RESEARCH PAPER

Compatibility Studies Of Reserpine And Different Grades Of Hydroxypropyl Methyl Cellulose Polymer In Sustained Release Formulation

Gaurav Kumar [1], Vikrant Verma[2]*

[1] *Research Scholar, Faculty of Pharmacy, Swami Vivekanand Subharti University, Meerut -250005, Uttar Pradesh, India*
[2]*Faculty of Pharmacy, Swami Vivekanand Subharti University, Meerut -250005, Uttar Pradesh, India.*

ABSTRACT
The main purpose of the current study was to examine the drug-excipient compatibility of reserpine with different grades of hydroxypropyl methylcellulose (HPMC) and common pharmaceutical excipients to produce a sustained-release oral formulation. Extensive preformulation studies were done to evaluate the physicochemical stability and compatibility of reserpine in the solid state. The melting point of reserpine, measured by the capillary method, was 241-241.5 °C. This value is very close to the range reported in the reference and confirms the drug's purity and thermal stability. Drug-excipient compatibility studies involved the preparation of physical mixtures of reserpine with lactose DC grade, HPMC K100 LV, HPMC K100 M, microcrystalline cellulose (MCC PH, 102), Aerosil, and magnesium stearate in a 1:1 ratio. These mixtures were kept under accelerated-stability conditions (40 ± 2 °C and 75 ± 5 % RH), and the initial, 14-day, and 28-day samples were analyzed using Fourier Transform Infrared (FTIR) spectroscopy. FTIR spectral analysis revealed that the characteristic functional group peaks of reserpine were preserved, with no additional peaks or significant shifts. In other words, no chemical interactions were detected. Spectral similarity indices after 14 days ranged from 0.981 to 0.998 and after 28 days from 0.980 to 0.995, thus demonstrating excellent compatibility of reserpine with all tested excipients..
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INTRODUCTION

Reserpine is directly used to control high blood pressure and blocks the transport of these neurotransmitters. [1] The chemical name of reserpine is methyl (3β,16β,17α,18β,20α)- 11,17-dimethoxy-18- [(3,4,5-trimethoxy benzoyl) oxy] yohimban-16-carboxylic acid. Reserpine is used to treat high blood pressure, usually in combination with a thiazide diuretic or a vasodilator. [2-5] Reserpine is soluble in organic solvents such as DMSO (Dimethyl sulfoxide) and DMF (dimethyl formamide), and is sparingly soluble in aqueous buffers. Reserpine is a very strong basic compound (based on its pKa). [6-8]

Reserpine side effects can cause unusual changes in mood or behaviour, Slow heartbeats, swelling in the hands or feet, weight gain, painful or difficult urination, uncontrolled muscle movement, hearing problems, and sudden lack of energy. [9]

Preformulation studies

Preformulation is defined as the study of the physical and chemical properties of an active pharmaceutical ingredient(API) prior to formulation development. The quality, safety, efficacy, and stability of the formulation are key considerations in any API development process. In the API development process, a detailed characterization of the API and other formulation components is carried out during preformulation studies. [10-15]

One of the objectives of this study is to develop sustained-release drug delivery systems, and linking the formulation development to establish the basics of pharmaceutical research in studying the drug-excipient compatibility, drug with various excipients, which is important for the safety, effectiveness, quality, formulation, stability, bioavailability, and pharmacokinetics of the drug, etc. [13-16]

Determination of physical chemical properties of API substance with the goal of developing a new formulation which is safe stable and efficacious, each API, has intrinsic chemical and physical properties that were considered prior to the development of pharmaceutical formulation, the purpose of preformulation study is to generate useful information for the formulator in the development of stable and bioavailable dosage form, inappropriate preformulation study results in poor stability of active ingredients increase the overall cost of development and increased development time, preformulation studies help to fortify the pharmaceutical scientific foundation of the guidance, provide regulatory relief and conserve resources in the drug development and evaluation process, enhance public safety standards, improve product quality, promote the implementation of new technologies, aids policy development and regulatory decision making and after compiling all data it is transferred to the development pharmacist and for the day work on formulation of dosage form. [15-19]

Preformulation study objectives: To establish the Physico-chemical parameters of a new sustained release formulation, determine its kinetics and stability, establish its compatibility with common excipients, it provides insights into how drug products should be processed and stored to ensure their quality, estimate problem may arise during formulation that is stability problem poor in-vivo

**Author for Correspondence: vijeetsingh84@rediffmail.com*

dissolution, poor bioavailability, to interpret BCS classification of drugs and its significance and develop optimal drug delivery system. [17-18]

