

COMPATIBILITY STUDY OF TRIPROLIDINE HYDROCHLORIDE WITH DIFFERENT POLYMERS USING FOURIER TRANSFORM INFRARED SPECTROSCOPY WITH ATTENUATED TOTAL REFLECTANCE

PRATIK SHEE^{1*}

RANITA PATRA²

DR. RABINDRANATH PAL³

M. PHARM

DEPARTMENT OF PHARMACEUTICS

CALCUTTA INSTITUTE OF PHARMACEUTICAL TECHNOLOGY & AHS

Howrah, West Bengal 711316

EMAIL ADDRESS : Pratikshee45@gmail.com

ABSTRACT

A compatibility study was conducted to evaluate potential physicochemical interactions between Triprolidine Hydrochloride (TRP HCl) and commonly used controlled-release polymeric excipients—Hydroxypropyl Methylcellulose K100M (HPMC K100M), Eudragit RSPO, and Eudragit RLPO—using (FTIR-ATR). Individual components and their binary physical mixtures were analyzed to detect any shifts, disappearance, or broadening in characteristic functional-group absorption bands. FTIR spectra of pure Triprolidine Hydrochloride exhibited distinct peaks corresponding to aromatic C–H stretching, tertiary amine vibrations, and the characteristic C=N and C–Cl functionalities. These diagnostic peaks remained identifiable and largely unchanged in all polymer–drug mixtures. No significant alterations in peak position or intensity were observed with HPMC K100M, indicating the absence of hydrogen-bonding or chemical interaction. Similarly, mixtures with Eudragit RSPO and RLPO retained the principal spectral features of both the drug and polymers without evidence of new absorption bands or major spectral distortions.

Overall, the spectral patterns suggest no appreciable chemical incompatibility between Triprolidine Hydrochloride and the selected polymers. The absence of interaction-related spectral changes supports their suitability for formulating sustained-release or matrix-based oral dosage forms. FTIR-ATR findings confirm that HPMC K100M, Eudragit RSPO, and Eudragit RLPO are compatible excipients for the development of Triprolidine Hydrochloride controlled-release formulations.

INTRODUCTION

Compatibility assessment between an active pharmaceutical ingredient (API) and selected excipients (HPMC K100M, Eudragit RSPO, and Eudragit RLPO) is a critical step in the early stages of dosage-form development. Physicochemical interactions —whether chemical, physical, or thermodynamic—can compromise the stability, bioavailability, or performance of the final product. Therefore, preformulation studies provide essential insights that guide excipient selection, processing conditions, and formulation design for robust and reliable drug delivery systems.

Triprolidine Hydrochloride (TRP HCl) is a first-generation antihistamine commonly used for symptomatic relief of allergic conditions. Its short biological half-life and pronounced sedative effects have motivated interest in modified-release formulations that can provide sustained therapeutic action while reducing dosing frequency. To achieve such controlled-release behavior, hydrophilic and hydrophobic polymers such as HPMC K100M, Eudragit RSPO, and Eudragit RLPO are frequently incorporated into matrix and reservoir systems. These polymers differ in viscosity, permeability, and swelling characteristics, enabling fine control over drug release kinetics.

Before integrating these polymers into a formulation, it is essential to ensure that they do

not chemically interact with Triprolidine Hydrochloride during processing or storage. Among analytical tools, Fourier Transform Infrared Spectroscopy with Attenuated Total Reflectance (FTIR-ATR) is widely employed for compatibility evaluation because it allows rapid, non-destructive detection of changes in functional-group vibrations. Shifts in peak positions, disappearance of characteristic bands, or formation of new absorption regions may indicate possible interactions such as hydrogen bonding, salt formation, or degradation.

This study investigates the compatibility of Triprolidine Hydrochloride with HPMC K100M, Eudragit RSPO, and Eudragit RLPO using FTIR-ATR. By comparing spectral patterns of pure components and their binary mixtures, the work aims to determine whether these polymers are suitable excipients for developing controlled-release formulations of Triprolidine Hydrochloride .

