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ORIGINAL ARTICLE **OPEN ACCESS**

Preformulation Analysis of Roxatidine Acetate to Establish a Stable, Robust and Therapeutically Effective Gastroretentive Dosage Form

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ABSTRACT

The primary objective of this research study was to perform a preformulation analysis of Roxatidine acetate to establish a stable, robust and therapeutically effective system. Preformulation studies of Roxatidine acetate was determine using Organoleptic properties, Determination of solubility, Melting point, FTIR Spectroscopy, Differential scanning calorimetry studies, Physical compatibility test , UV Spectroscopy (Determination of λ max) and HPLC analytical method. Standard UV curve was developed to aid in further analytical research studies. The preformulation evaluation studies of Roxatidine acetate yielded positive results, indicating that the drug possessed favorable feture such as Organoleptic properties, solubility, melting point, and Physical compatibility with drug. The drug's purity was verified through infrared spectrum analysis, and UV Spectroscopy, the λ max of Roxatidine acetate was found to be at 254 nm. The standard curve obtained was linear, with a correlation coefficient (R2 =0.999) and equation y = 0.004208x + 0.001416. No drug excipient interactions were observed, as there were no visual changes in drug samples with respect to discoloration, liquefaction, or odor. Finally, the HPLC data indicated that Roxatidine acetate was suitable for oral dosage form. Roxatidine acetate was found to be suitable drug candidate that possesses favorable properties for the development of an in-situ gel formulation. The selected numerous all factors indicated that the drug is stable and can be used for further research and development purposes.

KEYWORDS: *Preformulation, Roxatidine acetate, Drug characterization, Drug-excipients compatibility studies.*

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INTRODUCTION

Preformulation testing is designed to judge the influence of physicochemical properties of drug substances and excipients on formulation properties of dosage form, method of manufacture and pharmacokinetic biopharmaceutical properties of the resulting product. Preformulation studies help us to determine compatibility of API (new drug entity) with common excipients2. It guides formulator to choose correct form of a drug substance and to improve bioavailability3. It assists to gather complete knowledge of new drug entity. It also aids in determining the method of storage of formulation. Finally we can say preformulation studies will assists us in developing safe, effective and stable dosage form [1].

Roxatidine acetate is a specific and competitive H_2 receptor antagonist. It is a member of piperidines that is used to treat gastric ulcers, Zollinger–Ellison syndrome, erosive esophagitis, gastro-oesophageal reflux disease, and gastritis. Pharmacodynamic studies showed that 150 mg of Roxatidine acetate were optimal in suppressing gastric acid secretion, and that a single bedtime dose of 150 mg was more effective than a dose of 75 mg twice daily in terms of inhibiting nocturnal acid secretion.

It is a special H_2-receptor antagonist, prescribed for reflux esophagitis, benign gastric ulcer, duodenal ulcer and prophylaxis of recurrent ulcers. As a result, the production and secretion, particularly of gastric acid, are reduced.

Roxatidine acetate belongs to BCS class III drug which has half life 5-7 hrs [2]. Objective of the project was to conduct preformulation study of Roxatidine acetate in order to development of a stable, robust as well as the therapeutically effective and safe dosage form of Roxatidine acetate 6.

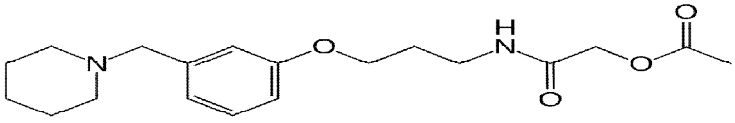

Figure:1. Structure of Roxatidine acetate

Preliminary data also suggest that Roxatidine acetate may be useful in the treatment of reflux oesophagitis and stomal ulcer, and in the prevention of pulmonary acid aspiration [3]. Roxatidine acetate is an H2-receptor antagonist which has been well tolerated in clinical trials. In order to achieve this objective characterization of Roxatidine acetate was done by finding out Organoleptic properties, Melting point, FTIR Spectroscopy, Differential scanning calorimetry, Physical compatibility test , Determination of solubility was determined. Infrared spectrum was done to determine purity of drug 8 and UV Spectroscopy (Determination of λ max) was developed which will help in further analytical studies. It was carried out to calculate assay compensation. Finally drug-excipients compatibility studies were carried out to rule out any drug excipient interactions with FTIR .

MATERIAL AND METHODOLOGY:

Roxatidine acetate was purchased from Cipla Limited Mumbai and all other chemicals and reagents were analytical garde [4].

1. Organoleptic properties

The sample of Roxatidine acetate was studied for organoleptic characters such as color, odor and appearance.

2. Melting point

The melting point of Roxatidine acetate was determined by using digital melting point apparatus. the drug was taken in a glass capillary one end was sealed by flame. The capillary containing drug was dipped in liquid paraffin inside the m.p apparatus which was equipped with magnetic stirring facility.The melting temperature was noted down from the digital display meter after the complete melting of drug.

3. FTIR Spectroscopy

The dry sample of Roxatidine acetate was mixed with IR grade KBr in the ratio of 1:100. This mixture was compressed in form of a pellet by applying 10 tons of pressure in hydraulic press. The pellets were scanned over wave number range of 4000 to 400 cm^{-1}. FTIR instrument and spectral analysis was done.

4. Differential scanning calorimetry studies

Thermal analysis was performed using Mettler Toledo DSC-912 system with a differential scanning calorimeter equipped with a computerized data station. The sample of pure drug, physical mixture of drug and polymer and mixture of polymers was weighed and heated at a scanning rate of 10°C/min between 40 and 200°C and 40 ml/min of nitrogen flow. The differential scanning calorimetry analysis gives an idea about the interaction of various materials at different temperature.

