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Original Article

Development and validation of ratio-derivative spectrophotometric method for simultaneous estimation of Gabapentin, Methylcobalamin and alpha lipoic acid in tablet formulation

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ABSTRACT

Aim: The purpose of this study is to develop simple, economic, specific, rapid, reliable, and reproducible method for simultaneous estimation of the Gabapentin, Methylcobalamin and Alpha lipoic acid.

Method: In this method the overlapping spectra of Gabapentin, Methylcobalamin and Alpha lipoic acid were well resolved by making use of the first-derivative of the ratios of their direct absorption spectra. The derivative ratio absorbance of Gabapentin, Methylcobalamin and Alpha lipoic acid were measured at 731.10 nm, 768.53 nm and 242.21 nm for their quantification. The method was validated for accuracy, precision, linearity, robustness and sensitivity.

Result & discussion: Gabapentin, Methylcobalamin and Alpha lipoic acid were shown linearity in the concentration range of 100–500 µg/ml, 0.5–2.5 µg/ml and 100–500 µg/ml respectively. The LOD & LOQ were found to be 3.09 µg/ml and 9.37 µg/ml; 0.03 µg/ml and 0.10 µg/ml; and 4.79 µg/ml and 14.52 µg/ml respectively. The % labelled claim for Gabapentin, Methylcobalamin and Alpha lipoic acid were found to be 98.71, 98.94 and 98.44 respectively.

Conclusion: Thus, the described method is suitable for routine analysis and quality control of pharmaceutical preparations containing these drugs in combination.

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1. Introduction

Gabapentin (GBP), 1-(aminomethyl) cyclo-hexaneacetic acid, is chemically unique cyclohexane derivative of gamma amino butyric acid (GABA) that was synthesized to cross blood brain

barrier, and mimic the inhibitory effects of this neurotransmitter on the CNS. Gabapentin is effective as adjunctive therapy for patients with partial and secondarily generalized tonic-clonic seizures.^{1,2} It is official in United State Pharmacopoeia 30.³ Methylcobalamin (MCB), (1R, 2R, 4S, 7S)-7-[[[(2S)-3-

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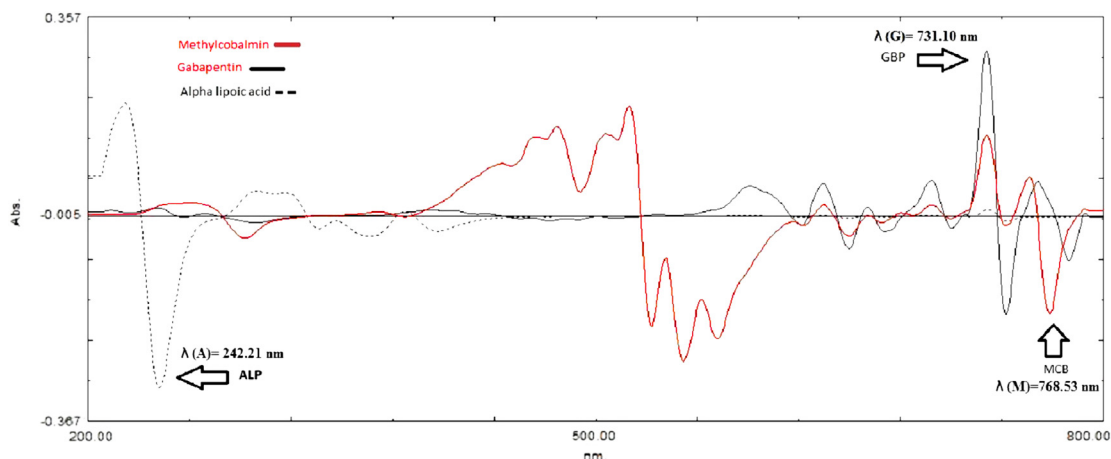


Fig. 1 – Overlaid ratio derivative spectra of Gabapentin, Methylcobalamin and Alpha lipoic acid in methanol.