TRIPROLIDINE HYDROCHLORIDE

Triprolidine Hydrochloride is a first-generation H₁-antihistamine commonly used to relieve symptoms of allergic conditions such as rhinitis, urticaria, and common cold. It acts by blocking histamine H₁ receptors, thereby reducing vasodilation, edema, itching, and nasal secretions. Due to its ability to cross the blood–brain barrier, it may cause mild sedation. Triprolidine HCl is available in oral formulations, often in combination with decongestants, and has a rapid onset of action 15 to 45 min with a duration of 4–6 hours. Triprolidine HCl is a first-generation antihistamine used to relieve symptoms of the common cold and allergies, such as sneezing, a runny nose, and itchy, watery eyes. Common side effects include drowsiness, which can be worsened by alcohol, and dizziness. It works by blocking the effects of histamine, the substance that triggers allergic responses. Triprolidine HCl is a 1st gen H₁ Antagonist. It acts as a competitive H₁-receptor antagonist. It blocks the action of histamine at H₁ receptors on effector cells in the respiratory tract, blood vessels, and gastrointestinal smooth muscle, which helps improve mood and reduce anxiety.

MECHANISM OF ACTION

Triprolidine Hydrochloride is a first-generation antihistamine that acts through competitive antagonism of H₁ receptors. By inhibiting histamine binding on vascular endothelium,

smooth muscle, and sensory neurons, it reduces vasodilation, capillary permeability, itching, sneezing, and mucous secretion. Its lipophilic structure enables penetration into the CNS, where it blocks central H₁ receptors and produces sedative effects. Mild anticholinergic activity further contributes to drying of secretions and relief of nasal symptoms.

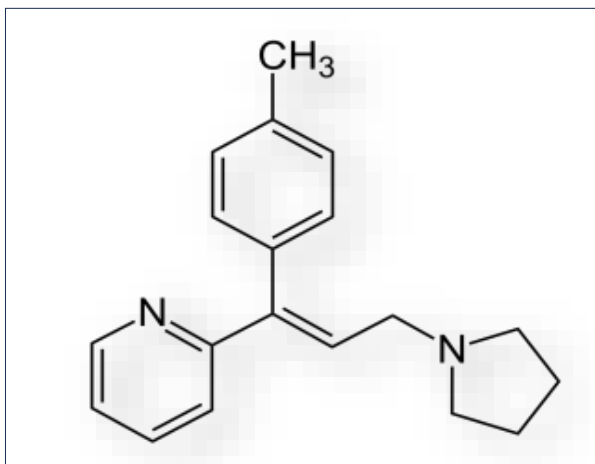
THERAPEUTIC USES

Histamine released during allergic reactions binds to H₁ receptors, producing vasodilation, increased capillary permeability, itching, and mucous secretion.

Triprolidine competes with histamine for these receptors and prevents histamine from exerting its effects.

This leads to:

- Allergic Rhinitis & Other Allergies: Provides relief from symptoms like sneezing, runny nose, and itching caused by hay fever . Helps with symptoms of allergic skin conditions like hives (urticaria).
- Common Cold: This Relieves the symptoms associated with the common cold, such as sneezing, runny nose, and watery eyes.
- Asthma: Used to provide symptomatic relief in some cases of asthma.

DRUG PROFILE**Figure: Chemical Structure of Triprolidine Hydrochloride****➤ Chemical Data:** All the chemical data are enlisted below;

- IUPAC Name: (E)-4-(5-Phenyl-1-pyrrolidinyl)-1-(2-pyridyl)-1-butene hydrochloride
- Chemical Formula: $C_{19}H_{22}N_2 \cdot HCl$
- Molecular Weight: 314.85 g/mol
- Solubility: Sparingly soluble in water, ethanol, and Chloroform
- Melting Point: 136°C– 138°C
- Appearance: White or almost white crystalline powder; odorless or with a faint characteristic odor; bitter in taste
- Concentration range: 2.5-30 $\mu\text{g/mL}$, with a maximum absorption at 290 nm in 0.1 N HCl
- Log P: approx 4.14
- BCS Class: Class II (Low Solubility & High Permeability)
- pH: 4-6 , λ_{max} : 290 nm
- Biological Half Life: 3-5 hrs
- Elimination Half-life : 5-8 hrs.