5. Physical compatibility test

Preformulation study was carried out with potential normal polymers to determine drug-polymer interaction/compatibility. Chitosan and *Vinga mungo* were uniformly mixed in 1:1 ratio with Roxatidine acetate. The mixture was placed in glass vials which were kept at room temperature. After 15 days samples were subjected to infrared spectroscopy and differential scanning calorimetry as described above for compatibility testing.

6. Determination of solubility

Solubility of Roxatidine acetate was determined in 0.1 N HCl, pH 4.6 acetate buffer and pH 6.8 phosphate buffer solutions. All media were prepared and excess amount of Roxatidine acetate was added to 25 ml of each medium placed in the 50 ml conical flask and kept for shaking on mechanical shaker for 48 h. After 48 h of shaking, 1 ml of aliquot was taken out from each sample and filtered through Wattman filter paper No 41. Absorbances were measured in the range of 200-400 nm on UV Visible Spectrophotometer and calculations for solubility were done.

7. UV Spectroscopy (Determination of λ max)

Stock solution (300µg/ml) of Roxatidine acetate was prepared in 0.1 HCL. This solution was appropriately diluted with 0.1 N HCl separately to obtain a concentration of 100 µg/ml Roxatidine acetate in 0.1 N HCl and water respectively. The UV spectrum was scanned and the range of 200-400 nm on UV Visible Spectrophotometer.the λ max of Roxatidine acetate was noted down .

8. Calibration curve of Roxatidine acetate in 0.1 N HCl.

Roxatidine acetate (30 mg) was accurately weighed and transferred to 100 ml volumetric flask. It was dissolved in 25 ml 0.1 N HCl and diluted. The above made solution was further diluted to obtain concentration ranging from 30-210 µg/ml. The absorbance of the resulting solutions was recorded at 280 nm using UV Visible Spectrophotometer. HCl (0.1N) was taken as a blank. Calibration plots were constructed and the linearity was established. Calibration curve was performed in triplicate.

9. HPLC analytical method [4-5].

A-Selection of mobile phase

The criteria employed for assessing the suitability of a particular solvent system for the analysis like cost, time required for analysis, sensitivity of the assay and solvent noise for the analysis of Roxatidine acetate.

The mobile phase consisted of 0.1M ammonium acetate buffer (pH 7.5): methanol (76:24 v/v).Ammonium acetate buffer and methanol were previously filtered under vacuum through 0.22 µm membrane filters and degassed by using sonicator before injection into the HPLC apparatus.

B-Preparation of standard stock solutions

Standard stock solution (1000 µg/ml) of Roxatidine acetate was prepared by dissolving 50 mg in 20 ml of mobile phase with shaking and volume was made up to the mark of 50 ml with the mobile phase. The stock solutions were degassed by using sonicator and filtered through a 0.22 µm membrane filter.

C-Chromatographic conditions

The chromatographic column used was a reverse phase 4.6 µ, 250 mm Thermo Scientific BDS C18 HPLC column with 5 µm (particles) packing. The column and the HPLC system were kept at ambient conditions. The mobile phase consisted of 1 M ammonium acetate buffer (pH 7.5): methanol (76:24 v/v) delivered at a flow rate of 1 ml/min. The injection volume was 20 µl. elute was analyzed by a UV detector set at 254 nm.

D-Preparation of curve of Roxatidine acetate

A standard curve was prepared by withdrawing appropriate aliquots from stock solutions into a series of 10 ml volumetric flasks. The volume was made upto the mark with mobile phase to obtain concentration range of 20-100 µg/ml of Roxatidine acetate. Triplicate dilutions of each concentration of drug were prepared. These triplicate solutions were injected into the HPLC system. Detection of Roxatidine acetate was performed with the UV detector set at 254 nm. Peak area was recorded and calibration curves were plotted with peak area v/s the respective concentration of Roxatidine acetate.

Forced degradation study of Roxatidine

Forced degradation study of Roxatidine acetate in bulk and formulation was carried out under the conditions of acid hydrolysis, alkaline hydrolysis, oxidation, neutral degradation and photodegradation.

a-Acid hydrolysis

For forced acid hydrolysis, working standard of 50 µg/ml of drug was obtained by adding 10 ml of 0.1M HCl to 10 ml of stock solution (100µg/ml). The solution was refluxed at (70°- 80°C) for 2 h. A 20 µl of this solution was injected into HPLC system, under optimized chromatographic conditions.

b-Alkaline degradation

For forced alkaline degradation study working standard of 50µg/ml of drug was obtained by adding 10 ml of 0.1M NaOH to 10 ml of stock solution (100µg/ml). The solution was refluxed at (70°- 80°C) for 2 h. A 20 µl of this solution was injected into HPLC system, under optimized chromatographic conditions.

c- Neutral hydrolysis studies

For forced neutral hydrolysis, working standard of 50µg/ml of drug was obtained by adding 10 ml HPLC grade distilled water to 10 ml of stock solution (100µg/ml). The solution was refluxed at (70°- 80°C) for 2 h. A 20 µl of this solution was injected into HPLC system, under optimized chromatographic conditions.

D-Oxidation studies

For forced oxidation studies 10% H_2O_2 solution was prepared in water. To 10 ml of stock solution (100 µg/ml), 10 ml of 10% H_2O_2 solution was added to obtain the working standard of 50 µg/ml of drug. The solution was refluxed at (70°- 80°C) for 2 h. A 20 µl of this solution was injected into HPLC system, under optimized chromatographic conditions.

E-Photochemical degradation

The photochemical stability of the drug was studied by exposing stock solution of Roxatidine acetate of 50µg/ml to direct sunlight for 1 h.

