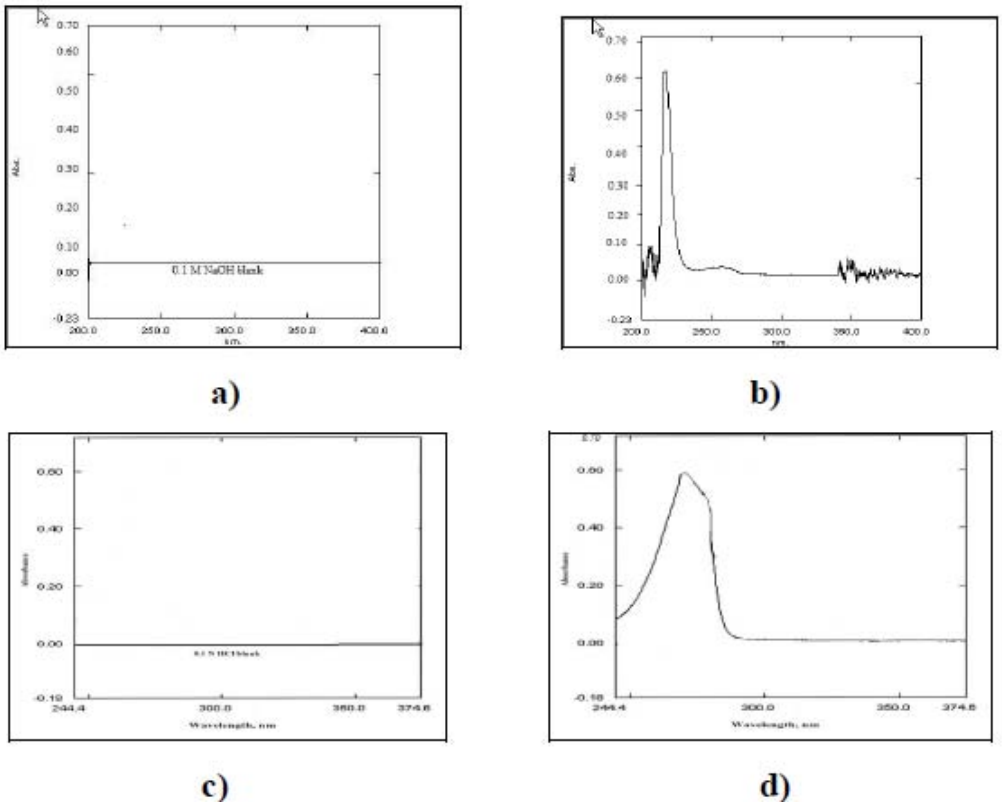

Figure 2: Absorption spectra of: **a)** 0.1M NaOH blank; **b)** NTG in 0.1M NaOH (36 µg mL^{-1} NTG); **c**) 0.1M HCl blank; **d**) NTG in 0.1M HCl (48 µg mL^{-1} NTG).

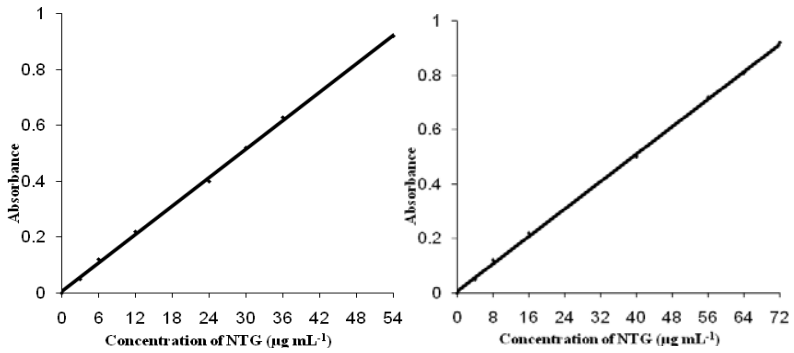

Figure 3: Calibration curve for NTG in: **a)** 0.1M NaOH, **b)** 0.1M HCl.

(MFH) in tablets. First method involved solving simultaneous equations based on measurement of absorbance at 216nm (NTG) and 233nm (MFH). The second was the first derivative method, and the wavelengths selected for quantitation were 216nm for NTG and 243nm for MFH. Beer's law was obeyed over 0.5-80µg/mL for NTG and 0.5-40µg/mL for MFH in both methods.