➤ Pharmacokinetics Data: All the pharmacokinetic data are enlisted below;

- Metabolism– in the Liver
- Bioavailability: 44%
- Absorption– in the GIT
- Excretion– mainly through urine.
- Dose: 2.5 mg to 5 mg two or three times daily or 10mg/day.

MATERIALS

- **Triprolidine Hydrochloride (TRP HCl):** Pharmaceutical-grade API obtained from UNION DRUGS PVT. LTD.
- **HPMC K100M:** High-viscosity hydrophilic polymer used in controlled-release matrix systems.
- **Eudragit RSPO & Eudragit RLPO:** Ammonio methacrylate copolymers with differing permeability characteristics.
- **Other Materials:** Analytical-grade potassium bromide (only if required for baseline checks), weighing boats, spatulas, and airtight storage containers.

INSTRUMENTATION

- **FTIR Spectrophotometer Equipped With Attenuated Total Reflectance (ATR) Accessory:** (diamond/ ZnSe crystal), controlled by standard spectral acquisition software.

METHODS

1. Preparation Of Samples –

- **Pure Drug And Pure Polymer Samples**
: Approximately 2–5 mg of Triprolidine Hydrochloride (TRP HCl), HPMC K100M, Eudragit RSPO, and Eudragit RLPO were used individually for spectral acquisition. Each material was gently dried at 40 – 45 °C

for 30 minutes to remove adsorbed moisture before analysis.

- **Binary Physical Mixtures:** Binary mixtures of drug and excipients were prepared in a 2:1 (w/w) ratio to maximize the likelihood of detecting interactions.
 - Components were weighed accurately using an analytical balance.
 - Mixing was performed using geometric dilution in a mortar and pestle to ensure uniform blending.
 - Samples were stored in amber vials until FTIR analysis to prevent moisture uptake.

2. FTIR-ATR Spectral Analysis–

- **Instrument Setup:**
 - The FTIR instrument was calibrated with a background scan prior to each sample measurement.
 - Spectra were obtained in the range 4000–400 cm^{-1} with 30 scans averaged per sample for optimal signal-to-noise ratio.
 - Spectral resolution was maintained at 4 cm^{-1} .
- **Sample Placement**
 - A small quantity of each sample was placed directly onto the ATR crystal.
 - A uniform pressure clamp was applied to ensure consistent contact between the sample and ATR surface.

3. Data Interpretation –

- Spectra were analyzed for :
 - Retention of characteristic peaks of the Triprolidine Hydrochloride.
 - Shift in peak positions (indicative of interactions such as hydrogen bonding or salt formation).
 - Broadening or splitting of key IR bands.
 - Appearance or disappearance of functional-group signatures.
- Comparative analysis was conducted by overlaying spectra of mixtures with those of pure components.

4. Documentation And Validation –

- All spectra were saved and labeled according to sample type.
- Replicate measurements were taken to confirm reproducibility.
- Instrument performance was validated using a standard polystyrene reference film.