F-Preparation of standard stock solutions

Standard stock solution (1000 µg/ml) of Roxatidine acetate was prepared by dissolving 50 mg in 20 ml of mobile phase with shaking and then volume was made up to the mark of 50 ml with the mobile phase. The stock solutions were degassed by using sonicator and filtered through a 0.22 µm membrane filter.

g) Chromatographic conditions

The chromatographic condition was a reverse phase 4.6 µ, 250 mm Thermo Scientific BDS C18 HPLC column with 5 µm (particles) packing. The column and the HPLC system were kept at ambient conditions. The mobile phase consisted of 1 M ammonium acetate buffer (pH 7.5): methanol (76:24 v/v) delivered at a flow rate of 1 ml/min. The injection volume was 20 µ l. Elute was analyzed by a UV detector set at 254 nm.

h)Preparation of curve of Roxatidine acetate

A standard curve was prepared by withdrawing appropriate aliquots from stock solutions into a series of 10 ml volumetric flasks. The volume was made upto the mark with mobile phase to obtain concentration range of 20-100 µg/ml of Roxatidinea acatate. Triplicate dilutions of each concentration of drug were prepared and these triplicate solutions were injected into the HPLC system. Detection of Roxatidine

acetate was performed with the UV detector set at 254 nm. Peak area was recorded and calibration curves were plotted with peak area v/s the respective concentration of Roxatidine acetate.

RESULTS AND DISCUSSION [7-10].

Organoleptic properties

The organoleptic properties Roxatidine acetate was found to be a white to off–white crystalline powder.

Melting point determination

The melting point of Roxatidine acetate matched with the value found in literature.The melting point of Roxatidine acetate represented that drug having good quality as like official guide line and result is shown in Table no -1

Table 1: Melting point of Roxatidine Acetate

Drug	Melting Point range	
	Reported	Practical
Roxatidine Acetate	130-132°C	128-130°C

3-Physical compatibility test [11-16].

For physical compatibility test FTIR of drug and excipients were mixed and kept strictly for 30 days. The test sample was scanned over a frequency range 4000-400 cm-1. FTIR spectra of drug-excipient mixtures retained the characteristic functional peaks of the drug as shown in Figure2 Thus, the polymer and the drug show no any interaction with each other .This result revealed that natural and synethetic polymer was found to be compatible for the development of oral dosage form.

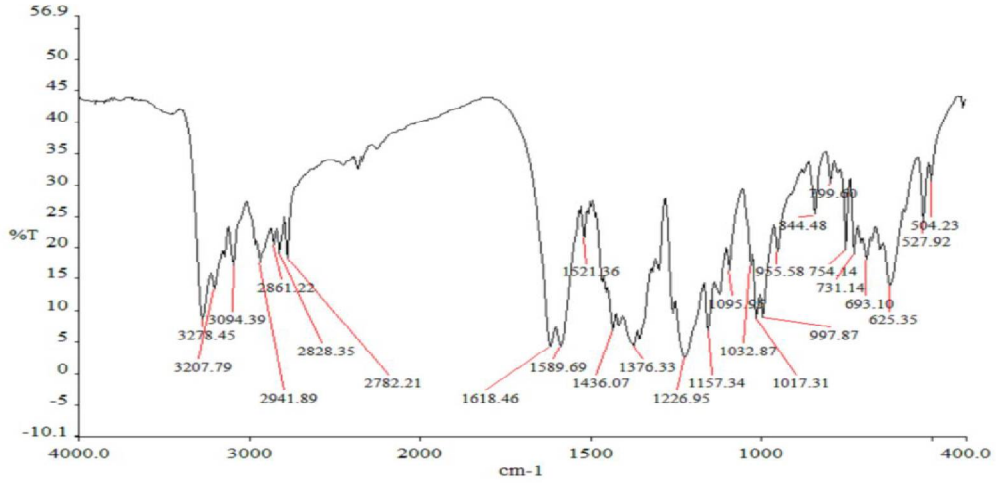

Figure 2: FTIR spectrum of Roxatidine acetate

Table 2: Interpretation of FTIR spectrum of Roxatidine Acetate

Sr.No.	Functional group	Reported Frequencies (cm-1)	Observed Frequencies (cm-1)
1	N -H Stretching	3280-3210	3207.79
2	C-H stretching in NO_2-CH	3100-3000	3094.39
3	C-H stretching of thiazole ring	3100-2900	2941.89
4	C-H stretching in -NCH_3	2900-2700	1436.07
5	C=C conjugated with-NO_2 group	1650-1600	1618.46
6	C-H deformation in -NCH_3	1600-1450	1589.49,1436,1521
7	Thiazole ring and asymmetric stretching in -NO_2	1400-1300	1376.33

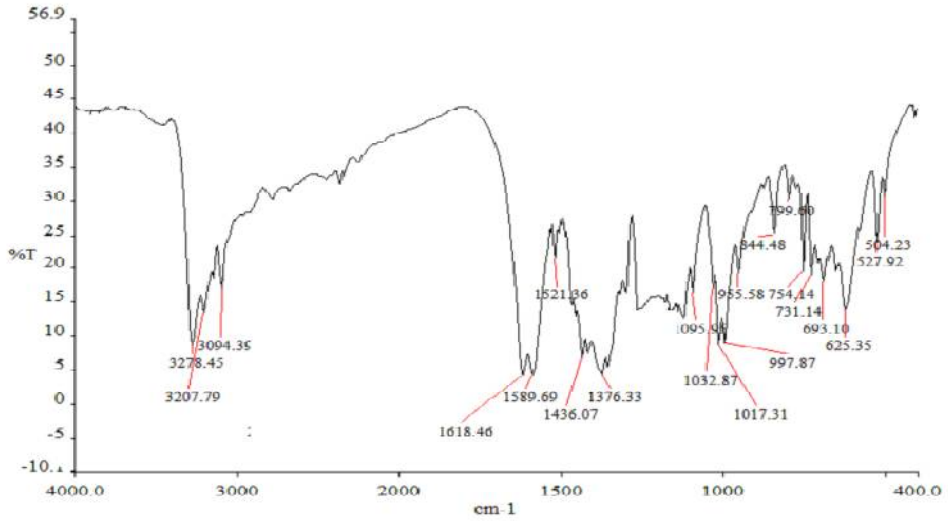

Figure 3: IR spectrum of Roxatidine acetate+ Chitosan + HPMC K100 M

Table 3: Interpretation of FTIR spectrum of Roxatidine acetate+ Chitosan+ HPMC K 100M.

