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A REVIEW ON DIFFERENT ANALYTICAL METHODS FOR THE ESTIMATION OF RABEPRAZOLE SODIUM

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ABSTRACT

Proton pump inhibitors like Rabeprazole Sodium are used to treat peptic ulcer disease by reducing the amount of acid in which the stomach secretes**.** Statistical design of experiments was used to optimize the chromatographic separation of pharmaceutical compounds from their respective potential impurities. A fractional factorial design was used to investigate the effects of pH, organic solvents in mobile phases and flow rate of the rabeprazole. A desirability function applied to the optimized conditions predicted a peak separation of 2.2 to 2.7 for the rabeprazole. The chromatographic procedure used as an acquity UPLC, BEH C18 column (100 x 2.1 mm ID, 1.7 µm particle size) with a mobile phase gradient program consisting of phosphate buffer, pH 6.5, and acetonitrile. The injection volume was 5 µl and the detection wavelength was 254 nm. The chromatographic method has been validated according to ICH guidelines. The results clearly demonstrate that quantification of the drug which is effectively applied to reduce the number of trials and to optimize the UPLC chromatography process with error-free experiments.

Key words:

Rabeprazole, Proton-pump inhibitor, UV–spectroscopy, RP-HPLC, UPLC, HPTLC.

Introduction:

Rabeprazole is chemically 2-[[[[4-(3-methoxypropoxy)-3-methyl-2-pyridinyl]-methyl] sulfinyl]]. By specifically inhibiting the gastric H, K ATPase enzyme system at the secretory surface of the gastric parietal cell, the proton-pump inhibitor-1H-benzimidazole reduces gastric acid secretion. (AlaaEl-Gindya,2003). Acid-peptic illnesses such duodenal, gastric, and oesophageal ulcers are treated with rabeprazole (A. Radia,2003). Additionally, it helps with disorders like Zollinger-Ellison syndrome that cause excessive stomach acid production (p. pattayak,2007). According to reports, rabeprazole's oral pharmacokinetics after a single dose is linear between 10.0 and 80.0mg. The reported maximum plasma concentration time point ranged from 2.9 to 3.8 hours and was dosage independent. After a single daily dose of 20.0 mg and a multiple dose of 40.0 mg, rabeprazole's pharmacokinetics was largely comparable. About 96.3% of plasma proteins were bound. Hepatic metabolism and renal excretion both quickly eliminated rabeprazole from the body. The oral clearance of rabeprazole ranged from 0.26 to 0.5 L/h/kg and was dosage independent. Its elimination half-life was around 1.0 h. Human Cytochrome P450 enzymes CYP2C19 and CYP3A4 metabolise rabeprazole to produce dimethyl

and sulfone metabolites. The main metabolite is a molecule called thio-ether carboxylic acid (sonusudd singh,2004)

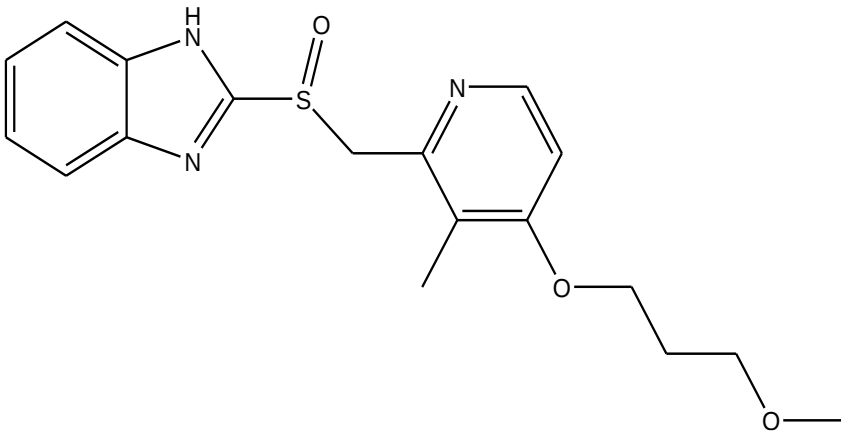

Fig.1 chemical structure of Rabeprazole

Methods for Rabeprazole:

UV Spectroscopic methods:

Various methods for the estimation of Rabeprazole in single and in combination with other drugs by UV spectroscopic methods developed which are enlisted in **Table-1**

Table-1: Methods for the estimation of Rabeprazole in single and combination with other drugs by UV-Spectroscopy:

S.no.	Drug	Application	Description
1.	Domperidone And Rabeprazole	Bulk dosage form	**Detection wavelength**: Domperidone:253.2nm Rabeprazole:266.4nm **Solvent**: Methanol **Linearity range:** Domperidone:9-45µg/ml Rabeprazole:6-30µg/ml co**orrelation coefficient**: Domperidone:0.9993 Rabeprazole:0.9995
	Amoxicillin And Rabeprazole	Combined dosage form	**Detection wavelength**: Amoxycillin:247nm Rabeprazole:292nm **Correlation coefficient**: Amoxycillin:o.9998 Rabeprazole:0.9999 **Wavelength accuracy:** ±0.5nm

3.	Paracetmol Aceclofenac Rabeprazole	Combined dosage form	**Wavelength detection**: Paracetmol:249nm Acelofenac:276nm Rabeprazole:284nm **Solvent**: Methanol. **Linearity range**: Paracetmol:3-30µg/ml Aceclofenac:2-20µg/ml Rabeprazole:2-20µg/ml.

Chromatographic methods:

Various chromatographic methods which include HPLC, UPLC, and HPTLC were developed for the estimation of rabeprazole in single and in combination with other drugs. Methods for the estimation of rabeprazole in single and in combination with other drugs which are enlisted in **table -2**

Table: 2 Methods for the estimation of Rabeprazole in single and combination with other drugs by RP-HPLC method.