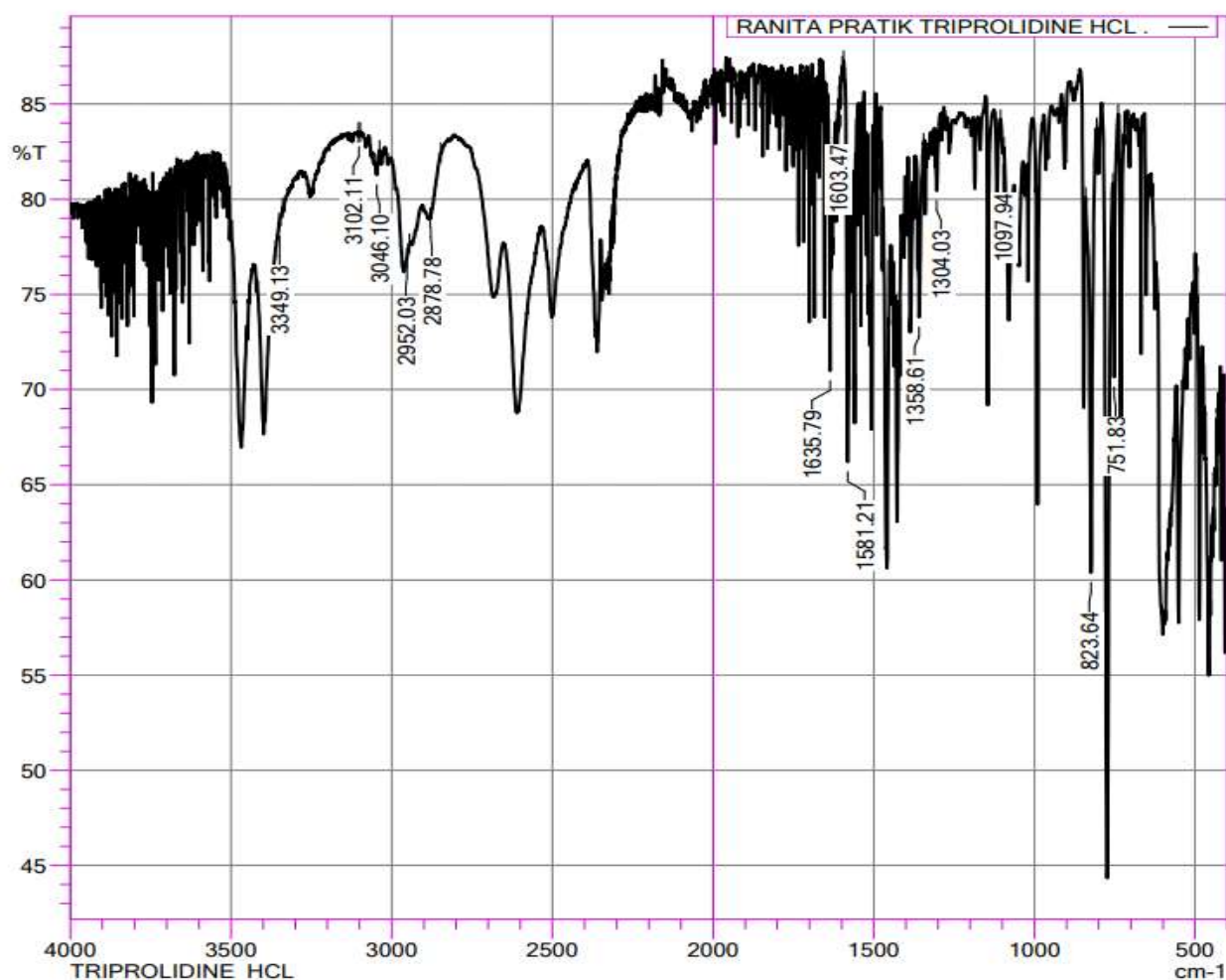
This methodology ensures a precise and systematic assessment of the physicochemical compatibility between the (TRP HCl) Triprolidine Hydrochloride and the selected controlled-release polymers using FTIR-ATR.



