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Determination of Domperidon in Polymeric Micellar Media by Redox Method

Neeti Nema* and Archna Pandey

Department of Chemistry, Dr. H.S. Gour University, Sagar (M.P.) 470 003 India

Mobile No.:09424445062, 9926373221
***E-mail: archnapandey@indiatimes.com**
E-mail: niti_nema@rediffmail.com

ABSTRACT: The objective of this research was to develop a kinetic spectrophotometric method for the determination of domperodon (DMPN) in pure form and pharmaceutical formulation. The method based on the reaction of imidazole group of the drug with a mixture ammonium metavanadate in polymeric micelllar medium at room temperature. It was observed that by oxidation of domperidon in the presence of polyvinylpyrrolidone (PVP) at first a pink red solution was obtained which becomes a purple solution after sometimes. The reaction is followed spectrophotometrically by measuring the decrease in absorbance 355 nm. A regression analysis of Beer's Lambert plots showed a good correlation in concentration range of 17 µg/mL - 340 µg/mL . The apparent molar absorptivity, Sandell's sensitivity, detection and quantification limit were successfully applied to the determination of DMPN in bulk and pharmaceutical formulations without any interference from common excipients.
KEYWORDS: Spectrophotometry, Domperidon, polyvinylpyroliddone, Validation, V(V)

INTRODUCTION

Domperidon, [5-chloro-1-{1-[3-(2-oxobenzimidazolin-1-yl)-propyl]-4-piperidyl } benzimidazoline-2-one] is a white, or almost white, powder. Practically insoluble in water, slightly soluble in alcohol and methyl alcohol, it is soluble in dimethylformamide[1]. DMPN is a synthetic benzimidazole compound that acts as a dopamine D_2 receptor antagonist. Its localization outside the blood – brain barrier and antiemetic properties has made it is a useful adjunct in therapy for Parkinson's disease. There has been rehabilitated curiosity in antidopaminergic prokinetic agents since the abandonment of cisapride, a 5-HT4 agonist, from the market. DMPN is also as a prokinetic negotiator for treatment of upper gastrointestinal motility disorders. It continues to be an attractive alternative to metoclopramide because it has fewer neurological side effects. Pateints receiving DMPN or other prokinetic agents for diabetic gastropathy or gastroparesis should also be managing diet, lifestyle, and other medications to optimize gastric motility [2].

Several methods have been reported for DMPN determination, including BP[3], spectrophotometric[4-5], high performance liquid chromatography (HPLC) [6-7], HPTLC[8], extractive Spectrophotometry[9], first derivative spectrophotometry[10], RP-HPLC[11-12] were reported for the estimation of DMPN in pharmaceutical preparation. The BP 1998 reported a titrimetric method [13]. This titrimetric procedure requires about 0.25 g to provide accurate results, yet, no work has been performed to use a redox reaction for the determination of domperidon. The purpose of the present study was to apply redox reaction in polymeric micellar media to develop simple, accurate, sensitive and reproducible methods that can be used in laboratories where modern and expensive apparatus, such as that required for GLC, HPLC is not available.

EXPERIMENTAL

MATERIAL AND METHODS

Pure DMPN was obtained from Torrent pharmaceutical Ahemdabad. The commercial products Domidac, domstal, Vomistop 10 mg were purchased from local market.

PVP (AR grade) was purchased from BDH. Ammonium metavanadate is obtained from Loba chemie. All other reagents used were of AR grade. Distilled water was used during the entire experiment.

The instrument used in present study was double beam UV/visible spectrophotometer with 10 mm matched quartz cell (model-UV-164 Elico).

PREPARATION OF STOCK SOLUTION

Domperidon(0.01 M): Stock solution of DMPN was prepared by dissolving 425 mg in 1:1 acetic acid and water and made up to the mark in 100 mL volumetric flask. The above stock solution was further diluted to get a working standard solution of 1 µg to 500 µg/mL.

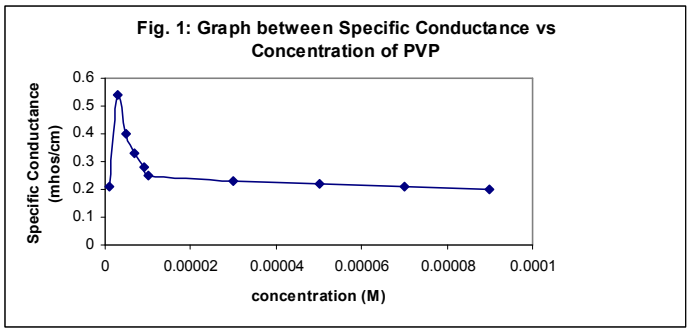
Ammonium metavanadate(0.1M): Oxidant solution ammonium metavanadate (Loba chemie) is used as a primary standard [14]. The solution of oxidant was prepared by suspending weighed in a standard H_2SO_4 (AR, BDH) till a clear solution was obtained. This solution so prepared remains stable for 1 month, and hence used as such stock solution. All of the chemicals used in this study were of the highest purity available and used without further purification,

PVP (0.01 M): 0.44 g of PVP dissolve in 100 mL distilled water and diluted to get a 0.00003 M solution of PVP (CMC of PVP).