Drug-Excipient compatibility study: The prior objective of this evaluation was to identify a stable storage condition for the API in solid state and to determine compatible excipients for its formulation. Incompatibilities are major concerns in formulation development. Selection of the proper excipient during preformulation studies is of prime importance. [18-19]

Dosage forms: A dosage form contains the API and pharmaceutical excipients in the final pharmaceutical product. Dosage forms ensure that the administration to the body can be used safely and effectively. The need for dosage forms to generate an ideal formulation and to ensure manufacturability of pharmaceutical products, such as accurate dose, coated tablets, sealed ampules, gastric juice, masking taste and odour, sustained-release medication, controlled-release medication, vaginal, rectal, and topical agents. Excipients can affect the physical and chemical form of pharmaceuticals through several mechanisms, such as hydrogen-bond interactions, polymorphic conversion, and others. Accordingly, drug-excipient compatibility should be assessed to determine any interactions that may affect the stability, bioavailability, and manufacturability of pharmaceutical dosage forms. [20-22]

Importance of Drug-Excipient Compatibility

Drug-excipient compatibility studies are a major step in pre-formulation studies of the development of a dosage form. The stability of the formulation can be affected by physical or chemical interactions between the API and excipients, which can alter the drug's appearance, bioavailability, and stability. It is necessary for the safety, quality, efficacy, stability, and manufacturability of the drug product. Incompatible molecule interactions can lead to product failure, regulatory issues, and potential harm to the patient. [21-24]

It helps to avoid the intended problem. By performing drug and excipient compatibility studies (DECS), we can assess potential reactions between molecules before the final formulation of the dosage form.

In the drug-excipient compatibility study, the physical and chemical interactions between the drug and excipient can affect the drug's chemical nature, stability, and the excipient's bioavailability. Its therapeutic efficacy, safety, and quality of solid dosage forms are generally less stable than those of their drug components, and, in addition to the importance of drug-excipient compatibility testing, there is no universally accepted criterion to assess such molecular interactions. [24-32]

Pharmaceutical excipients: Pharmaceutical Excipients are additive materials used to improve formulation characterization, such as ease of handling, binder, dissolution rate, disintegration, protection of the drug from degradation, and bioavailability, etc. Different types of dosage forms, such as Sachet Powders, tablets, capsules, oral liquids, injectables, suppositories, ointments, creams, topical agents, inhalers, eye products, gels, transdermal, and nasal products, etc., many types of excipients. To make it compatible and acceptable, various types of pharmaceutical excipients are added to different types of pharmaceutical dosage forms for their direct therapeutic action, support, protection, or enhancement of stability, bioavailability, or patient compliance. Each formulation must be physiologically and chemically stable, excipients must not be incompatible with the drug, and the regulatory acceptance criteria must be met. [33-35]

Evaluation of Drug-Excipient Compatibility

The compatibility study of APIs and excipients is important for predicting the API's stability in the final pharmaceutical product. It's the initial stage of formulation development where API are compatible and stable with excipients. Compatibility studies were conducted using thermal and humid methods to evaluate the formulation's physical and chemical properties. As part of a preformulation study, a compatibility study of API with individual excipients was prepared using physical blends, employing analytical methods to evaluate drug-excipient interactions. The most commonly used pharmaceutical analytical method include, thermal, and humid or non-thermal techniques such as Thermogravimetric Analysis (TGA), Differential Scanning Calorimetry (DSC), Hot stage microscopy (HSM) and Isothermal Microcalorimetry (IMC) etc, and humid or non-thermal techniques such as Infrared, Near-Infrared, UV Visible Spectrophotometric (UV), and Raman Spectroscopy (FT-IR), (NIR), Powder X-Ray Diffraction (PXRD), Solid-State Nuclear Magnetic Resonance Spectroscopy (ssNMR), Microscopic method: Scanning Electron Microscopy (SEM), Chromatographic techniques: High-Performance Liquid Chromatography (HPLC) and Thin Layer Chromatography (TLC) etc. [36-38]

Preformulation Parameters: For the solid dosage form of the API and excipients, the physical and chemical properties of the drug substance are investigated to guide the development of a suitable, safe, effective, stable, and bioavailable pharmaceutical dosage form. Suitable parameters of preformulation, such as particle size, shape, pH, and pKa determination, temperature, common ion effect, partition coefficient, solubility, melting point, dissolution rate, powder flow properties, bulk density, tapped density, Hausner Ratio, compressibility index, crystallinity, hygroscopicity, polymorphism, stability study, and drug excipient compatibility, etc. While other dosage forms are studied according to the importance of preformulation parameters before the start of formulation development. [31-39]