Though several solvent systems have been employed for the uv-spectrophotometric assay of NTG in pharmaceuticals, NaOH or HCl alone has not been used, and many reported methods [25,49-53] have not been validated as per the ICH guidelines. Hence, the aim of the present study was to develop rapid and reliable uv-spectrophotometric methods using 0.1N NaOH and 0.1 N HCl as diluents for the determination of NTG in bulk and tablet forms, and to validate them for linearity, LOD, LOQ, accuracy, precision, robustness, ruggedness and selectivity, following the ICH guidelines. Stability indicating ability of the methods was also evaluated by forced degradation study.

Materials and Methods

Apparatus

Shimadzu Pharmaspec 1700UV/Visible double beam spectrophotometer provided with matched 1-cm quartz cells (Hyderabad, India) was used for all absorbance measurements.

All chemicals and reagents used were of analytical reagent grade and double distilled water was used throughout the study. Aqueous solution of hydrochloric acid (HCl, 5M) or sodium

Table 1: Sensitivity and regression parameters.

Parameter	NaOH Method	HCl Method
λ_{max}, nm	210	270
Beer's law limits, µg/mL	3.0–54.0	4.0–72.0
Molar absorptivity(ε), L/mol/cm^{-1}	4.09×10^3	3.04×10^3
Sandell sensitivity, µg/cm^2	0.0776	0.0995
Limit of detection (LOD), µg/mL	0.91	0.72
Limit of quantification (LOQ), µg/mL	2.73	2.16
Regression equation, Y*		
Intercept (b)	0.0095	0.0102
Slope (m)	0.0169	0.0126
Correlation coefficient (r)	0.9995	0.9997
Standard deviation of intercept (S_b)	0.0027	0.0067
Standard deviation of slope (S_m)	0.0003	0.0002

*y= mx+b, where y is the absorbance, x concentration in µg/mL, b intercept and m slope.

hydroxide (NaOH, 5M) was prepared either by appropriate dilution of concentrated acid (S.D. Fine Chem Ltd, Mumbai, India) or by dissolving required quantity of chemical (Merck, Mumbai, India). Acid and alkali solutions, so prepared, were diluted stepwise to get 0.1M concentrations and standardised. Hydrogen peroxide (5% v/v) was prepared by suitable dilution of commercial sample (30%, S.D. fine Chem, Mumbai, India).

Pure sample of NTG was kindly supplied by Glenmark Pharmaceuticals, Mumbai, India, as gift. Stock standard 200µg/mL NTG solutions were prepared by dissolving 20mg of pure NTG in 0.1M NaOH and 0.1MHCl separately, and diluted to 100mL with the respective solvent, in calibrated flasks. The solutions were diluted to obtain 60 and 80 µg/mL NTG and used for assay by NaOH method and HCl method, respectively.

NTG - containing tablets; Natilide-60 (60mg) (Alembic Ltd., Vadodara, India), Glinate-60 (60mg) (Glenmark Pharma. Mumbai, India) were purchased from the local market.

Assay procedures

Procedure for bulk drug:

NaOH Method: Varying aliquots (0.5, 1.0, 2.0,…. 9.0 mL) of 60µg/mL NTG standard solution were taken in a series of 10mL volumetric flasks and volume was made up to the mark with 0.1M NaOH. The absorbance of each solution was measured at 210nm *vs* 0.1M NaOH.

HCl Method: Into a series of 10mL calibration flasks, aliquots of NTG standard solution equivalent to 4.0-72.0 µg/mL NTG were accurately transferred and volume was made up to the mark with 0.1M HCl. The absorbance of each solution was measured at 270nm *vs*0.1M HCl.

In either method, calibration curve was prepared by plotting absorbance *versus* concentration. The concentration of the unknown was computed from the respective regression equation derived using Beer's law data.

Procedure for tablets:

Twenty tablets from each brand were weighed and crushed into a fine powder. An amount of tablet powder equivalent to 20mg of

Table 2: Results of intra-day and inter-day accuracy and precision study.