METHODS

DETERMINATION OF CMC OF SURFACTANT SOLUTION

The CMC of the surfactant solution (PVP) was obtained using conductometric methods. Conductance was measured with an Equiptronics conductivity bridge. A dip type cell was used to measure the conductivity. Sets of measurements were taken until no significant change of conductance occurred. Specific conductance (κ) vs concentration of PVP plot is shown in fig 1.



PREPARATION OF CALIBRATION CURVE RANGING

Aliquot of standard solution of DMPN ranging from 0.002 – 0.8 mL were transferred to a series of 10 mL volumetric flask. To that 0.1 mL of ammonium metavanadate (0.01mol dm^{-3}) and 0.125 mL of PEG (0.000125mol dm^{-3}) were successively added, and than added distilled water up to the mark. The absorbance of light pink colored species formed was measured at 355 nm of DMPN present in the sample solution. The amount of DMPN was obtained from its calibration curve.

ASSAY PROCEDURE

At least ten tablets of the drug weighed in to a small dish, powdered and mixed well. A portion equivalent 10mg was weighed and dissolved in 1:1 acetic acid and. Aliquot of the test solution was diluted in 10 ml in test tube. An aliquot of diluted drug solution was then treated as described above in pure drug.

VALIDATION OF THE METHOD

Optical characteristics such as Beer's law limits, molar absorbitivity and Sandell's sensitivity for DMPN, are given in table 1. Beer's law obeyed in the concentration range of 17 µg/mL – 340 µg/mL which is shown in fig.2. Data of the regression analysis made for the calibration curve are also determined (Table 1). The accuracy and precision of the method made for the calibration checked by analyzing the Beer's law range containing the same amount of each drug.

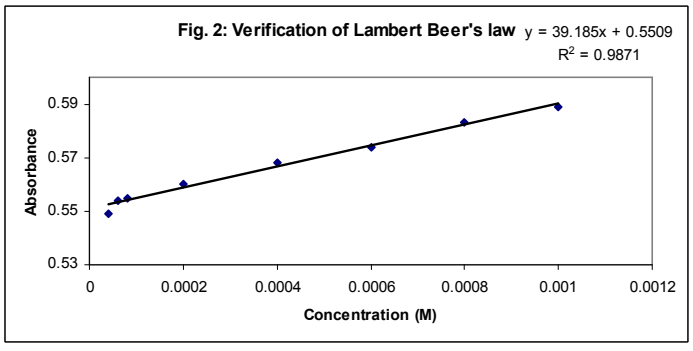


Table 1

S. No.	Parameters	Domperidon
1.	λ_{max}	355nm
2.	Beer's Range(µg/mL)	17µg/mL - 340µg/mL
3.	Molar Absorbtivity(L mol^{-1} cm^{-1})	1.069×10^4
4.	Sandell's Sensitivity(mol^{-1} L^{-2} cm)	0.0397
5.	Regression equation	0.9871
6.	Intercept	0.5509
7.	Slope	39.185
8.	Limit of Detection(mg/mL)	1.2×10^{-3}
9.	Limit of Quantization(mg/mL)	4.0×10^{-3}
10.	Standard Deviation of calibration line	0.0167

Table 2

Commercial formulation analyzed	Drug content	Label claim in mg	Amount of drug found	SD%
Domstal	DMPN	100 mg	98.53	0.66
Domidac	DMPN	100 mg	101.80	1.15
Vomistop	DMPN	100 mg	100.17	0.55

LOD and LOQ determination

The limit of detection (LOD) and the limit of quantization (LOQ) were determined by using the following equation –

LOD = 3 SD/m ……(1)

LOQ = 10 SD/m …… (2)

Where SD is the standard deviation of the absorbance values of the second smallest concentration, m is the slope of the calibration curve.

The accuracy of the proposed method was checked by performing recovery experiments. For this, a known amount of the pure drug was added to preanalysed dosage forms and then determined by the recommended procedure. The result obtained in table 3 showed that the mean recovery and relative standard deviation were in the range of 98.53±0.66 to 101.80±1.15 respectively. These results also suggested that there is no interference from the common excipients present in dosage forms.

CONCLUSIONS

The proposed method is found to be more sensitive and it does not require any pretreatment of the drug and tedious extraction procedure prior to its determination. The other ingredients and excipients usually present in pharmaceutical dosage form did not interfere in the estimation when some commercial dosage forms were analyzed by this method. The accuracy of this method was confirmed by the recoveries studies by adding a known amount of the pure drug to the formulations already analyzed by this method. The method was successfully applied to enable estimation of drug in pharmaceutical dosage forms at a lower concentration level (each tablet claiming 10 mg) and complete with other existing assay methods for routine quality control analysis of DMPN in pharmaceutical formulations.

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