***Fig: Fourier transform infrared (FTIR) spectrophotometer
Attenuated Total Reflectance***

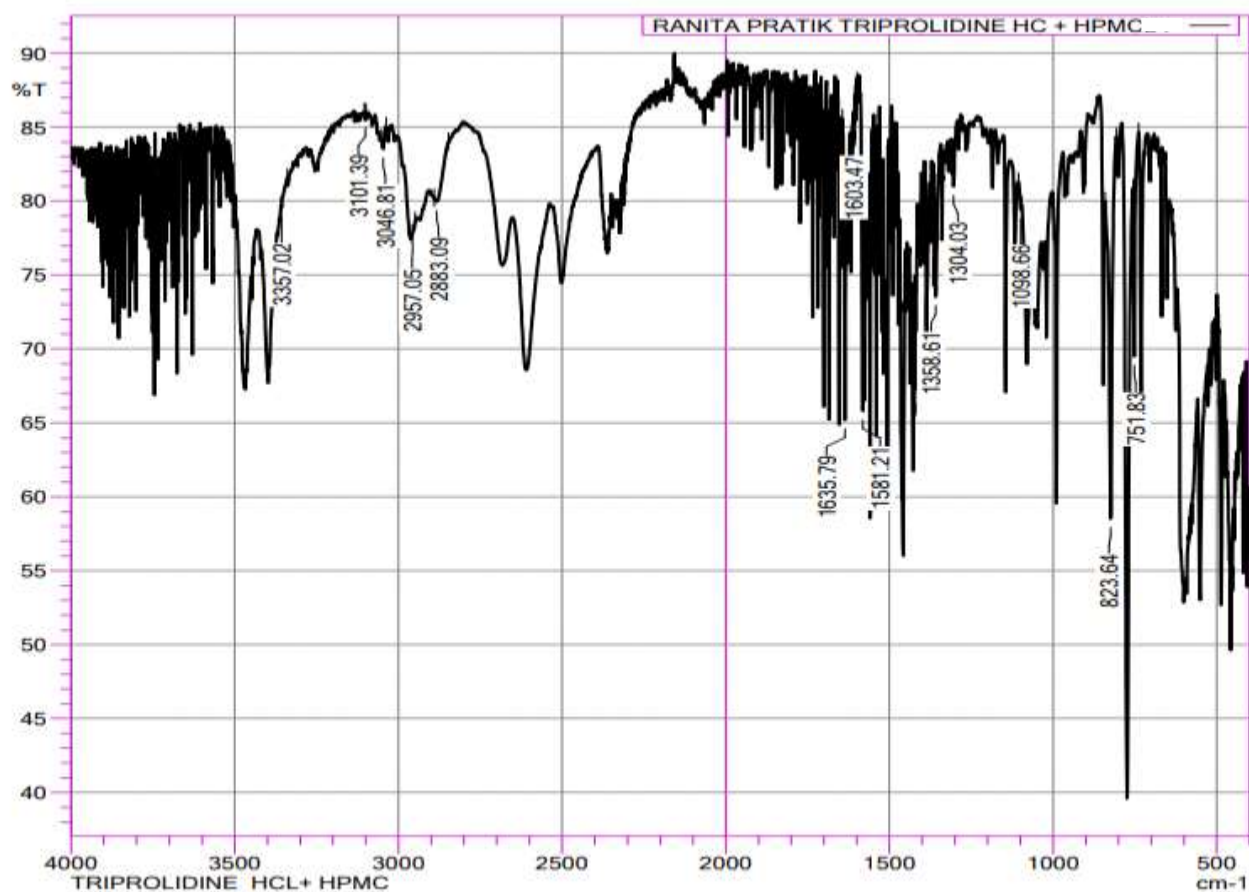
OBSERVATION

• FTIR(ATR) Study Of Triprolidine Hydrochloride :