Sr.No.	Functional group	Reported Frequencies (cm-1)	Observed Frequencies (cm-1)
1.	N -H Stretching	3280-3210	3207.79
2.	C-H stretching in NO_2-CH	3100-3000	3094.35
3.	C=C conjugated with-NO_2 group	1650-1600	1618.46
4.	C-H deformation in -NCH_3	1600-1450	1436.07
5.	Thiazole ring and asymmetric stretching in -NO_2	1400-1300	1376.33

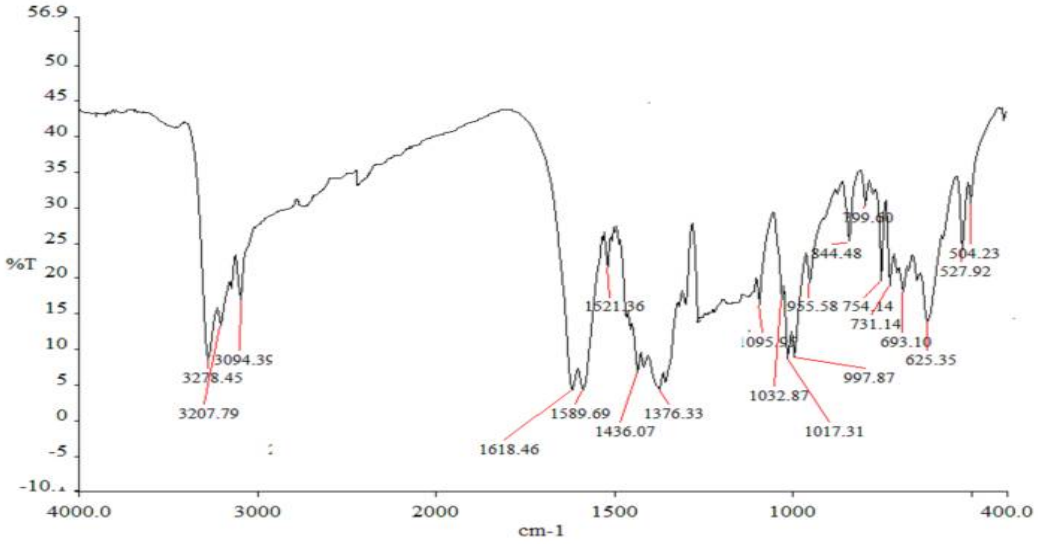

Figure 4: IR spectrum of Roxatidine acetate+ *Vinga mungo*+ HPMC K100 M

Table 4: Interpretation of FTIR spectrum of Roxatidine acetate+ *Vigna mungo*+ HPMC K100 M physical mixture

Sr.No.	Functional group	Reported Frequencies (cm-1)	Observed Frequencies (cm-1)
1.	N -H Stretching	3280-3210	3207.79
2.	C-H stretching in NO_2-CH	3100-3000	3094.35
3.	C=C conjugated with-NO_2 group	1650-1600	1618.46
4.	C-H deformation in -NCH_3	1600-1450	1436.07
5.	Thiazole ring and asymmetric stretching in -NO_2	1400-1300	1376.33

The interpretation of FTIR spectrum represented that N-H stretching at 3207.79 ,C-H stretching in No2-CH 3090.39 revealed the result of FTIR of roxatidine acetate drug having good quality of the official guideline.The characteristics peak of the pure Roxatidine acetate is as shown in Figure.2

3.2-Physical compatibility test using DSC [16-18]

The DSC thermograms of pure drug and its physical mixtures with various polymers are shown in the Figure 2. Differential Scanning Calorimetry studies indicated a sharp endothermic peak at 131.6°C corresponding to melting point of pure Roxatidine acetate. The peaks broadening as well as change in relative intensities were observed due to dilution of drug in physical mixtures of drug with both polymers. Physical compatibility test results concluded that the polymers and drug do not interact with each other. Also the drug didn't form a complex with the excipients as the endothermic peaks remained unchanged in position. Differential Scanning Calorimetry studies indicated a sharp endothermic peak at 130.2°C corresponding to melting of pure Roxatidine acetate is as shown in Figure.5