Method	NTG taken (µg/mL)	Intra-day (n = 5)			Inter-day (n = 5)		
		NTG found[a] (µg/mL)	%RSD[b]	%RE[c]	NTG found[a] (µg/mL)	%RSD[b]	%RE[c]
NaOH method	15	14.8	1.27	1.34	14.7	0.76	2.00
	30	30.3	0.92	1.00	29.5	1.63	1.67
	45	44.5	0.54	1.11	45.7	1.34	1.56
HCl Method	20	19.7	1.45	1.50	19.8	1.04	1.01
	40	39.5	1.05	1.25	40.7	1.27	1.75
	60	60.7	1.32	1.17	59.2	0.76	1.34

[a]Mean value of five determinations; [b]Relative standard deviation (%); [c]Relative error (%).

Table 3: Results of ruggedness expressed as intermediate precision, expressed as %RSD.

Method	NTG taken (µg/mL)	Method robustness*	Method ruggedness	
			Inter-analysts (n=3)	Inter cuvettes (n=3)
NaOH method	15	1.25	1.02	1.04
	30	0.96	1.21	1.54
	45	1.41	0.91	0.78
HCl method	20	0.63	1.57	1.09
	40	1.16	0.72	1.53
	60	0.72	0.82	1.19

*The wavelengths were 209, 210 and 211 nm (NaOH method) and 269, 270 and 271 nm (HCl method).

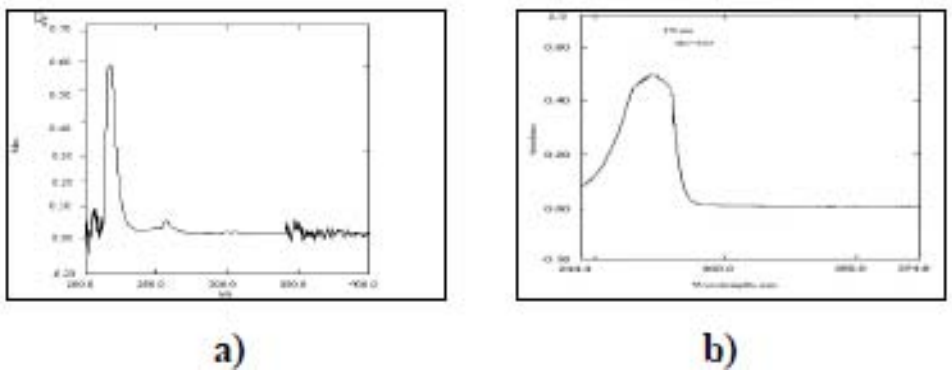

Figure 4A: UV-spectra of 40 µg mL^{-1} NTG after subjecting to acid hydrolysis: a) NaOH Method and b) HCl Method.

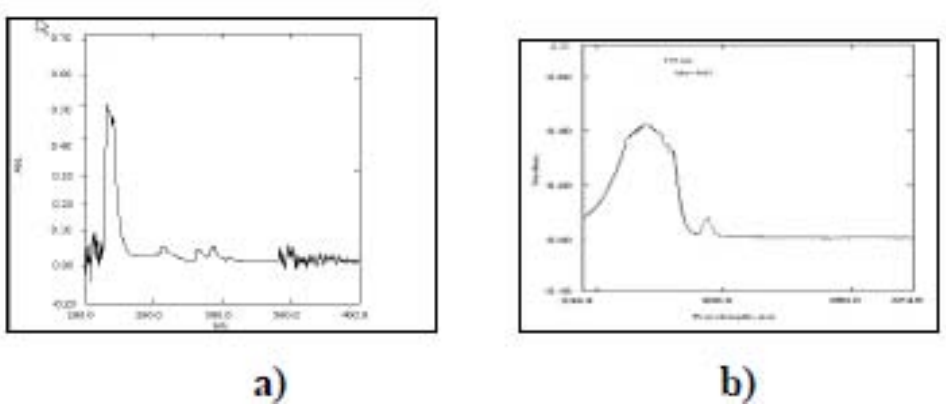

Figure 4B: UV-spectra of 40 µg mL^{-1} NTG after subjecting to base hydrolysis: a) NaOH method and b) HCl method.