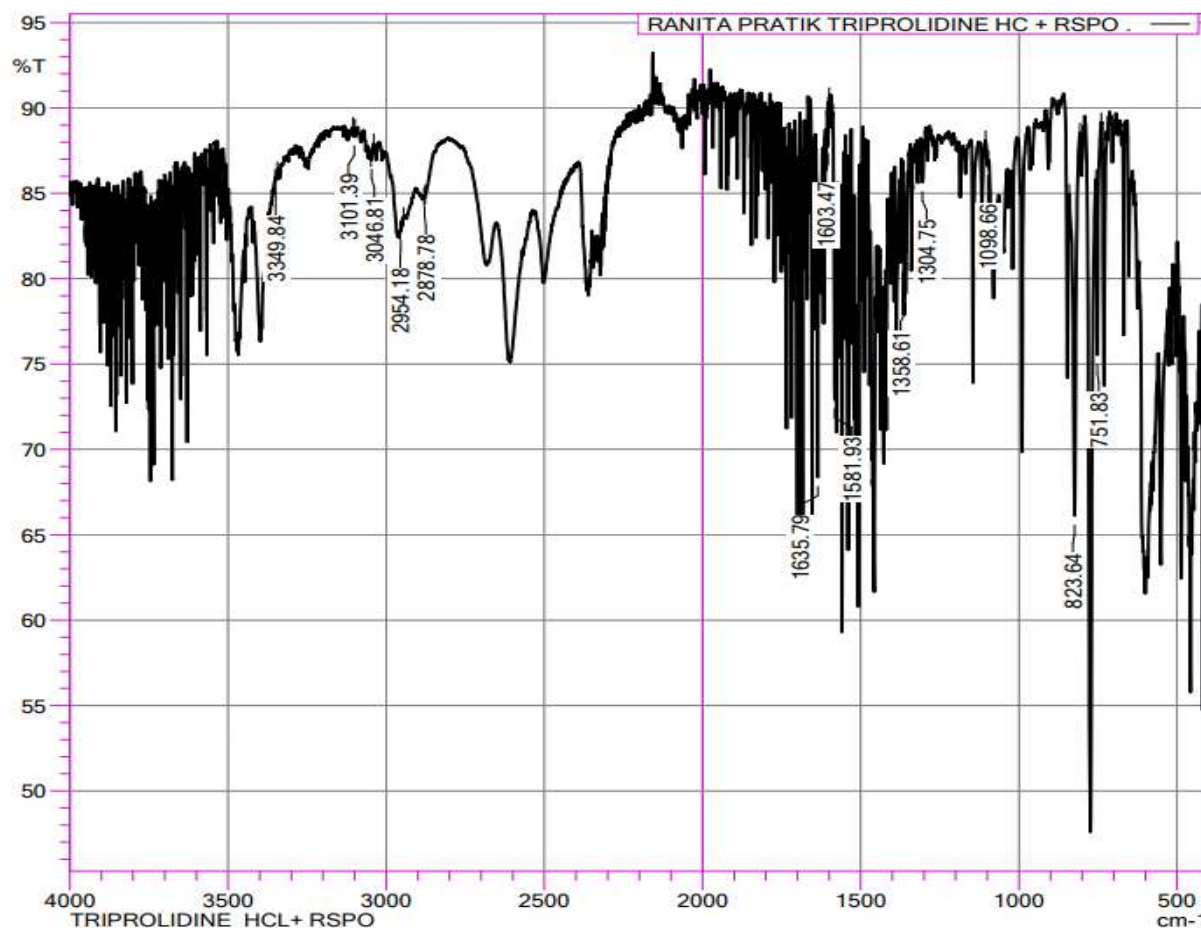
Functional Group	Range	Triprolidine Hydrochloride
N-H Stretching	3400-3350	3349.13
=C— Stretching	3100-3040	3046.10
C-H stretching	3000-2850	2952.03
C=C stretching	1660-1600	1635.79
C=N stretching	1590-1500	1581.21
C-O stretching	1150-1000	1097.94
C-Cl stretching	800-750	751.83
C-N stretching	1310-1250	1304.03

• FTIR(ATR) Study Of Triprolidine Hydrochloride + HPMC K100M :