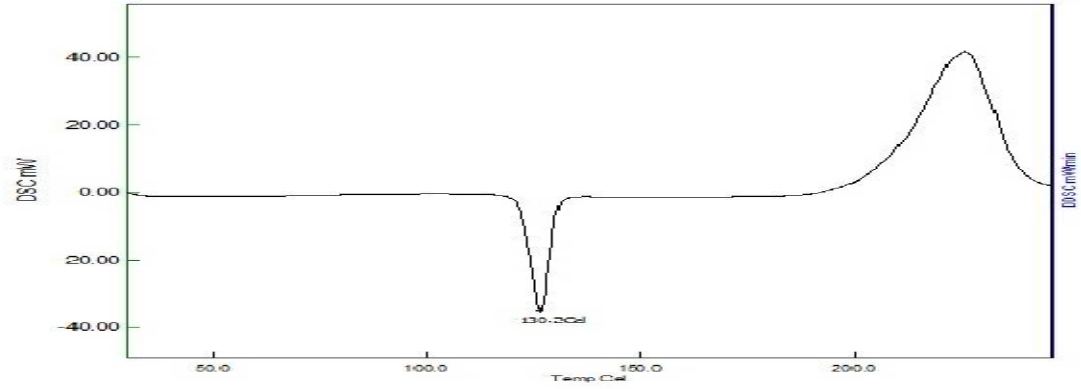

Figure 5: DSC Thermogram of Roxatidine acetate

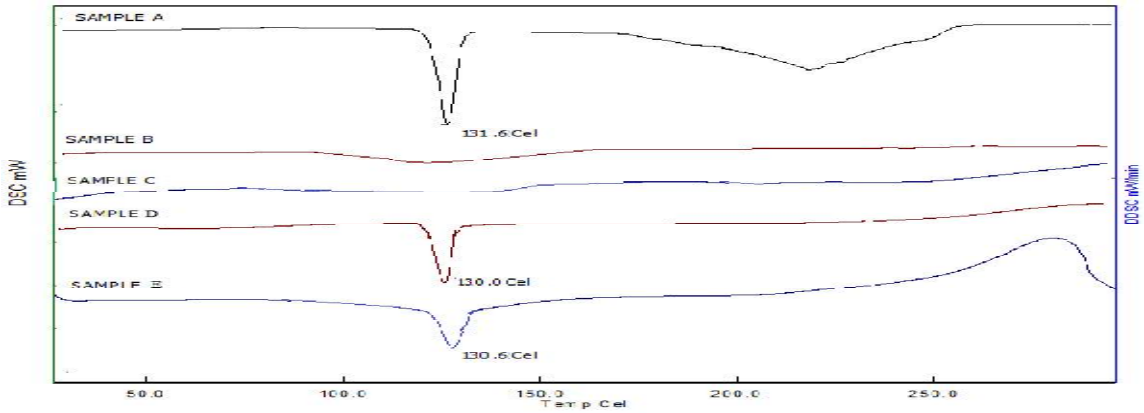

Figure 6: DSC Thermogram of (A) Roxatidine Acetate, (B) Chitosan, (C) *Vigna mungo*, (D) Chitosan physical mixture, (E) *Vinga mungo* physical mixture.

From the above observation from FTIR and DSC study, it was concluded that the polymer and drug did not interact with each other and are compatible.

Determination of solubility of Roxatidine acetate

The solubility of Roxatidine acetate was informed and noted in 0.1 N HCl (pH 1.2) and buffers of pH values 4.6 (acetate buffer) and 6.8 (phosphate buffer) are presented in Table 5. Roxatidine acetate exhibited a pH dependent solubility in these aqueous buffers. Higher solubility of Roxatidine acetate was observed at acidic pH values, while the solubility dropped rapidly as the pH increased. Table 5

Table 5: Solubility analysis of Roxatidine acetate

Solvent	Solubility (mg/ml)
pH 1.2 (0.1N HCl)	59.8
pH 4.5	45.2
pH 6.8	18.5

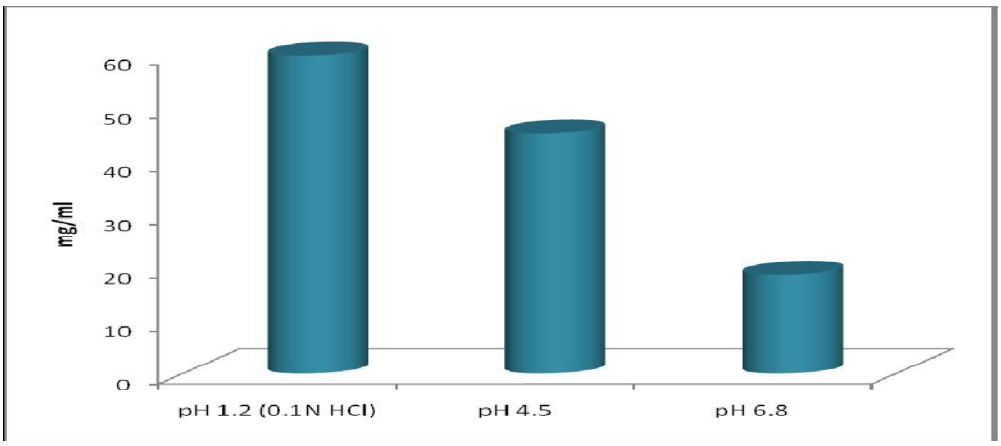

Figure 7: Solubility analysis of Roxatidine acetate

UV-VIS Spectrophotometric method for λmax determination of Roxatidine acetate

Wavelength of maximum absorbance (**λ**max) of Roxatidine acetate was found to be 280 nm in 0.1 N HCl.

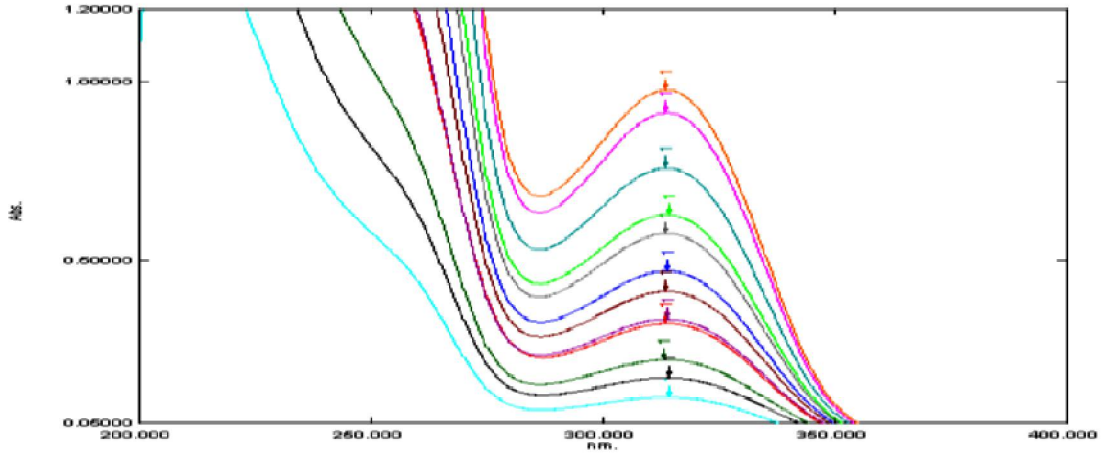

Figure 8: Typical UV spectrum of Roxatidine acetate in 0.1 N HCl.