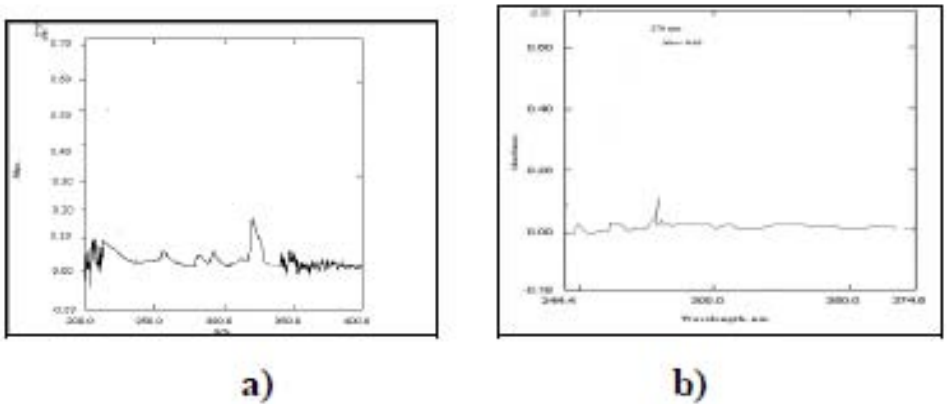

Figure 4C: UV-spectra of 40 µg mL^{-1} NTG after subjecting to oxidative condition: a) NaOH method and b) HCl method.

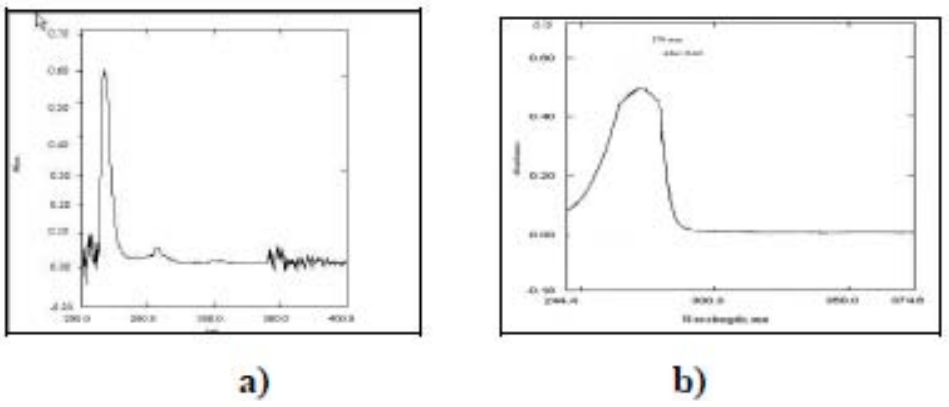

Figure 4D: UV-spectra of 40 µg mL^{-1} NTG after subjecting to thermal degradation: a) NaOH method and b) HCl method.

NTG was transferred into two 100mL separate volumetric flasks. The content was shaken well for 20min with about 50 mL of 0.1M NaOH or 0.1M HCl and the content was diluted to the mark with the respective solvent. It was filtered using Whatman No. 42 filter paper. First 10mL portion of the filtrate was discarded and appropriate portions were diluted to get 60 and 80 µg/mL NTG levels separately using the respective solvent, and a suitable aliquot was taken for absorbance measurement.

Procedure for placebo blank and synthetic mixture analyses

A placebo blank of the composition: acacia (10mg), starch (15mg), hydroxyl cellulose (15mg), sodium citrate (10mg), magnesium stearate (10mg), talc (15mg) and sodium alginate (15mg) was prepared by homogeneous mixing. A 20mg portion was extracted with either 0.1N NaOH or 0.1N HCl as described under "procedure for tablets". A 2 mL aliquot was taken for assay following

