**English summary for the master thesis**

**Establishing Stability Indicating Methods for Analysis of Some Nitrogen Containing Drugs and Stability Studying of These Drugs**

The objects of the thesis were to develop simple, accurate and selective stability indicating methods for the quantitative determination of the drugs:

a)- Omeprazole (OPZ): anti-peptic ulcer.

b)- Meloxicam (MXC): non steroidal anti-inflammatory (NSAID) .

some of the suggested methods were used in the kinetic studies of the mentioned drugs according to the conditions specified by FDA guideline.

The thesis comprised six parts

**Part I**

It contained general introduction as follow:

1. The importance of studying the stability of the drugs, generally.
2. Illustration of the international documents used in stability testing of the drugs and method validation.
3. Common causes of the chemical degradation of the drugs.
4. Solution kinetics.
5. Techniques used as stability indicating methods.

**Part II**

It comprised establishment of **stability indicating methods** for determination of OPZ and MXC in a buffer solution (pH=7.5) and in 0.1N H2SO4 aqueous solution, frequently, in presence of **the acid induced degradation products** and using these methods in **studying the stability** of the mentioned drugs in **low pHs media**, in **studying the effect of the heat on the reaction rate and in calculation of the activation energy**.

1. D1RS for determination of OPZ was established. The measurement was at λmax 265nm. The recovery % was 100 ± 1.6.
2. D2R and D3R for determination of MXC were established. The measurement were at λmax 326.5and 423nm, frequently. The recoveries % were 100.13 ± 0.63 and 99.9 ± 0.74, frequently.

**Part** **III**

It comprise establishment of **stability indicating methods** for determination of OPZ in presence the **acid induced degradation products** by three different methods as follow:

1. HPLC: The conditions were C18, methanol, deionized water, triethylamine and phosphoric acid by the ratio (770:330: 5: 0.8 v/v/v/v) and UV detection at 302nm (\*). The recovery % was 100.55 ± 1.63.
2. TLC: The conditions were silica gel F254 , ammonia solution 25% and water by the ratio (1: 15 v/v) saturated with n-butanol and UV detection at 280nm (#). The recovery % was 100.41 ± 1.76.
3. D2R and D3R: The measurement were at λmax (310 & 330nm) and (319.5 & 335nm), frequently. The recoveries % were 99.98 ± 0.40, 99.99 ± 0.21, 100.10 ± 0.40 and 99.94 ± 0.34, frequently.

**Part IV**

It comprised establishment of **stability indicating methods** for determination of OPZ and MXC in presence of the **oxygen induced degradation products** and using these methods in **studying the stability** of the mentioned drugs in **oxygenated solution (3% O2) and in studying the effect of the heat and** **pH on the reaction rate.**

1. D3R for determination of OPZ was established. The measurement was at λmax 263nm. The recovery % was 99.94 ± 0.39.
2. D1R for determination of MXC was established. The measurement was at λmax 394.55nm. The recovery % was 100.36 ± 0.39.
3. TLC for determination of MXC. The conditions were silica gel F254 , ethyl acetate, methanol and ammonia solution 25% by the ratio (8.5: 1: 0.5 v/v/v) and UV detection at 320nm (+). The recovery % was 99.80 ± 1.80.

**Part V**

It comprised establishment of **stability indicating methods** for determination of OPZ and MXC in presence of the light induced degradation products and using these methods in **studying the stability of the** mentioned drugs when exposed to **UV radiation**) and in **studying the effect of the oxygen and pH on the reaction rate.**

1. D2R for determination of OPZ was established. The measurement was at λmax 330nm. The recovery % was 100.09 ± 0.53.
2. D2R for determination of MXC was established. The measurement was at λmax 415nm. The recovery % was 99.67 ± 0.83.

**Part VI**

It comprised establishment of **stability indicating methods** for determination of OPZ and MXC in presence of the **UV induced degradation products.**

1. TLC for determination of MXC. Under the conditions (+). The recovery % was 100.53 ± 0.41.
2. TLC for determination of OPZ. Under the conditions (#). The recovery % was 99.99 ± 0.78.
3. HPLC for determination of OPZ. Under the conditions (\*). The recovery % was 100.19 ± 0.22.
4. D1RS for determination of OPZ was established. The measurement was at λmax 309.5nm. The recovery % was 100.60 ± 0.43.

*the statistical comparisons and the statistical analysis of the data were applied. These statistical studies were illustrated in 40 tables. These proved that the suggested methods are applicable for determination of the mentioned drugs in presence of their different types of degradation products and in their pharmaceutical products, separately*.

**The thesis comprised 76 figures, 40 tables and 182 references and finished by Arabic summary.**