Drug-excipient compatibility and formulation stability do not depend on the API only, but are also affected by the excipient. Excipients play an important role in the dosage form, but, side by side, they also increase compatibility issues, so proper selection of excipients is very important in the development of a formulation. Incompatibility can result mainly in any of the following changes: Changes in organoleptic properties, changes in dissolution performance, decrease in potency, and increase in degradation rate, etc. [40-45]

Drug-excipient physicochemical characterization is a systematic approach to designing therapeutically active and stable dosage forms. The new developments in formulation

have led to increased interest among formulation scientists in the roles and functions of excipients. In the present study, Reserpine was proposed, and excipient compatibility studies are major concepts in any API development process, as they relate to formulation efficacy, safety, quality, and stability. In the API development process, a detailed characterization of the API and other formulation components is usually carried out during the preformulation stage, with different excipients commonly used in the formulation development of the reserpine tablet for oral administration.

MATERIALS AND METHODS

Reserpine and all excipients (Lactose, Lactose DC Grade HPMC K 100 LV, HPMC K 100 M, MCCP 102, Aerosil, Mag. Stearate) as a gift from HiGlance Laboratories Pvt. Ltd., India.

Equipment

Fourier Transform Infrared (FTIR) spectrometer (Agilent Carry 630), Melting Point Apparatus (Veego), Balance, Humidity Chamber.

Preformulation studies

Preformulation studies are initiated to define the agent's physical and chemical properties. The key goals of preformulation studies are to ensure the delivery of a drug product with acceptable stability, bioavailability, and manufacturability.

Melting point determination of Reserpine

The most common and most basic method of estimation is the capillary method. The melting point of Reserpine was estimated using the capillary method; a one-sided closed capillary filled with the drug was placed in the Melting Point Apparatus. The temperature at which a solid drug changed into a liquid was noted.

Drug-excipient compatibility studies

A physical mixture of Reserpine and all excipients was prepared in a 1:1 ratio and subjected to analytical methods, such as FTIR spectroscopy. FTIR spectra of both pure drug and physical mixes were obtained, and the spectra graphs of the drug and the mixture of all excipients with the drug were compared for any incompatibilities.

FTIR Spectroscopy Study

FTIR study: The KBr-disc method was used to record the FTIR spectra, and KBr pellets were prepared at a 1:100 ratio of sample to KBr. FTIR spectra were recorded using an FTIR spectrometer in a range of 4000-400 cm^{-1}. Different functional groups of the test compound are identified by their distinctive vibrational frequencies using FTIR spectroscopy. FTIR spectra were used to investigate interactions in the physical mixture of the API and the excipient by shifts in peak positions to higher or lower wavenumbers and by the appearance or disappearance of characteristic functional group peaks of the pure API in the physical mixture. FTIR spectroscopy study was performed to check the compatibility between the API and different excipients in the amount (5 mg: 5 mg) as a ratio (1:1), as shown in Table 1. The FTIR spectra of the API alone and with all the individual excipients were obtained using the KBr method and compared with the standard FTIR spectrum of the pure API. An infrared spectrophotometer is used not only to determine the compatibility of excipients with the API but also to identify the API.

Preparation of IR Samples

The sample was determined by the disc method. Triturate 5 mg of the substance to be examined with 300-400 mg of finely powdered and dried potassium bromide R or potassium chloride R. Each excipient was mixed with Reserpine equally, then potassium bromide is added to the mixture. Carefully grind the mixture, spread it uniformly in a suitable die, and submit it to a pressure of about 800 MPa (8 $t \cdot cm^{-2}$). Then the tablets were inserted into the device, and the Infrared spectra were recorded in the mid-infrared light at wavenumbers from 4000 cm^{-1} to 400 cm^{-1}. After that, the spectra were compared with the reference.

Infrared Spectral Study of Samples at 40°C ±2°C, 75% ± 5%

Compatibility studies were performed by preparing a blend of different excipients with Reserpine at 40°C ± 2°C and 75% ± 5%.