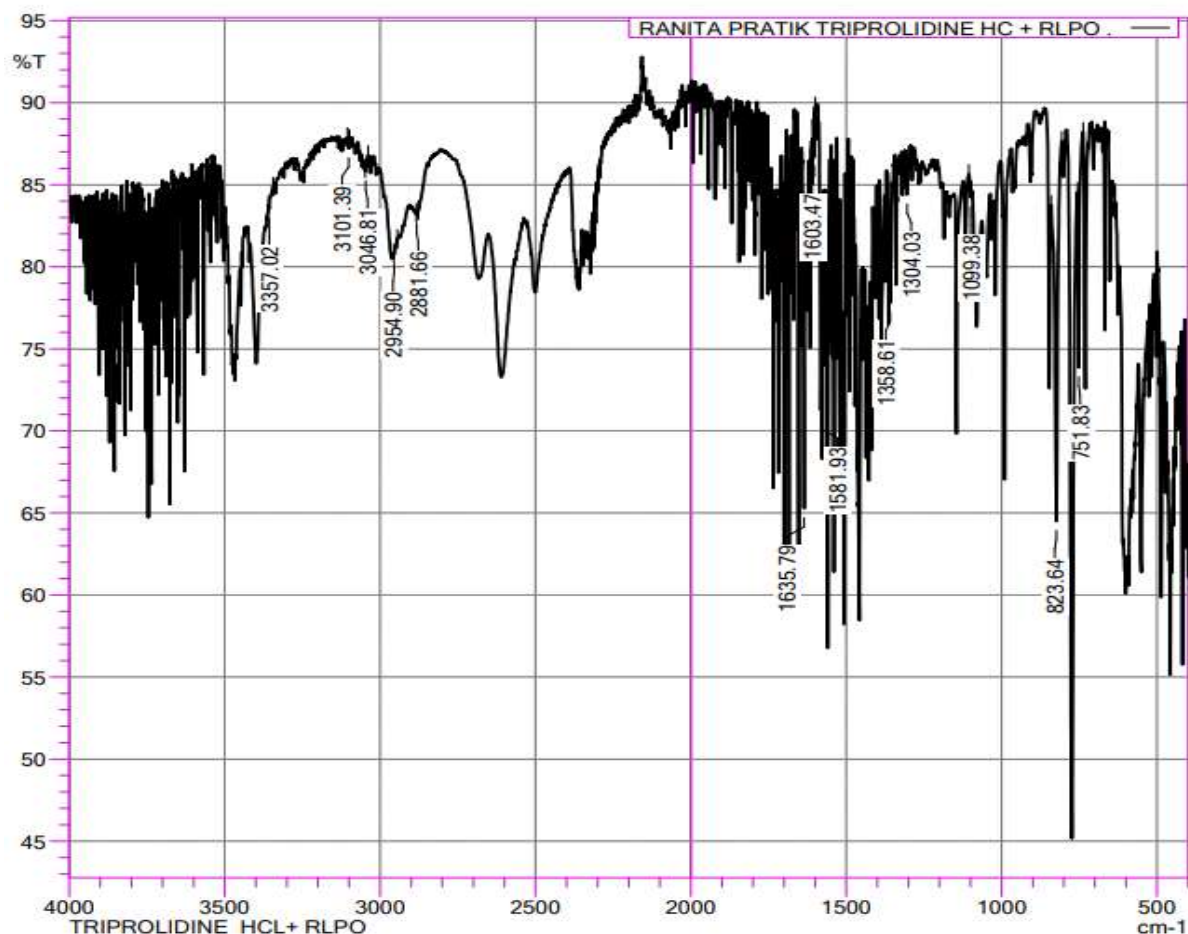
Functional Group	Range	Triprolidine Hydrochloride	Triprolidine Hydrochloride + HPMC K100M
N-H Stretching	3400-3350	3349.13	3357.02
=C-H Stretching	3100-3040	3046.10	3046.81
C-H stretching	3000-2850	2952.03	2957.05
C=C stretching	1660-1600	1635.79	1635.79
C=N stretching	1590-1500	1581.21	1581.21
C-O stretching	1150-1000	1097.94	1098.66
C-Cl stretching	800-750	773.37	751.83
C-N stretching	1310-1250	1304.03	1304.03

• **FTIR(ATR) Study Of Triprolidine Hydrochloride + Eudragit RSPO :**



Functional Group	Range	Triprolidine Hydrochloride	Triprolidine Hydrochloride +Eudragit RSPO
N-H Stretching	3400-3350	3349.13	3349.84
=C-H Stretching	3100-3040	3046.10	3046.81
C-H stretching	3000-2850	2952.03	2954.18
C=C stretching	1660-1600	1635.79	1635.79
C=N stretching	1590-1500	1581.21	1581.93
C-O stretching	1150-1000	1097.94	1098.66
C-Cl stretching	800-750	773.37	751.83
C- N stretching	1310-1250	1304.03	1304.75

