



Received on 24 November, 2011; received in revised form 14 January, 2012; accepted 21 March, 2012

## DEVELOPMENT OF NEW ANALYTICAL METHODS FOR QUANTITATIVE ESTIMATION OF RACECADOTRIL AS AN ACTIVE PHARMACEUTICAL INGREDIENT BY UV SPECTROPHOTOMETER

Pintoo Tank\*, Aarti Zanwar, A.K. Seth and Sharad Kumar

Department of Pharmacy, Sumandeep Vidyapeeth, Vadodara- 391 760, Gujarat, India

### Keywords:

Racecadotril,  
Racecadotril tablet formulation,  
Methanol,  
Shimadzu UV-1700 UV/VIS  
Spectrophotometer

### Correspondence to Author:

#### Pintoo Tank

Department of Pharmacy, Sumandeep  
Vidyapeeth, Vadodara- 391 760, Gujarat,  
India

### ABSTRACT

A simple and sensitive spectroscopic method was developed for the estimation of Racecadotril in pharmaceutical dosage forms. This method is based on Racecadotril, showing absorbance at 231 nm in methanol. This method obeys Beers law in the concentration range of 8 to 100  $\mu\text{g mL}^{-1}$  respectively. The proposed method is precise, accurate and reproducible and can be extended to the analysis of Racecadotril in bulk and tablet formulations. The method was linear ( $r=0.9998$ ) at concentrations ranging from 8 to 100  $\mu\text{g mL}^{-1}$ , precise (repeatability and intermediated precision), exact (method of standard addition), and Limit of detection  $\mu\text{g mL}^{-1}$  (0.088749). Limit of quantification  $\mu\text{g mL}^{-1}$  (0.268938) was found and the % recovery is found 99.69%.

**INTRODUCTION:** Analytical methods are required to characterize drug substances and drug products composition during all phases of pharmaceutical development. Development of methods to achieve the final goal of ensuring the quality of drug substances and drug products must be implemented in conjunction with an understanding of the chemical behaviors and physicochemical properties of the drug substance. This determination requires highly sophisticated methods and instruments like Spectrophotometer.

Racecadotril (N- [2- [(Acetylthio)methyl]- 1- oxo- 3- phenylpropyl] -glycine phenylmethyl ester) it contain white crystalline powder. Racecadotril soluble in methanol, ethanol and acetonitrile. Racecadotril is an anti diarrheal drug, acts by inhibition of enkephalinase, this produces an increases in the levels of enkephalins that act in the enterocyte, thus inhibits hypersecretion. Racecadotril is used in the treatment of acute water diarrhea in children and adults.

Racecadotril is an antidiarrheal drug which acts as a peripherally acting enkephalinase inhibitor. Unlike other medications used to treat diarrhea, which reduce intestinal motility, racecadotril has an antisecretory effect- it reduces the secretion of water and electrolytes into the intestine.

### MATERIALS AND METHODS:

**Instrument:** A Shimadzu UV-1700 UV/VIS Spectrophotometer was used with 1 cm matches quartz cell.

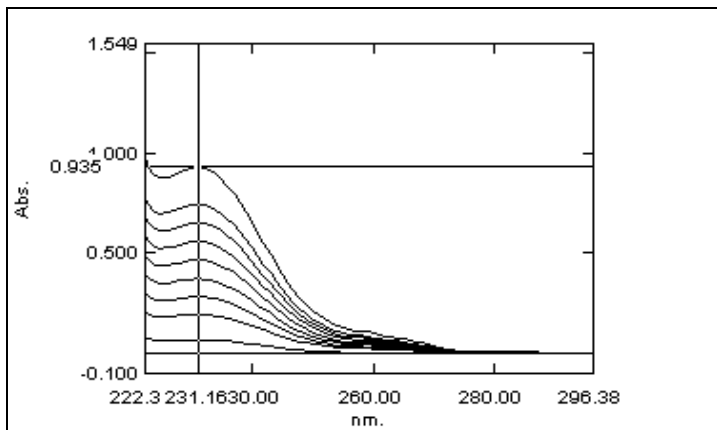
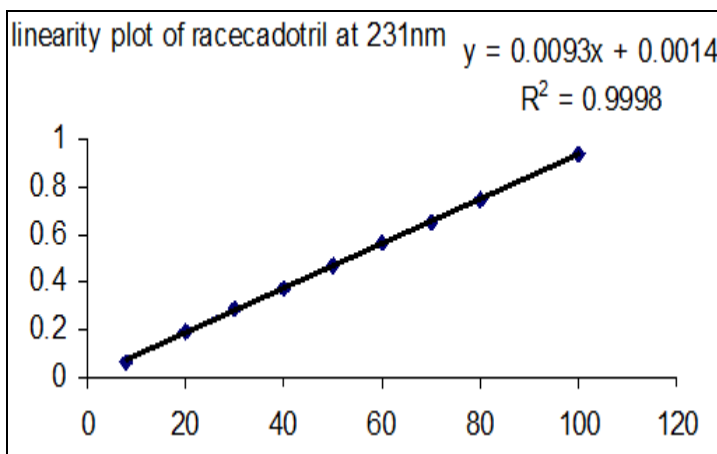
### Materials:

1. Racecadotril: Working standard grade was supplied by Cadila Healthcare Limited (Ahmedabad, India) and its claimed purity was 100.0%
2. Drug products of racecadotril (label claim 10 mg ) and placebo (Batch No- 8+50/ F002) were manufactured and supplied by Cadila Healthcare Limited (Ahmedabad, India).