Table 1: The Drug and Excipients Compatibility Studies

S. No.	Materials	Excipient: Drug
1.	Reserpine	1
2.	Reserpine + Lactose DC Grade	1:1
3.	Reserpine + HPMC K 100 LV	1:1
4.	Reserpine + HPMC K 100 M	1:1
5.	Reserpine + MCCP 102	1:1
6.	Reserpine + Aerosil	1:1
7.	Reserpine + Mag. Stearate	1:1

RESULTS AND DISCUSSION

Preformulation studies

Melting point determination of Reserpine

The melting point of pure Reserpine was determined by the open capillary method. The capillary tube was closed at one end by fusion and was filled with Reserpine by repeated tapping. The capillary tube was placed in a digital melting point apparatus. The instrument was set to automatically increase the temperature of the heating bath. The rise in temperature was observed on the screen. The temperature at which the drug started melting was recorded. The melting point range of Reserpine was identical to the reference melting point reported in MP (239-241.5°C). The sample started to melt at 241°C, and turned into liquid at 241.5°C, indicating that the sample used is pure. The melting point of reserpine was found to be consistent with pharmacopeial limits, as shown in Table 2.

Table 2: Results of Melting Point of Reserpine

Test	Test Temp Rang Analysed (Melting)	Results
Test I Reserpine	240.8–241.5 °C	241.2 °C
Test II Reserpine	240.6–241.3 °C	241.0 °C

Characterization of Reserpine by FTIR

FTIR spectrum studies indicated that major functional groups peak present in Reserpine and excipients compatibility IR spectrum initial to after 14 days shows in Figures (1) to (7) and initial to after 28 days peaks shows in Figures (8) to (14) observed at different wave numbers and the functional group associated with these peaks for drug and drug with different excipients at 40°C ± 2 °C, 75 % ± 5 %. The major peaks are identical to functional group of Reserpine. Hence, it was confirmed that the drug was compatible with various excipients, indicating that no interaction occurred between the drug and the formulation excipients.The spectral similarity indices obtained from FTIR analysis under accelerated stability conditions are presented in Table 3.

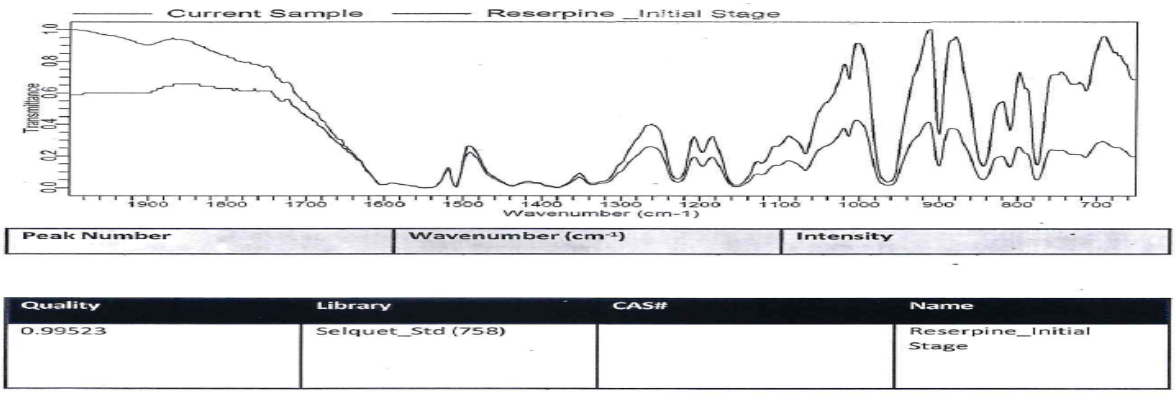


Fig. 1: IR of Reserpine

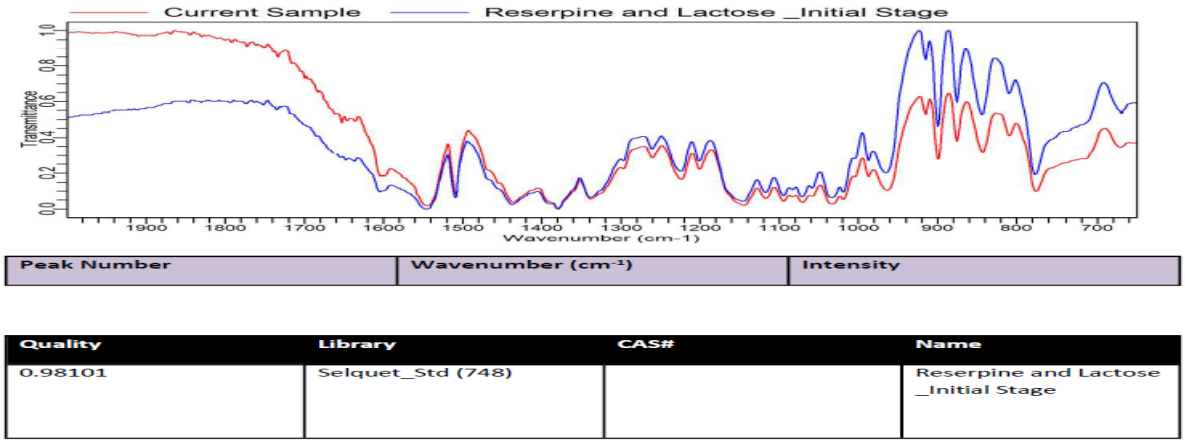


Fig. 2: IR of Reserpine with Lactose DC Grade.