● **FTIR(ATR) Study Of Triprolidine Hydrochloride + Eudragit RLPO :**



Functional Group	Range	Triprolidine Hydrochloride	Triprolidine Hydrochloride +Eudragit RLPO
N-H Stretching	3400-3350	3349.13	3357.02
=C-H Stretching	3100-3040	3046.10	3046.81
C-H stretching	3000-2850	2952.03	2954.90
C=C stretching	1660-1600	1635.79	1635.79
C=N stretching	1590-1500	1581.21	1581.93
C-O stretching	1150-1000	1097.94	1099.38
C-Cl stretching	800-750	773.37	751.83
C-N stretching	1310-1250	1304.03	1304.03

RESULT & DISCUSSION

1.FTIR-ATR Spectra Of Pure Triprolidine Hydrochloride :

The FTIR spectrum of pure Triprolidine Hydrochloride displayed well-defined functional-group vibrations characteristic of its molecular structure. Major absorption peaks included:

- N-H Stretching around 3400-3350 cm^{-1}
- = C-H Stretching near 3100-3040 cm^{-1}
- Aromatic C-H stretching around 3000-2850 cm^{-1}
- C=C stretching around 1660-1600 cm^{-1}
- C=N stretching around 1590-1500 cm^{-1}
- C-O stretching near 1150-1000 cm^{-1}
- C-Cl aromatic stretching around 800-750 cm^{-1}
- C-N stretching near 1310-1250 cm^{-1} .

These peaks served as reference markers for comparison with polymer-drug mixtures (HPMC K100M, Eudragit RSPO, and Eudragit RLPO).

2.FTIR-ATR Spectra Of (TRP HCl) Triprolidine Hydrochloride With Excipients

➤ Binary Mixtures with HPMC K100M

The FTIR spectra of Triprolidine Hydrochloride-HPMC K100M mixtures retained all major drug peaks without significant shifts, broadening, or disappearance.

- The N-H, C=C, C=N and C-Cl peaks remained sharp and unchanged.
- No new absorption bands were detected in C-N stretching region, indicating lack of hydrogen-bond formation or chemical linkage.

Interpretation:

HPMC K100M does not interact chemically with the drug and is compatible for use in hydrophilic matrix systems.

➤ Binary Mixtures with Eudragit RSPO

Mixtures of Triprolidine Hydrochloride with Eudragit RSPO showed clear retention of the drug's diagnostic absorption bands.

- The C=C and C-Cl peaks remained sharp and unchanged.
- No significant shift and No new functional groups found.

Interpretation:

This confirms no acid-base interaction or salt formation between the API and the polymer. This indicates RSPO is suitable for sustained-release formulations requiring low permeability.

➤ Binary Mixtures with Eudragit RLPO

The FTIR spectra of the Triprolidine Hydrochloride – Eudragit RLPO mixtures similarly preserved all characteristic drug peaks.

- C=C , C-Cl, C-N peaks remained sharp and unchanged.
- Slight variations in band intensity were attributed to physical mixing and not chemical transformation.
- No new functional-group bands emerged.

Interpretation:

RLPO does not engage in significant physicochemical interactions with the API and is appropriate for formulations requiring higher permeability compared to RSPO.

CONCLUSION

The compatibility study of Triprolidine Hydrochloride with HPMC K100M, Eudragit RSPO, and Eudragit RLPO using FTIR-ATR demonstrates that the drug maintains its characteristic functional-group vibrations in all binary mixtures. No significant peak shifts, disappearance of major absorption bands, or formation of new spectral features were observed, indicating the absence of chemical or physicochemical interactions.

These findings confirm that all three polymers are compatible excipients for Triprolidine Hydrochloride and these can be safely incorporated into controlled-release matrix or reservoir formulations without compromising

➤ **Overall Compatibility Assessment**

Across all polymer–drug mixtures:

- No major peak shifts, peak disappearance, or formation of new absorption bands were detected.
- Characteristic functional-group vibrations for both Triprolidine Hydrochloride and the polymers remained stable.
- Spectral overlays demonstrated excellent congruence between pure drug spectra and corresponding mixture spectra.

drug integrity or stability. The results support their suitability for further formulation development and optimization of modified-release dosage forms.

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