CHAPTER - 3

AIM OF PRESENT WORK
3. **Aim of Present Work**

Gatifloxacin is an extended spectrum 8-methoxy fluoroquinolone antibacterial agent and is not official in any pharmacopeia. It has an improved profile for therapy of infection caused by both Gram-positive and Gram-negative and anaerobic species, based on the inhibition of both DNA gyrase and topoisomerase IV.

Analytical methods reported for determination of gatifloxacin in pure form and in its dosage form includes HPLC, spectrophotometric, spectrofluorimetric methods and methods for determination of gatifloxacin in biological fluids include HPLC, fluorimetric and mass-spectrometry.

Omidazole is a nitroimidazole, antiprotozoal and antibacterial agent having excellent activity against anaerobic microorganisms. Analytical methods reported for determination of omidazole in pure form and in its dosage form includes HPLC, spectrophotometric methods and methods for determination of Omidazole in biological fluids include HPLC and GC. An analytical method reported for simultaneous estimation of omidazole and a fluoroquinolone derivative includes RP-HPLC and spectrophotometric.

Methods of analysis based on UV-visible spectrophotometry are simple and useful for the routine analysis of the drug formulation in industry. Therefore, it was thought of interest to develop and validate UV-visible spectrophotometry and HPTLC method for the analysis of marketed tablet dosage form of plain gatifloxacin and in its combination with omidazole.

The application of developed and validated HPTLC method was extended to estimate gatifloxacin in human urine. The developed HPTLC and spectrophotometric method were compared.
Urine provides a non-invasive sample collection method and the
determination of drug levels in urine is comparatively less complex.
Since a considerable amount of gatifloxacin (70-80%) excreted
unchanged in urine, therefore the application of developed HPTLC
method for gatifloxacin was extended to estimate the gatifloxacin in
urine. The developed method in urine was used also to obtain the
urinary excretion data after the administration of gatifloxacin tablet
to six healthy human volunteers. The obtained data was used to
study the pharmacokinetics of gatifloxacin.

The quality control parameters e.g. disintegration test, dissolution
test, hardness test, tensile strength etc., were also evaluated for
tablet formulation.

**Objectives of present work**

➤ To develop and validate spectrophotometric method for the
estimation of gatifloxacin in bulk powder and tablet dosage
form.

➤ To apply developed spectrophotometric method for the study of
release pattern of gatifloxacin from conventional dosage form.

➤ To develop and validate HPTLC method for estimation of
gatifloxacin in tablet formulation.

➤ To develop and validate HPTLC method for the simultaneous
estimation of gatifloxacin and ornidazole in combined dosage
form.

➤ To develop and validate HPTLC method for estimation of
gatifloxacin in human urine.

➤ To apply the developed method for estimation of gatifloxacin in
human volunteers after administration of gatifloxacin tablets
(400mg) and determine pharmacokinetic parameters.