**Solvent used:** Methanol

**Preparation of Standard Solution:** It was used stock solutions of  $1\text{ mg mL}^{-1}$  Racecadotril in mixture of methanol. The working solution of  $0.1\text{ mg mL}^{-1}$  prepared by transferring 5mL from respective stock solution to a 50 mL volumetric flask and completing to volume with the mixture of methanol.

**Preparation of Pharmaceutical Sample Solution:** A total of powder from 10 sachets was accurately weighed and an amount equivalent to 100mg was taken and dissolved in 60 ml of methanol and sonicate for five minutes. About 10 ml of methanol was added and sonicate for another 5 minutes. The mixture was shaken well for 2 minutes and transferred to a 100ml volumetric flask through  $0.45\mu$  nylon membrane filter. The residue was washed thrice with 10ml methanol and the combined filtrate was made up to the mark with methanol. The sample solution thus prepared was diluted.

**RESULT AND DISCUSSION:****SPECTRUM OF RACECADOTRIL AT 231nm****LINEARITY PLOT FOR RACECADOTRIL AT 231nm****Analysis of Tablet Formulation of Racecadotril**

Tablet	Label claimed (mg)	Conc. found (mg)	%Recovery $\pm$ SD
REDOTIL	10	9.98	99.69 $\pm$ 0.909

**Calibration parameters:**

Parameter	Results
Absorption Maxima (nm)	231
Beer's Law limits ( $\mu\text{g/ml}$ )	8-100
Molar extinction coefficient ( $\text{mole}^{-1}\text{cm}^{-1}$ )	0.009275
Sandell's sensitivity ( $\mu\text{g/cm}^2/0.001$ absorbance units)	0.0927921
Regression equation (y)*	0.9998
Slope (b)	0.0093
Intercept (a)	0.0014
Coefficient of variance	0.9111333
Standard deviation **	0.00334
Limit of detection $\mu\text{g ml}^{-1}$	0.088749
Limit of quantification $\mu\text{g ml}^{-1}$	0.268938

**CONCLUSION:** For routine analytical purpose, it is always necessary to establish methods capable of analysing huge number of samples in a short time period with due accuracy and precision. Spectrophotometer technique coupled with multivariate algorithms can generate large amount of quality data which serve as highly powerful and convenient analytical tool. Furthermore, the proposed methods did not require the elaborate treatment and procedures, which are usually associated with Spectrophotometer methods. Hence they are generally fast and economical in comparison to the more time-consuming Spectrophotometer techniques, often used for the assay of formulations.

**ACKNOWLEDGEMENTS:** The authors are thankful to the Principal Dr. A. K. Seth, Department of Pharmacy, Sumandeep Vidyapeeth, Pipariya, Taluka- Waghodiya, Dist. Vadodara, Gujarat for providing necessary facilities and Racecadotril Working standard grade was supplied by Cadila Healthcare Limited (Ahmedabad, India) and its claimed purity was 100.0% We are also thankful to Mrs. Aarti zanwar for his moral support and guidance.

**REFERENCES:**

- Sharma BK: Introduction for analytical chemistry. In, Instrumental Methods of Chemical Analysis, 7<sup>th</sup> edition. Meerut, Goel Publishing House 2000;1-2.

2. Fifield FW: Introduction to analytical chemistry. In, Principle and practice of analytical chemistry, 5<sup>th</sup> edition. Australia, Black science pvt. ltd 2000; 1-6.
3. Indian pharmacopoeia: The Indian pharmacopoeia commission, Govt of India ministry of health and family welfare, Ghaziabad 1996; 2: A-169.
4. Skoog, Holler, Nieman. introduction to validation: In, Principals of Instrumental Analysis, 5<sup>th</sup> Edition. U.S.A. Harcourt Publishers International Company 2001; 56-9.
5. United States Pharmacopoeia (USP-NF XXIV): Rockville MD 20852, United States Pharmacopoeia Convention Inc 1985; 2149-51.
6. Gulhati CM: Monthly index of medical specialties (MIMS) India. New Delhi, Mims India publication 2004; 24:98.
7. Reddy K, Babu J, Sudhakar P, Sharma M, Reddy G, Vyas K: Structural studies of racecadotril and its process impurities by NMR and mass spectroscopy Pharmazie 2006;61(12): 994-8.
8. Xu F, Yang L, Xu G: A rapid and validated HPLC method to quantify racecadotril metabolite, thiorphan, in human plasma using solid-phase extraction. J Chromatogr B Analyt Technol Biomed Life Sci 2007;861(1): 130-5.
9. Xu Y, Huang J, Liu F, Gao S, Guo Q: Quantitative analysis of racecadotril metabolite in human plasma using a liquid chromatography/tandem mass spectrometry. J Chromatogr B Analyt Technol Biomed Life Sci 2007;852(1- 2): 101-7.
10. Dinesh, A S, prashant S.L: Determination of racecadotril by HPLC in capsules. Ind.j.pharma.chem 2007;69(6): 819-21.
11. Rao PS, Nappinnai M: UV and RP-HPLC Estimation of Racecadotril. Asian Journal of Chemistry 2007;19(5): 3697-702.
12. Vetrichelvan T, S.Prabakaran: New spectrophotometric methods for the determination of racecadotril in bulk drug and capsules. Indian Journal of Pharmaceutical Sciences 2007;69(2): 307-9.

\*\*\*\*\*