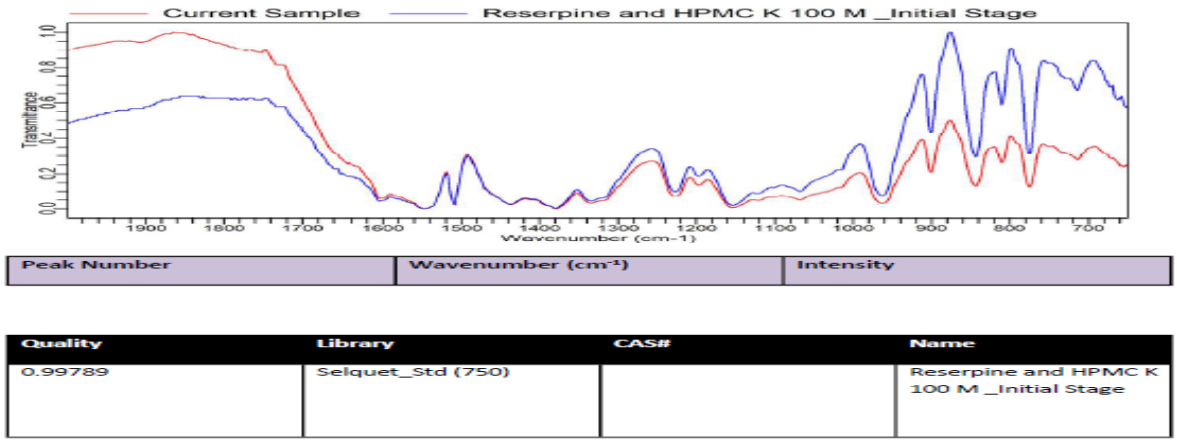
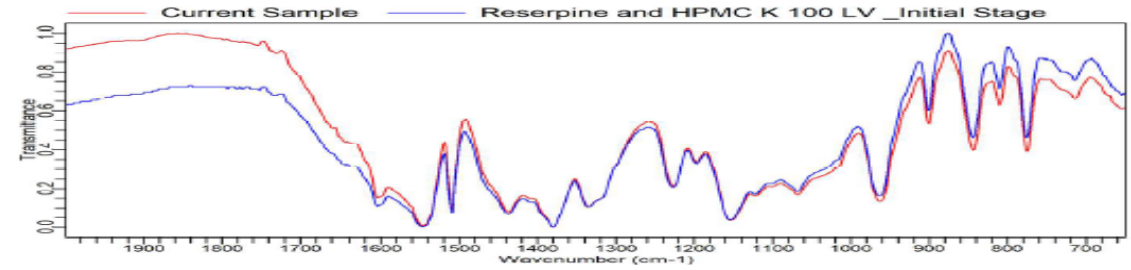


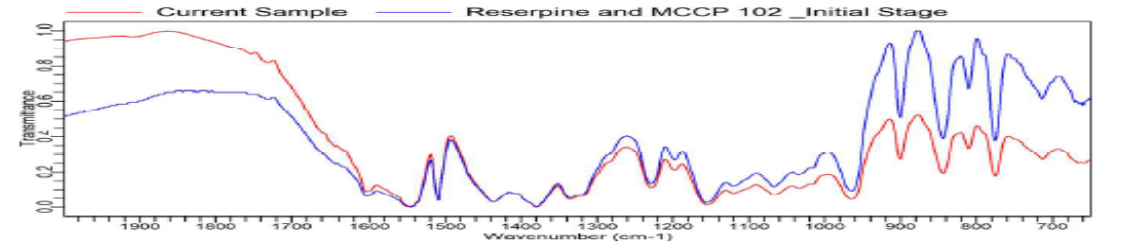
Fig. 3: IR of Reserpine with HPMC K 100 LV



Peak Number	Wavenumber (cm⁻¹)	Intensity

Quality	Library	CAS#	Name
0.99727	Selquet_Std (749)		Reserpine and HPMC K 100 LV _Initial Stage

