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Research Article

QUANTITATIVE ESTIMATION OF NATEGLINIDE IN PHARMACEUTICAL DOSAGE FORMS BY VISIBLE SPECTROPHOTOMETRY

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ABSTRACT

A literal and specific Visible spectrophotometric method was raised for the estimation for Nateglinide in solid pharmaceutical dosage form. The λ-max of Nateglinide was found to be 465nm to both crude and marketed sample and is analyzed using Beer-Lamberts law. Beer's law was obeyed at the concentrations ranging 2-10µg/ml. The developed methods were absolute, definite, explicit and consistent and found to be aproto type for routine determination for Nateglinide. The method was validated statistically and by recovery studies .The LOD (limit of detection) and LOQ (limit of quantification) for visible spectra were found to be 0.625µg/ml and1.101µg/ml. The correlation coefficient value was found to be 1. The purity was found to be 99.29%.

Keywords: Nateglinide, Methanol, UV-visible spectrophotometer.

INTRODUCTION

Nateglinide[1-3]chemically [N-(trans-4-isopropyl cyclohexyl carbonyl)-D-phenylalanine] is a novel, non sulfonyl urea derivative used for the treatment of type II diabetes mellitus[4-6]. It is used in novel drug delivery system[7] and In-vitro studies of drugs[8].It is not official in any Pharmacopoeia. Literature survey reveals that micellar electro kinetic chromatography (MEKC)[9],Spectrophotometric methods[10-15], HPLC[16-17], Liquid Chromatography[18], HPTLC[19-20].In the present study, an attempt has been made to develop Visible spectrophotometric method for the determination of nateglinide in bulk and marketed formulations using methanol. ANOVA test was applied for comparison of both the methods. The developed methods were found to be simple, sensitive and reproducible.

MATERIALS AND METHODS

Visible Spectroscopy

The visible spectrum characterised by two satellite maxima and an inverted band of which the minimum corresponds to the λ-max of the fundamental band.

Experimental Method

UV – Visible Spectroscopy

Instrument

Lab India Ltd. UV 3000+, with bandwidth of1nm, wavelength accuracy of 0.5T% and matched quartz cells are used. UV win software was used.

Chemicals

Nateglinide, Methanol, Distilled water.

Preparation of Standard Stock Solution

A standard stock solution (1000µg/ml) was prepared by dissolving accurately 50mg of crude Nateglinide in pure methanol. This

stock solution was used to prepare further standard solutions of the drug. And a 100µg/ml (stock solution2) solution was prepared by dissolving 1ml of standard stock solution in 10ml of methanol.

Establishment of Optimal Level of Various Parameters

Absorption Maximum

Standard stock solution of drug was diluted to yield different concentrations of 2-10µg/ml. The absorbance was measured between 400-800nm.The standard curve was plotted against concentration versus absorbance of dilutions. The concentration 8-22µg/ml was obeyed Beers law. And square correlation coefficient was found to be 1.

Market Sample Analysis

Twenty tablets were weighed and powderd.A quantity equivalent to 60mg of Nateglinide was weighed accurately transferred into a volumetric flask dissolved in solvent, filtered through whattmann filter paper and made up to 60ml with solvent. And the amount of Nateglinide was found by the calibration curve (10µg dilution of drug).

Wavelength of Marketed Sample

The wavelength of marketed sample of Nateglinide was found was found to be 465nm. Correlation coefficient value was found to be 1.

Recovery Studies

To study the accuracy and reproducibility of the proposed methods, recovery experiments were carried out by adding a known amount of drug to pre analysed sample and the percentage recovery was calculated.

RESULT AND DISCUSSION

The Visible Spectroscopy was developed for the estimation of Nateglinide in pharmaceutical dosage forms. The λ max of Nateglinide was found to be 465nm.Linearity was found to be 8-22µg/ml. Correlation coefficient (1) indicate good linearity between concentration and slope area. The amplitude of the respective derivative spectrum is converted in terms of absorbance. Beer's law was obeyed by the fundamental spectrum. The method was found to be simple, accurate, and economical for the routine analysis of Nateglinide and its dosage forms. Recovery studies were found to be close to 99.5% that indicated the accuracy and precision of the above proposed method.

Quantitative analysis

%Assay = sample absorbance/standard absorbance x100
= 0.639/0.643 x100
=99.37%

Calculations

LOD (LIMIT OF DETECTION)

It is the lowest amount of analyte, in a sample that can be detected. Limit tests merely sustained that the amount of analyte is above or below a certain level.

DL=3.3/s.d.S

LOQ (LIMIT OF QUANTIFICATION)

It is the lowest concentration of an analyte in sample that can be determined with acceptable precision and accuracy.

QL=10/s.d.S

SANDELL'S SENSITIVITY

It is useful to detect the metals present in the sample. it is mainly useful for coloured compounds

Sand ell's sensitivity =molecular weight x no.of atoms present in molecule/Molar absorpitivity.

Molar absorpitivity

ε =E1cm1% x molecular weight /10.