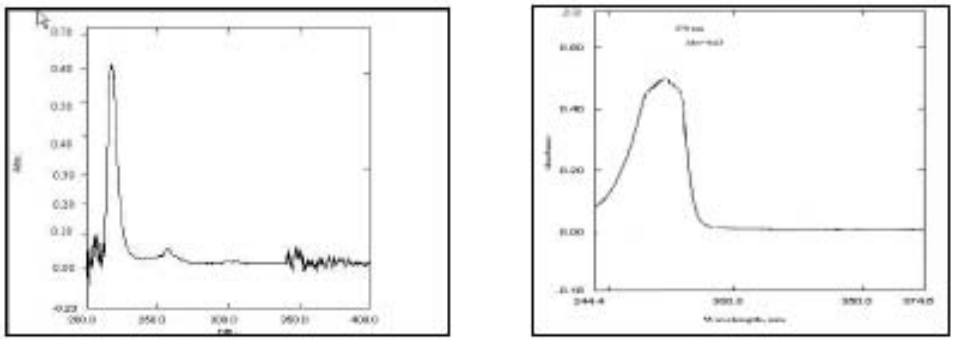

Figure 4E: UV- spectra of 40 µg mL^{-1} NTG solution after subject ingto photolytic condition: a) NaOH method and b) HCl method.

Table 4: Results obtained by the analysis of tablets by the proposed methods and statistical comparison of results with the reference method.

Tablet brand name	Label claim mg/tablet	Found (Percent of label claim ±SD)[a]		
		Official method	Proposed methods	
			NaOH method	HCl method
Natelide-60	60	99.87±1.03	101.5±1.12	101.9±1.45
			t = 2.39	t = 2.55
			F= 1.18	F = 1.98
Glinate-60	60	99.96±1.89	101.2±1.63	102.1±1.89
			t = 1.11	t = 1.87
			F= 1.34	F = 1.21

[a]Mean value of five determinations.

the recommended procedure. A synthetic mixture was prepared by adding 20 mg pure NTG to 20mg placebo blank and homogenized. Its solution was prepared as described under "procedure for tablets". The extract was subjected to assay following the general procedures (n=5) after appropriate dilution and the percentage recovery of NTG was calculated in each method.

Procedure for forced degradation study

Two standard solutions equivalent to 200µg/mL NTG were prepared in 0.1M NaOH and 0.1M HCl separately. Two mL each of this solution were accurately transferred into separate 10mL volumetric flasks. One mL of 5M HCl, 5M NaOH or 5% H_2O_2 was added to the flasks separately and the flasks were heated for 2h in a water bath maintained at 80°C. Then, the solutions were cooled to room temperature and neutralized by adding base or acid; the volume in each flask was brought to the mark with the respective solvent, and absorbance measured at 210nm (NaOH method) or 270nm (HCl method). For thermal degradation, solid drug was kept in Petri dish in an oven at 100°C for 24h. To study the effect of light solid sample was exposed to 1200K lux intensity light for 48h in an uv chamber. Solid samples after degradation were used to prepare 60 and 80 µg/mL solution in 0.1M NaOH and 0.1M HCl, respectively. Finally, the absorbance of solutions from acid, base, oxidant, heat and light-induced degradation of NTG, was measured at the respective wavelengths.

Results and Discussion

Spectral characteristics

NTG solutions in 0.1M NaOH and 0.1M HCl showed absorbance maxima at 210 and 270 nm, respectively, and absorbance at these wavelengths was found to be linearly dependent upon the concentration of drug. The corresponding blank solutions showed negligible absorbance as shown in Figure 2.

Method validation

Linearity, sensitivity, limits of detection and quantification: A linear correlation was found between absorbance at λmax and concentration of NTG (Figure 3). The slope (m), intercept (b) and correlation coefficient (r) for each system were evaluated by using the method of least squares. Optical characteristics such as Beer's law limits, molar absorptivity and Sandell sensitivity values [54] of both the methods were calculated. The limits of detection (LOD) and quantitation (LOQ) were also calculated according to *ICH* guidelines [55], and all these data are presented in Table 1.

Precision and accuracy: To check the repeatability and reproducibility of the proposed methods, the assays described under

Table 5: Results of recovery study using standard addition method.

Tablet studied	NaOH method				HCl method			
	NTG in tablet, µg/mL	Pure NTG added, µg/mL	Total NTG found, µg/mL	Pure NTG recovered (Percent±SD*)	NTG in tablet, µg/mL	Pure NTG added, µg/mL	Total NTG found, µg/mL	Pure NTG recovered (Percent±SD*)
Natelide-60	20.30	10.0	29.97	98.92±1.05	20.38	10.0	30.87	101.6± 1.19
	20.30	20.0	40.95	101.6±1.43	20.38	20.0	40.23	99.63± 1.67
	20.30	30.0	50.85	101.1±1.67	20.38	30.0	51.24	101.7± 1.89
Glinate-60	20.24	10.0	30.91	102.2±1.36	20.42	10.0	31.15	102.4± 0.57
	20.24	20.0	41.01	101.9±0.98	20.42	20.0	41.59	102.9± 1.88
	20.24	30.0	49.16	97.86±0.83	20.42	30.0	49.85	98.87± 1.42

*Mean value of three determinations.