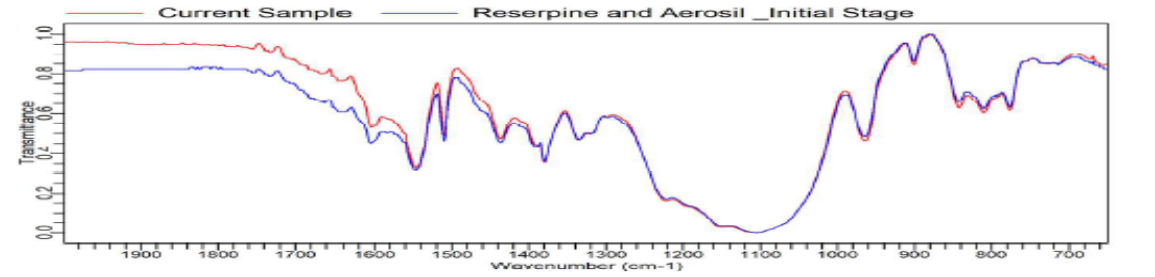
Fig. 4: IR of Reserpine with HPMC K 100 M



Peak Number	Wavenumber (cm⁻¹)	Intensity

Quality	Library	CAS#	Name
0.99878	Selquet_Std (751)		Reserpine and MCCP 102 _Initial Stage

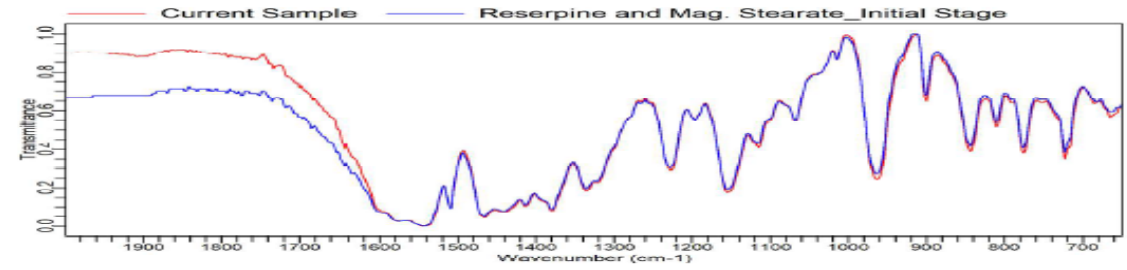
Fig. 5: IR of Reserpine with MCCP 102



Peak Number	Wavenumber (cm⁻¹)	Intensity

Quality	Library	CAS#	Name
0.99735	Selquet_Std (752)		Reserpine and Aerosil _Initial Stage

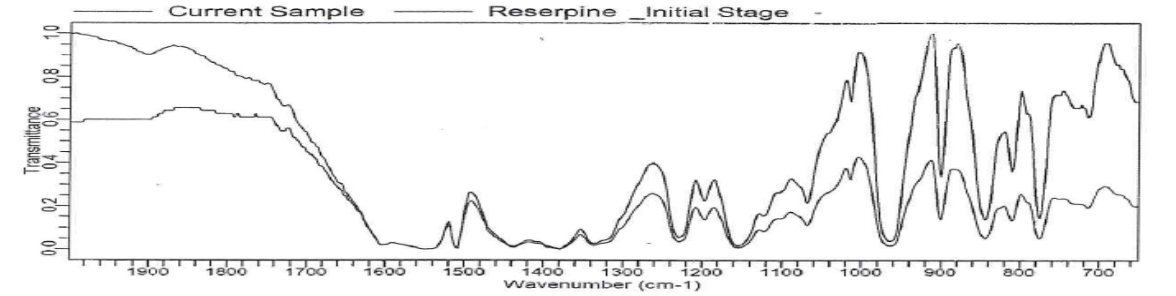
Fig. 6: IR of Reserpine with Aerosil



Peak Number	Wavenumber (cm⁻¹)	Intensity

Quality	Library	CAS#	Name
0.99603	Selquet_Std (753)		Reserpine and Mag. Stearate_Initial Stage