CONCLUSION

The Visible spectroscopic method of analysis though expensive, can also be used in the routine analysis of Nateglinide in formulations, because multiple samples can be analysed simultaneously. The results obtained by these methods including recovery studies were comparable which proves the repeatability and suitability of the method.

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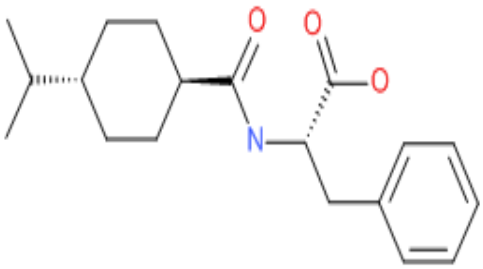

Fig. 1: Structure of Nateglinide

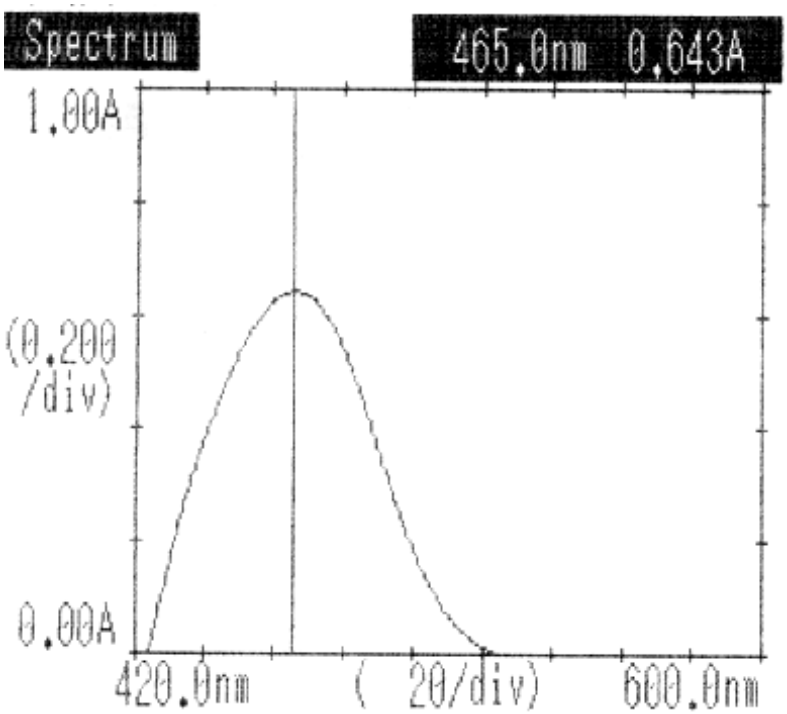

Fig: 2: Determination of Nateglinide by visible spectrophotometry method

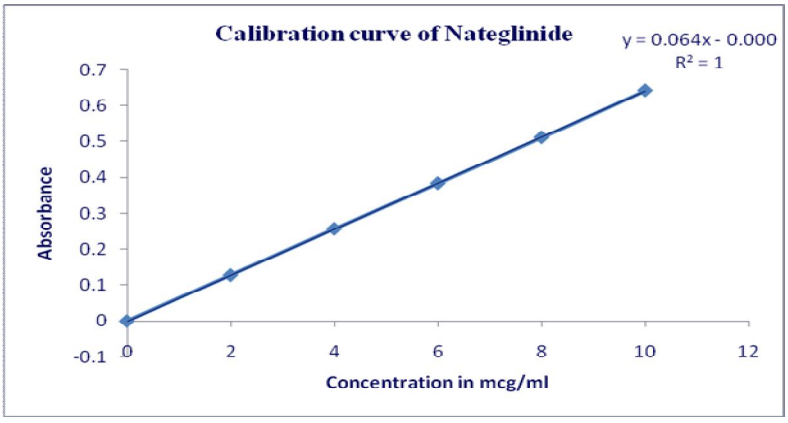

Fig. 3: calibration curve of Nateglinide

Table1:

No.	P/V	Wavelength(nm)	Abs.
1	Peak	465	0.643

Table 2: Absorbance at 465nm

No.	ID	Type	Conc./ml	Abs
1	Nateglinide-1	Standard	2	0.128
2	Nateglinide-2	Standard	4	0.257
3	Nateglinide-3	Standard	6	0.384
4	Nateglinide-4	Standard	8	0.512
5	Nateglinide-5	Standard	10	0.643

Table 3:

No.	P/V	Wavelength(nm)	Abs.
1	**Peak**	**465**	**0.693**

Table 4: Absorbance at 465 nm

No.	ID	Type	Conc/ml	Abs
1	Nateglinide test-1	Standard	2	0.130
2	Nateglinide test-2	Standard	4	0.262
3	Nateglinide test-3	Standard	6	0.391
4	Nateglinide test-4	Standard	8	0.522
5	Nateglinide test-5	Standard	10	0.639

Table 5: Analysis of Nateglinide Tablets

Drug	Label claim	Amount found(mg)	%Label claim	%Deviation	S.D
Nateglinide	60	59.57	99.29	0.968	0.581
	60	59.87	99.72	0.332	0.230
	60	59.66	99.44	0.242	0.171

