UV-Spectrophotometric Estimation of Ranitidine and Domperidone in Tablet Formulations

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A simple, fast, precise multicomponent mode analysis method has been developed for simultaneous estimation of ranitidine and domperidone in tablet formulation. The sampling wavelengths selected for both the drugs were 229 nm, 245 nm, 270 nm, 285 nm, 294 nm on trial-and-error basis using methanol as solvent. The linearity for both the drugs at all the selected wavelengths lies between 3.0 and 50 µg/ml for ranitidine and 0.2 and 3.5 µg/ml for domperidone. The concentrations of both the drugs were evaluated in laboratory mixture and marketed formulation. The recovery study was carried out by standard addition method.

Ranitidine, 1,1-ethenediamine-N-[2[[[5(dimethylamino) methyl]-2-furanyl]methyl]thio] ethyl]-N'-methyl-2-nitro monohydrochloride, is used as H_2 receptor antagonist and is also used in management of ulceration. It is official in IP[1] and USP[2]. Domperidone is white, or almost white, powder; chemically it is 5-chloro-1-[1-[3-(2,3-dihydro-2-oxo-1H-benzimidazole-1-yl) propyle]-4-piperidinyl]-1,3-dihydro-2H-benzimidazole-2-one. It is used as dopamine antagonist and antiemetic drug. It is official in BP[3].

Literature survey revealed that there are many methods like HPLC[4,5], UV[6,7]-spectrophotometric HPTLC[8,9], NMR[10] for individual determination of ranitidine and domperidone. The only method reported for simultaneous estimation of ranitidine and domperidone in their combined dosage form is by HPLC[11]. An attempt was made to develop accurate, precise and economical multicomponent mode analysis method for estimation of both these drug in combined dosage form. The instrument used in present study was double beam UV/Visible spectrophotometer with 10 mm matched quartz cell (Model UV-1601, Shimadzu, Japan).

The solutions of ranitidine (RAN) and domperidone (DOM), each of strength 1 mg/ml, were prepared in methanol. Weighed quantity of DOM equivalent to 25 mg was dissolved in methanol, and volume was made up to 25 ml with methanol. From this solution, 3.0 ml was added to the accurately weighed quantity of RAN equivalent to

50 mg in 100 ml volumetric flask, and then it was dissolved and volume was adjusted to 100 ml. From adjusted stock solution, 10 ml was pipetted in 100 ml volumetric flask and volume was adjusted. The standard solutions were mixed and diluted to get six different concentrations in the ratio of 15:1, as shown in Table 1. The obtained solutions were again diluted (10 µg/ml) and scanned in the range of 220-304 nm. The wavelengths selected were 229 nm, 245 nm, 270 nm, 285 nm and 294 nm. Sampling wavelengths were selected on trial-and-error basis. The concentrations of individual drug were fed to the multicomponent mode of the instrument. The entire six mixed standards were scanned in the range of 220-304 nm. Mixed standard solution of both the drugs was scanned on all the selected wavelengths to study the range of Beer Lambert's range.

Accurately weighed quantity of DOM equivalent to 25 mg was dissolved and volume was made up to 25 ml with methanol. The solution was further diluted with distilled water to obtain a final concentration range of mixed standards. The sample solutions were scanned over the range of 220-304 nm in the multicomponent mode of the instrument, and concentration of each component was obtained by analysis of spectral data of sample solution

TABLE 1: MIXED STANDARDS OF PURE DRUGS

Name of Drugs	Std. 1	Std.2	Std.3	Std.4	Std.5	Std.6
RAN	1.0132	2.064	3.0396	4.0528	5.0660	6.0792
DOM	0.0632	0.1265	0.1898	0.2531	0.3164	0.3796

All the mixtures were prepared in the ratio of 15:1, RAN - Ranitidine, DOM - Domperidone

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with reference to that of six mixed standards, in terms of µg/ml. Twenty tablets were weighed, crushed and mixed thoroughly. Weighed tablet powder equivalent to 50 mg of RAN was taken in 100 ml volumetric flask and dissolved, and volume was adjusted with methanol. From the above prepared solution, final dilution was done as that of sample solution and scanned over the range of 220-304 nm in multicomponent mode of instrument. The accuracy of proposed method was ascertained by carrying out recovery studies by standard addition method. The recovery study was performed to determine if there was positive or negative interference from excipients present in the formulation. The method was ascertained on the basis of recovery study by standard addition method applied to reanalyzed sample.

The multicomponent mode method was developed for estimation of RAN and DOM in their combined tablet dosage form. DOM was standardized by official method reported in British Pharmacopoeia, and the purity of the sample was found to be 99.80%. The purity of RAN was considered as supplied by M/s Cadila Pharmaceuticals Ltd., viz., 99.92%.

The scanning range selected was on the basis that both the drugs show maximum absorbance. The sampling wavelengths were selected on trial-and-error basis. The wavelengths selected were 229 nm, 245 nm, 270 nm, 285 nm and 294 nm. The concentrations of individual drug were fed to the multicomponent mode of the instrument. The entire six mixed standards were scanned in the range of 220-304 nm.

The linearity curve response for both the drugs was obtained to study Beer Lambert's range. RAN and DOM in mixture have shown linearity response over the range of 3.0-50.0 µg/ml for RAN and 0.2-3.5 µg/ml for DOM at all the selected wavelengths. The percent estimation of drug in laboratory mixture with ±S.D. was found to be 100.01±0.64 and 99.78±1.45 for RAN and DOM respectively. The percent drug estimation in marketed formulation ±S.D. was found to be 99.98±0.47 and 99.96±0.612. The accuracy of the proposed method

was evaluated by percentage recovery (by standard addition method) of both the drugs. The average recovery was found to be 100.31±0.24 and 100.62±0.90. The results of the method lie within the prescribed limit of 98-102%, showing that method is free from interference from excipients. The obtained results for the multicomponent mode method for simultaneous estimation of ranitidine and domperidone indicate the accuracy and reproducibility of the method and hence can be used for routine analysis of commercially available drugs.

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