Calibration curve for Roxatidine acetate

The calibration curve for Roxatidine acetate in 0.1 N HCl is shown in Figure 8. The graph of absorbance vs. concentration for Roxatidine acetate was found to be linear in the concentration range of 30-180 µg/ml at 280 nm. The R^2 of the calibration curve was found to be 0.9998. The standard calibration curve detail for Roxatidine acetate is shown in Table 7.

Table 6: Concentration and absorbance values for Roxatidine acetate in 0.1 N HCl

Sr. No.	Concentration (µg/ml)	Absorbance Mean ±SD (n=3)
1	30	0.1331±0.00811
2	60	0.2499±0.0091
3	90	0.3789±0.0079
4	120	0.5051±0.0057
5	150	0.6371±0.0071
6	180	0.7572±0.0052
7	210	0.8854±0.0085

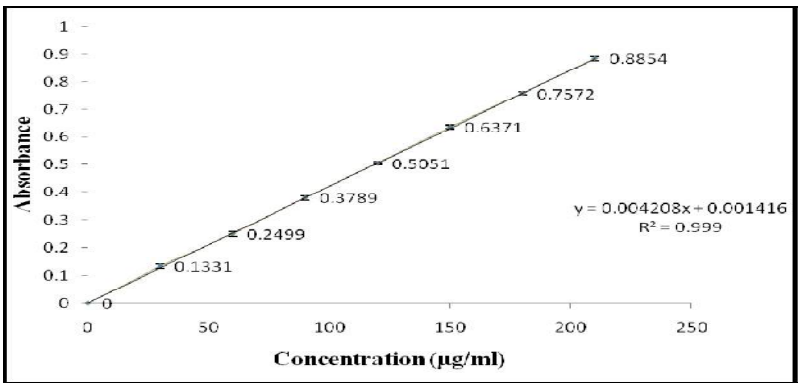

Figure 9: Calibration curve of Roxatidine acetate in 0.1 N HCl

HPLC analytical method

- **Standard calibration curve of Roxatidine acetate**

The calibration curve for Roxatidine acetate was found to be linear in the concentration range of 20-100 µg/ml. Calibration curve and typical chromatogram of Roxatidine acetate are shown in Figure 9 and 10 respectively. The standard calibration curve detail for Roxatidine acetate is shown in Table 7.Under the experimental conditions described, all peaks were well defined and free from tailing. The retention time (Rt) was 12.92 min.

Table 7: Standard calibration details of concentration and AUC for Roxatidine acetate

Sr. No.	Concentration (µg/ml)	AUC(254 nm)
1.	20	148832
2.	40	298801
3.	60	445842
4.	80	587698
5.	100	745991
6.	Regression (r^2)	0.999
7.	Slope	7419
8.	Intercept	223

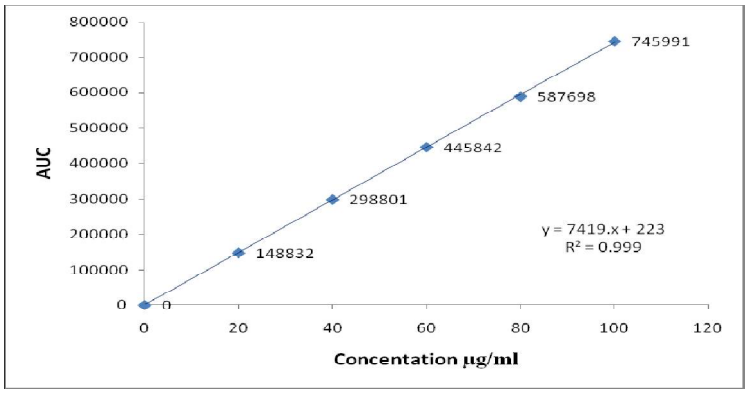

Figure 10: Standard curve of Roxatidine acetate using RP- HPLC at 254 nm.

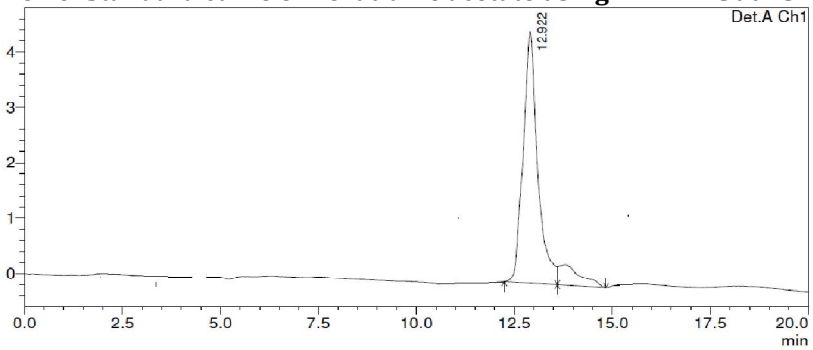

Figure 11: Chromatogram of Roxatidine acetate (50 µg/ml) at 254 nm using RP HPLC.

Forced Degradation Study of Roxatidine acetate

a) Acid degradation study

Roxatidine acetate solution when interacts with 0.1 M HCl. There was no extra peak for degraded product than pure drug peak at Rt 12.931 min suggesting that drug is stable in acidic environment (pH 1.2).