Table 6: Recovery studies

Sample added(mg)	Amount of drug recovered(mg)	Amount of drug	Recovered
1	10	9.84	98.45
2	10	9.76	97.67
3	10	9.95	99.53

Table 7: Parameters

Sl. No	Parameters	Nateglinide
1	λ-max	465
2	Linearity	2-10
3	slope(m)	0.064
4	Intercept	0.000
5	correlation coefficient	1
6	Regression equation	Y=0.064X-0.000
7	Molar absorptivity	20.383
8	Sandell's sensitivity	0.015
9	Limit of detection	0.625
10	Limit of quantification	1.101

REFRENCESS

1. Available from http://www.drugs.com/cons/ Nateglinide.html.last accessed on 2005 Jun8
2. Available from http://www.rxlist.com/cgi/generic2/Nateglinide.html .last accessed on 2006 April.
3. Available from http://www.pdrhealth.com/drug_info/rxdrugprofiles/drugs/sta1565.shtml.last accessed on 2006 Jul.
4. DeFronzo RA.Pharmacologic therapy for type 2 diabetes mellitus. Ann Intern Med.1999; 131:281–303.
5. DeFronzo RA, Ferrannini E and Simonson DC. Fasting hyperglycemia in non-insulin-dependent diabetes mellitus: contributions of excessive hepatic glucose production and impaired tissue glucose uptake. Metabolism. 1989;38:387–95.

6. Kahn SE. The relative contributions of insulin resistance and beta-cell dysfunction to the pathophysiolog14. Suddhasatiya dey,Dhiraj kumar, D Sandeep Kumar. Formulation Characterizations and In-vitro evaluation of floating microspheres of Nateglinide.I.J.P.B.Sci-ISSN.NO.0975-6299.
7. Suddhasatiya Dey, Dhiraj Kumar and Sandeep Kumar D. Formulation Characterization and In-vitro evaluation of floating microspheres of Nateglinide.I.J.P.B.Sci-ISSN.NO.0975-6299.
8. Kranthi Kumar Reddy M, Narasimha Rao B and Ravindra Reddy K. Study on Effect of Excipients in Enhancing the Solubility of Nateglinide by Solid Dispersions. Research article.ISSN-2231–5705.
9. Yan H, Yang G, Qiao F and Chen Y. Determination of nateglinide in animal plasma by micellar electrokinetic chromatography and on-line sweeping technique. J Pharm Biomed Anal. 2004;36:169-74.
10. Rajasekaran A, Abdul Hathi MK, Murugesan S, Ajith SN, Devi G Aruna, Sowmiya G and Dharmar. Spectrophotometric determination of nateglinide. Indian J Pharm Sci. 2004;66:806-7.
11. Thomas AB and Patil SD. Simultaneous spectrophotometric estimations of Nateglinide and Metformin hydrochloride in pharmaceutical formulation. Der Pharma Chemica. 2011;3(3): 271-276.
12. Aradhaya Rastogi. The Determination of Nateglinide in bulk and Pharmaceutical Preparations UV Spectrophotometric Method. Pharma Research ISSN 0975-8216.
13. Sagar GV, Rao NV and Sastry BS. Assay of nateglinide in tablets by extraction spectrophotometry. Indian J Pharm Sci 2004;66:353-5.
14. Suresh Jain, Anil Bhandari and Suresh Purohit. Spectrophotometric determination of nateglinide in bulk and tablet dosage forms. 2009:218-221.
15. Jain S, Bhandari A, Purohit S. Spectrophotometric determination of nateglinide in bulk and tablet dosage forms. Asian J Pharm 2009;3:218-21.
16. Bauer S, Stormer E, Kirchheiner J, Michael C, Brockmoller J and Roots I. Rapid and simple method for the analysis of nateglinide in human plasma using HPLC analysis with UV detection. J Pharm Biomed Anal. 2003;31:551-5.
17. Thomas A, Patil S, Nanda R, Kothapalli L and Deshpande .A Stability-indicating RP-HPLC method for determination of Metformin Hydrochloride and Nateglinide in bulk and tablet formulations. Current Pharmaceutical Analysis. 2012;8(4):381-388
18. El-Wasseef DR. Simultaneous determination of metformin, nateglinide and gliclazide in pharmaceutical preparations using micellar liquid chromatography.I J Bio Scie. 2012;8(2):144-151.
19. Asha Byju Thomas, Shrikrushna Digambar Patil, Rabindra Kumar Nanda, Lata Prasad Kothapalli, Shital Shridhar Bhosle and Avinash Devidas Deshpande. Stability-indicating HPTLC method for simultaneous determination of nateglinide and metformin hydrochloride in pharmaceutical dosage form. Saudi Pharmaceutical Journal.2011.
20. Kale,DL and Kakde. HPTLC estimation of nateglinide in bulk drug and tablet dosage form. Asian Journal of Chemistry. 2011;23(10):4351-4354.
21. ICH Guidance on Analytical Method Validation. In Proceedings of the international Conference of Harmonization, Geneva: 1996.
22. Text on Validation of Analytical Procedures Q2B in, I.C.H. Harmonised Tripartite Guidelines; Nov. 1996.