Table 6: Results of stability indicating study by forced degradation study.

Stress condition	% Degradation	
	NaOH method	HCl method
Acid hydrolysis	No degradation	No degradation
Alkali hydrolysis	15.5	29.8
Oxidation	99.9%	99.8%
Thermal (105°C, 3 hours)	No degradation	No degradation
Photolytic (1.2 million lux hours)	No degradation	No degradation

*Mean value of three determinations.

"general procedures" were repeated seven times within the day (intra-day precision) and five times on five successive days (inter-day precision). These assays were performed for three levels of analyte. The RSD values were ≤ 1.45% (intra-day) and ≤ 1.63% (inter-day), indicating very good precision of the methods. The accuracy of the methods was evaluated as percentage relative error, %RE, between the measured mean concentrations and nominal concentrations for NTG. The %RE values of ≤ 2.0% demonstrate high accuracy of the proposed methods. The results of this study are summarized in Table 2.

Robustness and ruggedness: Robustness was determined by the analysis of standard solution at three concentration levels at three wavelengths (λmax and λmax±1nm). Analyses were also performed by three analysts using the same cuvette and a single analyst using three cuvettes in the same laboratory. Intermediate %RSD values in both instances were in the range 0.63–1.57% indicating acceptable robustness and ruggedness. These results are presented in Table 3.

Selectivity: Selectivity of the methods was assessed by placebo blank and synthetic mixture analyses. The absorbance of the placebo blank was the same as that of 0.1M NaOH or 0.1M HCl. When the synthetic mixture solution was subjected to analysis at 30 and 40 µg/mL concentration levels by NaOH method & HCl method, the percent recoveries were 97.36 and 98.72, respectively, with %RSD being less than 2.2, implying that the assays were free from matrix interference.

Application to tablets: Commercial NTG tablets were analyzed by the developed methods and also by the official USP method [23]. Tablet powder extract was analysed by HPL using phosphate buffer and methanol system as mobile phase with uv detection at 210 nm. The results obtained were compared statistically by the Student's t-test and the variance-ratio F-test. The calculated t- and F- values did not exceed the tabulated values of 2.77 and 6.39, respectively, at the 95% confidence level and for four degrees of freedom (Table 4), indicating close similarity between the proposed methods and the reference method with respect to accuracy and precision.

Accuracy by recovery study: To ascertain the accuracy and reliability of the proposed methods, recovery test was performed *via* standard-addition procedure. Pre-analyzed tablet powder was spiked with pure NTG at three different levels and the total was determined by the proposed methods. Each determination was repeated three times. The percent recovery of pure NTG added was within the acceptable limits, indicating the absence of interference from the inactive ingredients in the assays. These results are as illustrated in Table 5.

Results from forced degradation study

The susceptibility to degradation was evaluated by measuring the absorbance of NTG solution after subjecting the sample to forced degradation. The percentage recovery of NTG was calculated in each case and is presented in Table 4. From this study, it can be concluded that the drug remained inert to acid hydrolysis, thermal and photolytic degradation. NTG degraded slightly under base-induced stress condition. Oxidative degradation was very extensive and the analyte was undetectable at the selected wavelengths. Chromatograms of 40µg/mL NTG solution, post degradation, are shown in Figure 4A to 4E.

Conclusions

The study presents two rapid and useful uv-spectrophotometric methods, which are stability-indicating, for the determination of nateglinide in pharmaceutical samples. Majority of the reported methods [43-52] employ organic solvents as diluents and suffer from two disadvantages of narrow linear dynamic range and poor sensitivity. The proposed methods use inexpensive chemicals as diluents and characterized by wide linear dynamic ranges and often more sensitive than the reported uv-spectrophotometric methods interms of LOD. High accuracy and precision of the methods, besides ease of performance and speed make them suitable for routine use.

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