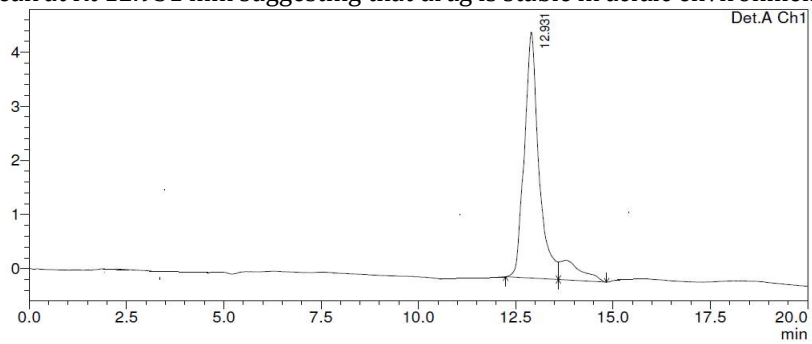

Figure 12: Chromatogram of Roxatidine acetate after forced acid degradation.

b) Alkaline degradation study

On forced degradation of Roxatidine acetate with alkali, there was no new peak was observed and the Rt of the original peak was found to be 12.912 min suggesting that drug is stable in alkaline environment (pH 1.2)

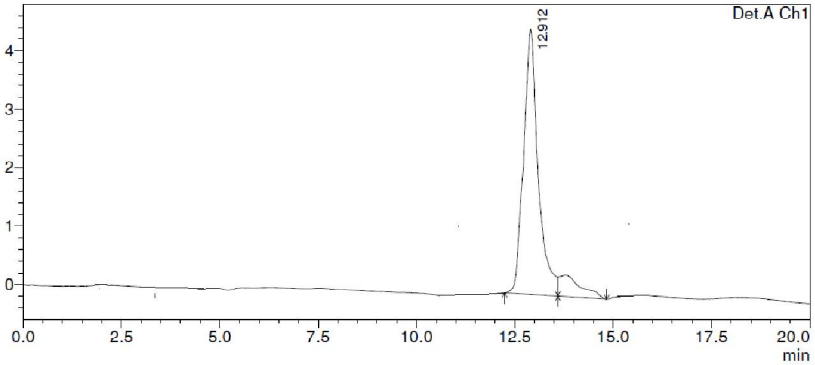

Figure 13: Chromatogram of Roxatidine acetate after forced alkali degradation.

c) Neutral degradation study

On forced degradation with neutral pH solution, there was no new peak formed and no shifting of peak occurs suggesting that drug is stable in water.

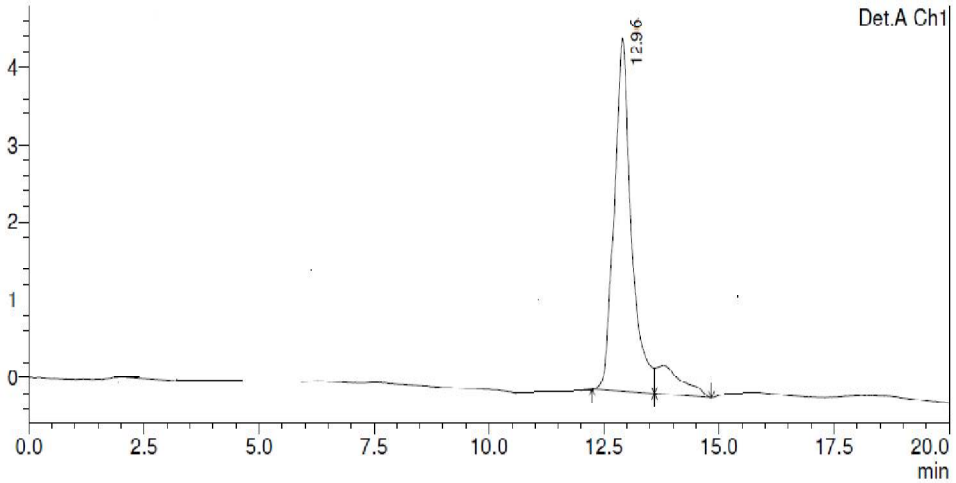

Figure 14: Chromatogram of Roxatidine acetate after neutral degradation

d) Oxidation studies

When Roxatidine acetate solution was exposed to chemical oxidation with H_2O_2, one new peak was seen in the chromatogram at 2.5 min and the Rt of the original peak shifted by 0.028 min suggesting that drug is unstable to oxidative stress.

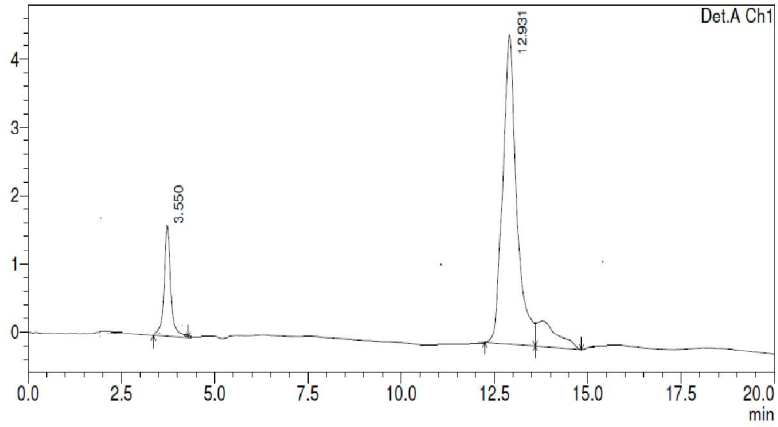

Figure 15: Chromatogram of Roxatidine acetate after forced oxidative degradation.

e) Photo stability studies

When Roxatidine acetate solution was exposed to photo degradation, there was no any peak of degraded product and RT of original peak was not shifted, which suggests its photo stability.