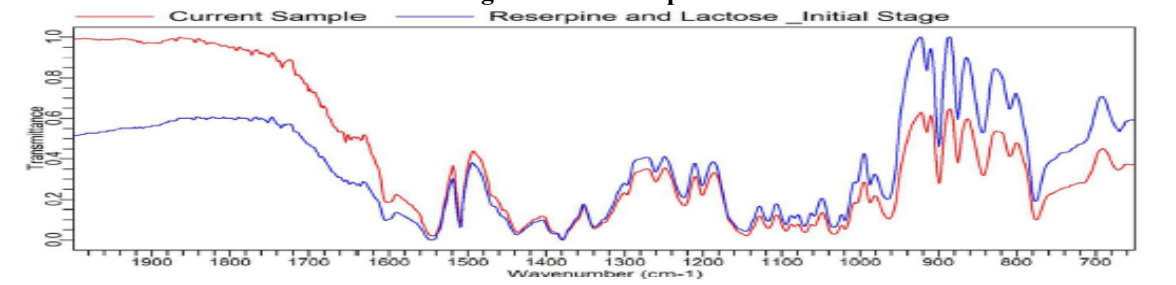
Fig. 7: IR of Reserpine with Magnesium Stearate



Peak Number	Wavenumber (cm⁻¹)	Intensity

Quality	Library	CAS#	Name
0.99412	Selquet_Std (758)		Reserpine_Initial Stage

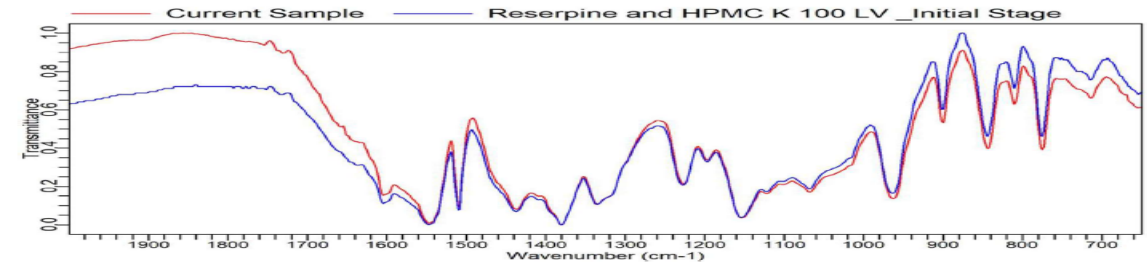
Fig. 8: IR of Reserpine



Peak Number	Wavenumber (cm⁻¹)	Intensity

Quality	Library	CAS#	Name
0.98022	Selquet_Std (748)		Reserpine and Lactose _Initial Stage

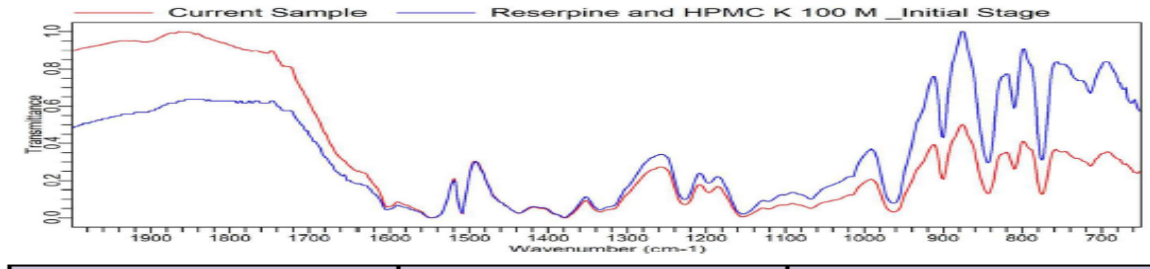
Fig. 9: IR of Reserpine with Lactose DC Grade



Peak Number	Wavenumber (cm⁻¹)	Intensity

Quality	Library	CAS#	Name
0.99513	Selquet_Std (749)		Reserpine and HPMC K 100 LV _Initial Stage

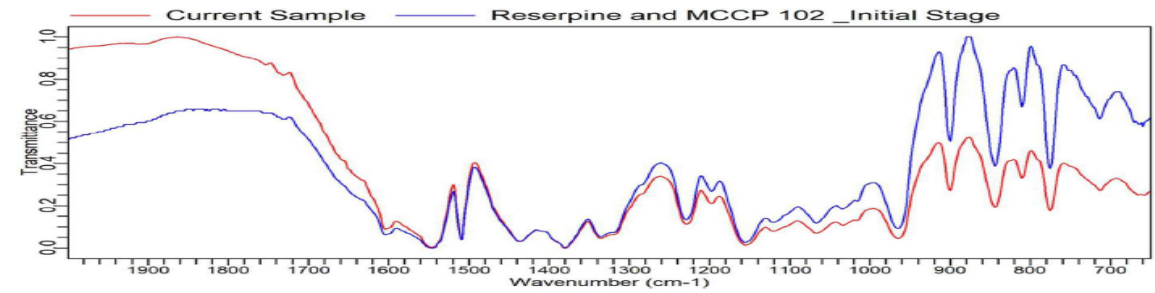
Fig. 10: IR of Reserpine with HPMC K 100 LV



