DEVELOPMENT AND VALIDATION OF ANALYTICAL METHODS FOR SIMULTANEOUS ESTIMATION OF OFLOXACIN AND FLAVOXATE HCL IN BULK AND ITS TABLET DOSAGE FORM

By

MODI HARDIKKUMAR KISHORBHAI Enrollment No.112140813022

Guide:

Dr. Priyanka Patil M.Pharm, Ph.D Assistant Professor **Industrial guide:**

Mr.Hemant Mehta Q.C.Manager, Vapi Care Pharma Pvt.Ltd

A Thesis Submitted to
"Gujarat Technological University"
In partial fulfillment of the requirements for the degree of
"Master of Pharmacy"
In Quality Assurance Techniques

May-2013



PIPR

Parul Institute of Pharmacy and Research
Parul Trust
Limda, Ta. Waghodia, Dist. Vadodara

ABSTRACT

A rapid, sensitive, and specific RP-HPLC and UV Spectroscopy Method was

developed and validated for simultaneous estimation of Ofloxacin and Flavoxate HCl

in bulk and tablet dosage form. Spectrophotometric (Simultaneous Equation Method)

and RP-HPLC were developed and validated in terms of linearity, precision, accuracy,

LOD and LOQ for the simultaneous estimation of Ofloxacin and Flavoxate HCl.

In Simultaneous Equation Method the linearity range was found to be 5-30 µg/ml

for both the drugs. Percentage recovery for Ofloxacin was found to be in range of

99.85-101.60%, while for Flavoxate HCl, it was found to be in range of 100.40-

101.66%. LOD and LOQ values were found to be 0.78 and 2.37µg/ml for Ofloxacin

and 0.99 and 3.00 µg/ml for Flavoxate HCl.

RP-HPLC method was carried out on Kromasil C18(250 x 4.6mm,i.d 5μ) column

using filtered and degassed mixture of ACN: Methanol: water (30:20:50 v/v) pH 3

adjusted with 0.1% TEA and ortho-phosphoric Acid as a mobile phase at a flow rate

1ml/min and effluent was monitored at 322nm. Linearity range was found to be 10-

60μg/ml for Ofloxacin and 10-60μg/ml for Flavoxate HCl. Percentage recovery for

Ofloxacin was found to be in range of 99.18-99.37%, while for Flavoxate HCl, it was

found to be in range of 99.33-100.08%. LOD and LOQ values were found to be 0.59

and 1.79 µg/ml for Ofloxacin and 0.90 and 2.74 µg/ml for Flavoxate HCl.

Key word: UV Spectrophotometry, RP-HPLC, Ofloxacin, Flavoxate HCl

xiv