hydroxy-2-phenylpropanol]oxy]-9,9-dimethyl-3-oxa-9-azonia tricycle [3.3.1.02,4] nonane, is a supplement for vitamin, used in treatment of Vitamin B₁₂ deficiency of dietary origin.^{1,4} It is official in Japanese pharmacopoeia.⁵ Alpha lipoic acid (ALP), (R)-5-(1, 2-dithiolan-3-yl) pentanoic acid, is antioxidant, and used in treatment of diabetes and HIV. It also has been used for cancer, liver ailments, and various other conditions.^{1,4} It is official in United State Pharmacopoeia 30.³ Combination of Gabapentin, Methylcobalamin and Alpha lipoic acid treats both the problems associated with all types of neuropathy i.e., neuralgia (neuronal pain) and neuron degeneration. Gabapentin is proved to be very effective and well tolerated in the treatment of neuropathic pain. Alpha lipoic acid is an universal antioxidant which prevents oxidative damage of neurons. Methylcobalamin increases myelin sheath formation thereby regenerates neuron.

Literature survey reveals many reported methods for the analysis of GBP by ultra-violet (UV),^{6,7} high-performance liquid chromatography (HPLC)^{8–11} and high-performance thin-layer chromatography (HPTLC).¹² Various methods have been reported for determination of MCB by UV,^{13–17} HPLC^{5,17,18} and HPTLC.¹² Estimation of ALP by UV,^{19,20} HPLC^{3,21,22} and GC,²¹ either individually or in combination with other drugs are reported. To the best of our knowledge, there is no

analytical method reported for simultaneous determination of ternary mixture containing GBP, MCB and ALP. Therefore, an attempt has been made to develop a simple, accurate, rapid and reproducible ratio spectra derivative spectroscopic method for simultaneous determination of GBP, MCB and ALP in tablet dosage form and validate it, in accordance with ICH guidelines.²³

2. Materials and methods

Pharmaceutical grade of GBP (Zydus Research Center, Ahmedabad, Gujarat, India), ALP (Centurion Laboratories, Vadodara, Gujarat, India) and MCB (Centurion Laboratories, Vadodara, Gujarat, India) were kindly supplied as gift samples, certified to contain >99% (w/w) on dried basis. Commercially available trigabatin 100 (Sun Pharma, Sikkim) tablets claimed to contain 100 mg Gabapentin, 0.5 mg Methylcobalamin and 100 mg Alpha lipoic acid have been utilized in the present work. Methanol of Analytical grade was purchased from Merck Chemicals, India and Rankem Chemicals, India. Sartolon Polyamide, 0.20 μm pore size membrane filter, Sartorius AG, 37070 Goettingen, Germany, and 0.45 μm pore size, 47 mm Ø, Sartolon Polyamide, Sartorius AG, Germany.

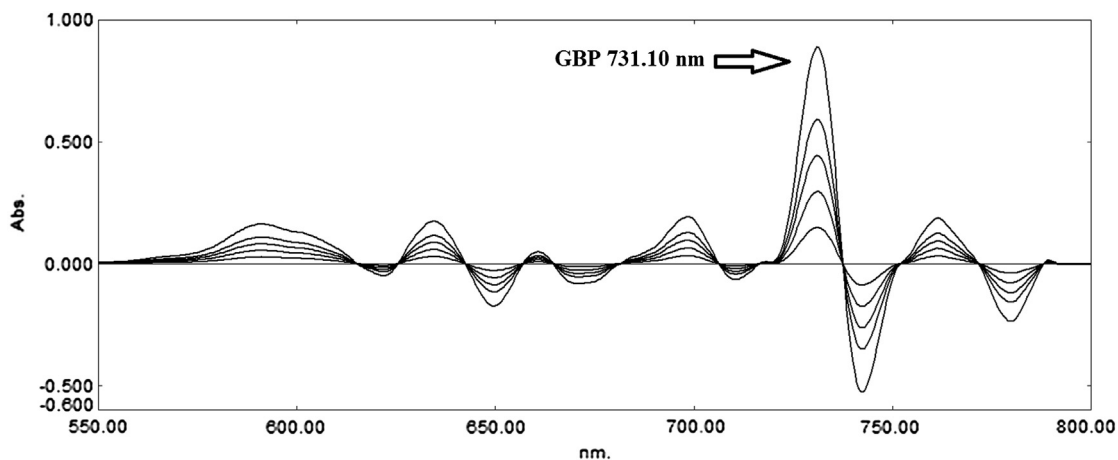


Fig. 2 – Linearity of ratio derivative spectra of Gabapentin (100–500 μg/ml) at 731.10 nm.

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