Peak Number	Wavenumber (cm⁻¹)	Intensity

Quality	Library	CAS#	Name
0.99055	Selquet_Std (750)		Reserpine and HPMC K 100 M _Initial Stage

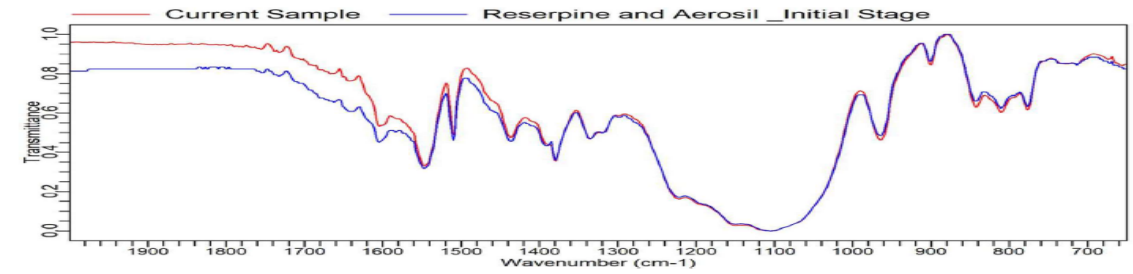
Fig. 11: IR of Reserpine with HPMC K 100 M



Peak Number	Wavenumber (cm⁻¹)	Intensity

Quality	Library	CAS#	Name
0.99204	Selquet_Std (751)		Reserpine and MCCP 102 _Initial Stage

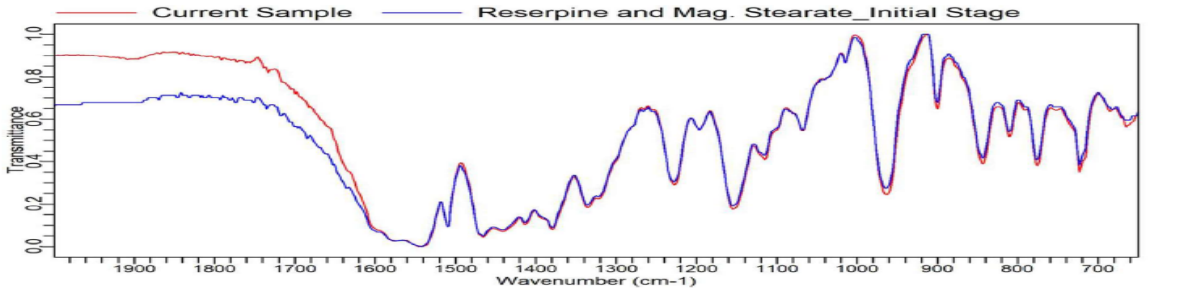
Fig. 12: IR of Reserpine with MCCP 102



Peak Number	Wavenumber (cm⁻¹)	Intensity

Quality	Library	CAS#	Name
0.99109	Selquet_Std (752)		Reserpine and Aerosil _Initial Stage

Fig. 13: IR of Reserpine with Aerosil



Peak Number	Wavenumber (cm⁻¹)	Intensity

Quality	Library	CAS#	Name
0.99311	Selquet_Std (753)		Reserpine and Mag. Stearate_Initial Stage

Fig. 14: IR of Reserpine with Magnesium Stearate

Table 3: FTIR spectral similarity indices of reserpine–excipient mixtures under accelerated conditions

S. No.	Materials	Quality Results at 40°C ±2°C, 75% ± 5%	
		Initial day to After 14 days	Initial day to After 28 days
1.	Reserpine	0.99523	0.99412
2.	Reserpine + Lactose DC Grade	0.98101	0.98022
3.	Reserpine + HPMC K 100 LV	0.99727	0.99513
4.	Reserpine + HPMC K 100 M	0.99789	0.99055
5.	Reserpine + MCCP 102	0.99878	0.99204
6.	Reserpine + Aerosil	0.99735	0.99109
7.	Reserpine + Mag. Stearate	0.99603	0.99311

CONCLUSION

It was concluded that Reserpine was compatible with various excipients selected for the formulation development of the sustained-release tablet, and that all excipients were

stable with Reserpine, as determined by IR. The results demonstrate that reserpine is compatible with the selected excipients and that preformulation studies play a crucial role in the development of sustained-release formulations.

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