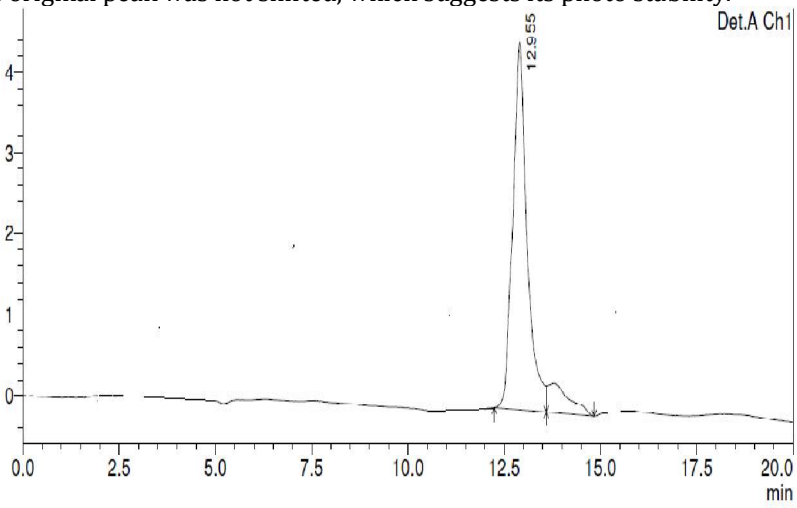

Figure 16: Chromatogram of Roxatidine acetate after forced photo degradation.

CONCLUSION:

Preformulation study is most important phase in developing safe, effective and stable dosage form. Data generated through these studies has great impact on subsequent development of final dosage form. . Roxatidine acetate,was taken as drug condidate in this study,the drug showed favorable properties for the development of an in-situ gel formulation. This study showed a satisfactory result for all characterization and on the basis of this study we concluded that the drug was suitable for choice of formulation.

CONFLICT OF INTEREST:

No conflicts of interest are mentioned by the researchers. The composition and writing of the document are the sole responsibility of the writer.

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REFERENCES

1. Chaurasia G. (2016). A Review on Pharmaceutical Preformulation Studies in Formulation and Development of new Drug Molecules. Int J Pharm Sci Res.,7(6), 2313-2320.
2. Mohammed Gulzar Ahmed MG, Kapor C, Adinarayana S. (2017). Formulation and Evaluation of Oral Sustained In Situ Gelling System of Roxatidine. Indonesian J. Pharm., 28(3), 179-184.

3. Sundaramoorthi Nainar, Kingston Rajiah, Santhosam Angamuthu, D Prabakaran and Ravisekhar Kasibhatta. (2012). Biopharmaceutical Classification System in Invitro/In-vivo Correlation: Concept and Development Strategies in Drug Delivery. Tropical Journal of Pharmaceutical Research April., 11 (2): 319-329
4. Desu PK, Vaishnavi G, Divya K and Lakshmi U. (2015). An overview on preformulation studies. Indo American Journal of Pharmaceutical Sciences., 2(10): 1399-1407
5. Nandgude TD and Bhise KS. (2011). Characterization of drug and polymers for development of colon specific drug delivery system. Asian J Biomed Pharm Sci., 1: 17-21.
6. Manish Wani, Swati Jagdale, Pawan Khanna, Ravindra Gholap and Akshay Baheti. (2020). Formulation and Evaluation of Ophthalmic In-Situ Gel using Moxifloxacin Coated Silver Nanoparticles. Research J. Pharm. and Tech., 13(8): 3623-3630.
7. Ashok Hajare and Vrushali Patil. (2012). Formulation and Characterization of Metformin Hydrochloride Floating Tablets. Asian J. Pharm. Res., 2(3): 111-117.
8. Ardita V, Simon Ž and Albin K. (2019). A review of methods for solubility determination in biopharmaceutical drug characterization. Drug Development and Industrial Pharmacy., 45.(11): 1717-1724.
9. Prakash Goudanavar, Doddayya Hiremath, Spandana D and Reddy SR..(2011). Development and Evaluation of Fast Disintegrating Tablets of Granisetron HCl with Natural and Synthetic Polymers. Asian J. Pharm. Res., 1(3): 72-77.
10. Karkhanis VV, Captain AD and Patel PH. (2013) Development and Validation of UV Spectrophotometric method for estimation of Glipizide in Bulk and Pharmaceutical Dosage Forms. Int J Pharm Sci Res., 4(5): 1865-1867.
11. Kumar M, Shukla AK, Bishnoi RS, Jain CP. (2018). Development of UV spectrophotometric method for the determination of benidipine hydrochloride by using quality by design (QbD) approach. Int J App Pharm., 10(4):92-97.
12. Kumar, M., Trivedi, V., Shukla, AK, Dev, SK. (2018). Effect of polymers on the physicochemical and drug release properties of transdermal patches of atenolol. International Journal of Applied Pharmaceutics., 10(4):68-73.
13. Shukla AK, Bishnoi RS, Kumar M, Jain CP. (2019). Development of natural and modified gum based sustained-release film-coated tablets containing poorly water-soluble drug. Asian J Pharm Clin Res,,12(3):266-271.
14. Shukla AK, Bishnoi RS, Kumar M, Jain CP. (2019). Isolation and characterization of natural and modified seed gum. Asian Journal of Pharmac and Pharmaco., 5(2): 409-418.
15. Shukla AK, Kumar M, Bishnoi RS, Jain CP. (2017). Review article application of fenugreek seed gum: In novel drug delivery. Asian J Biomat Res., 3:1-10.
16. Shukla AK, Kumar M, Bishnoi RS, Jain CP. (2019). Development of Natural Gum Based Sustained Release Tablets of Propranolol hydrochloride. Research J. Pharm. and Tech., 12(7): 3295-3300.
17. Shukla AK, Singh SK, Mishra SP, Sarthi AS, Dewangan E, Bharti VR, Sonkar SK. (2022). Development and Characterization of Natural Polymer Based Nifedipine Sustained Release Matrix Tablet. Journal of Pharmaceutical Negative Results., 13(8):3663-3668.
18. Shukla AK, Yadav A, Vishwakarma RK, Mishra SK. (2020). Applications, isolation and characterization of fenugreek seed gum as pharmaceutical excipient. Journal of Medical Pharmaceutical and Allied Sciences., 9(2):2484-2491.

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