S. No	Drug	Application	Description
1.	Rabeprazole	Tablet dosage form	**Column**:RP-C_{18} **Mobile phase:** Methanol and water in the ratio of 65:35(v/v) **Mode:** Isocratic mode **Detection wavelength**:284nm **Flow rate**:0.8mL/min **Correlation coefficient:**0.9999
2.	Rabeprazole sodium and acelofenac	Combined dosage form	**Column:** Pursit C_{18} **Mobile phase:** Methanol: Acetonitrile: Water (60:10:30 v/v/v) **Flow rate:**1.0ml/min **Detection wavelength**:280nm **Retention time:** For Rabeprazole 5.611 min. For acelofenac 2.102 min **Linearity range:** For Rabeprazole1-10µg/ml, For acelofenac:3-15µg/ml
4.	Paracetmol, Acelofenac Rabeprazole	Bulk and combined tablet dosage form	**Column:** Agilent CN column **Mobile phase**: Ammonium acetate buffer and Acetonitrile in the ratio of 70:30 (v/v). **Detection wavelength:**213nm **Retention time:** paracetmol:3.678 Acelofenac 5.556 Rabeprazole:9.572 min **Flow rate:**1.0 ml/min

Table-3: Methods for the estimation of Rabeprazole in single and in combination with other drugs by using UPLC:

S.no	Drug	Application	Description
1.	Rabeprazole	Pharmaceutical formulation	**Column:** A waters symmetry C_{18} column **Mobile phase**: Phosphate buffer and Acetonitrile in the ratio of 65:35 (v/v) **Flow rate**:0.4 ml/min **Injection volume**:20µl **Detection wavelength**:280nm **%RSD:,**1.5%
2.	Rabeprazole sodium and mesapride citrate	Tablet dosage form	**Column:**C_{18} Column **Mobile phase:** Ammonium acetate buffer: Acetonitrile (60:40%v/v) **Flow rate:**0.4ml/min **Wavelength detection**:270nm **Injection volume**:2µl **Linearity range**:60-300µg/ml
5.	Rabeprazole sodium and itopride hydrochloride.	Capsule formulation	**Column:** C_{18} **Mobile phase:** Acetonitrile, phosphate buffer (35:65v/v) **$P^{H:}$**7.0 **Flow rate**: 1.0mL/min. **Detection wavelength**:276nm **Retention time:** Rabepreazole:8.76min Itopride hydrochloride:4.22 min
6.	Rabeprazole Pantoprazole Itopride	Combined dosage form	**Column:** C_{18} Guard column **Mobile phase:** Potassium dihydrogen phosphate: Acetonitrile 70:30 (v/v) **Flow rate**: Rabeprazole:0.9ml/min Pantaprazole:1.0ml/min Itopride:1.1ml/min **Wavelength detection**: Rabeprazole:285nm Pantaprazole:288nm Itopride:290nm **Retention time:** Rabeprazole:5.35 Pantaprazole:7.92 Itopride:11.16 min **Injection volume:** For Rabeprazole:10µl For Pantaprazole:20µl For Itopride:30µl

Table-4: Methods for the estimation of Rabeprazole in single and in combination with other drugs by using HPTLC:

S. No	Drug	Application	Description
1.	Rabeprazole and itopride hydrochloride	Combined dosage form	**Mobile phase**: n-butanol, toluene, ammonia (8.5:0.5:1v/v/v) **Detection Spot**:288nm **Retardation factor**: For rabeprazole0.23 For itopride hydrochloride:0.750 **Correlation coefficient**: For rabeprazole 0.99848 Itopride hydrochloride:0.99030 **TLC plate**: pre coated silica gelG60F254
2.	Rabeprazole and itopride hydrochloride	Tablet dosage form	**Mobile phase**: Ethyl acetate: Methanol: Ammonia (8.5:1.0:0.5v/v) **TLC plate**: Pre coated plate of silica gel $60F_{254}$. **Detection Spot**:285nm **Correlation coefficient:** For rabeprazole :0.9999 For itopride hydrochloride:0.9954 **Linearity range**: For rabeprazole 10-50 ng/spot For itopride hydrochloride: 75-375 ng/spot
3.	Rabeprazole and Domperidone	capsules	**Mobile phase**: Ethyl Acetate-methanol-benzene-Acetonitrile (30:20:30:20v/v) **Detection Spot**:287nm **TLC plate**:$60F_{254}$ **Correlation coefficient**: For rabeprazole 0.993, For domperidone:0.990
4.	Domperidone and Rabeprazole	Combined solid dosage form	**Mobile phase**: Toluene: methanol (9:1v/v) **Detection spot**:287nm TLC plate:60 F_{254} **Concentration range:** For domperidone 60-300 ng/spot, for rabeprazole 40-200 ng/spot. **Correlation coefficient**: For Domperidone :0.996 For Rabeprazole :0.9998

CONCLUSION:

Proton pump inhibitors (PPIs), mainly rabeprazole, significantly reduce stomach acid and are used to treat peptic ulcers, H. Pylori, Zollinger-Ellison syndrome, GERD, etc. This review discussed the methods for quantitative estimation by visible UV spectroscopy, detection of RP-HPLC and UPLC in their single or combined formulation. It can be concluded that most of the proven methods are simple, fast, reproducible, and economical. All HPLC and UPLC methods are reverse phase Chromatography with UV detection, and many spectrophotometric methods work by reacting with reagents or developing colours. This method is reliable and can be useful for rapid estimates in industries during in-process quality control testing.

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