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In-Vitro Evaluation of Lincomycin Hydrochloride Combined with Binary Plant Extracts of *Moringa oleífera* and *Solanum lycopersicum*: Method Development, Validation, and Compatibility Studies

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ABSTRACT

The present study reports the formulation, analytical validation, and In-Vitro evaluation of Lincomycin Hydrochloride combined with ethanolic extracts of *Moringa oleífera* and Solanum lycopersicum, aiming to explore potential synergistic antimicrobial and pharmaceutical benefits. The formulation was developed using lincomycin as the active pharmaceutical ingredient along with pharmacopeial excipients selected through compatibility and accelerated stability studies. Comprehensive pre-formulation and post-formulation evaluations were conducted to assess physicochemical properties, content uniformity, and stability of the developed dosage form.. The validated method demonstrated satisfactory system suitability, accuracy, precision, linearity, robustness, and recovery. Comparative In-Vitro dissolution studies were performed in 0.1 N HCl (pH 1.2), acetate buffer (pH 4.5), and phosphate buffer (pH 6.8). The optimized formulation achieved more than 85% drug release within 15 minutes and exhibited acceptable similarity ($f_2 > 50$) and difference ($f_1 < 15$) factors relative to reference lincomycin capsules. This approach may offer a promising strategy for developing

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plant-augmented antibiotic formulations suitable for local pharmaceutical manufacturing and regulatory compliance.

Keywords: Lincomycin Hydrochloride formulation; Plant-based antibiotic synergy; *Moringa oleifera; Solanum lycopersicum*; *In Vitro* Dissolution Testing

INTRODUCTION

Antimicrobial resistance increase and the appearance of adverse drug reactions remain significant issues in contemporary medicine. Among the frequently used antibiotics, lincomycin hydrochloride is a member of the lincosamide group and a semi-synthetic derivative of the earlier-used antibiotics such as lincomycin and chlortetracycline (1). In comparison to its parent compared to its parent compound, the hydrochloride form of this antibiotic is Lincomycin hydrochloride is superior in its therapeutic efficacy because of its pharmacologic properties as a bacteriostatic antibiotic: it prevents the synthesis of bacterial proteins (2).

It acts by binding reversibly to the 30S ribosomal subunit and thus inhibiting the binding of aminoacyl-tRNA and thereby interfering with the extension of the peptide chains in the process of protein synthesis. This step prevents the growth of bacteria and doubling.Due to this action, lincomycin hydrochloride is active against a number of key microorganisms such as Cutibacterium acnes, Chlamydia trachomatis, Mycoplasma pneumoniae and a number of Rickettsia species. However, in spite of these strengths, lincomycin hydrochloride also has some weaknesses including potential chemical stability problems, adverse side effects and difficulty in effective drug delivery in some of its dosage forms, new pharmaceutical research is increasingly looking at the use of natural plant based compounds in drug formulations.

Moringa oleífera and *Solanum lycopersicum* have undergone considerable scientific attention as phytochemical extracts due to the abundance of antimicrobial, antioxidant, and anti-inflammatory activity demonstrating a wide range of bioactive compounds including: flavonoids, phenolic compounds, tannins, and essential vitamins (3).*Moringa oleífera* possesses many bioactive phytochemicals which may be used synergistic with conventional antibiotics with excellent antimicrobial, activity In a similar fashion, it has been proven to be effective to use extracts of both *Moringa oleífera* and *Solanum lycopersicum* (tomato) due to their high amounts of lycopene, vitamins and other phenolic chemicals, which offer significant biological activity such as antioxidant and antimicrobial properties (4).The probable impact of a co combination of both *Solanum lycopersicum* (tomato) and *Moringa oleífera* could be a combination of both which lead to enhanced stability and therapeutic efficacy of pharm (5).

The study consists of a number of important stages, which are pre-formulation studies, formulation development, post-formulation evaluation, analytical method validation, In-Vitro dissolution studies, and compatibility studies. Through all these measures, it is hoped that the study will enhance the overall performance of the drug formulation and favor the use of cost-effective and environmental-friendly natural additives (6).In the end, the findings of the study can be used to develop more effective treatment methods of bacterial infections and inflammatory heart diseases of the skin (7).

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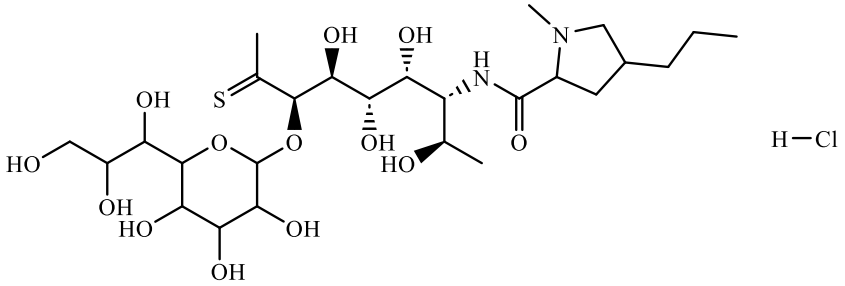

Figure 01 Chemical Structure of Lincomycin Hydrochloride

EXPERIMENTAL

Materials

The extracts of the beneficial *Moringa oleífera* and *Solanum lycopersicum* were combined into a binary mixture and then stuffed into the high grade pharmaceutical grade hard gelatin capsules, which were obtained via trusted and certified suppliers.The active pharmaceutical ingredient was the Lincomycin Hydrochloride (HCl),and the specification of the United States Pharmacopeia (USP), British Pharmacopoeia (BP) and European Pharmacopoeia (Eur. Ph.), was satisfied. In the study, the known potency Standard of analytical calibration of the *Moringa oleífera* leaf extract was utilized, method validation, and quantitative estimation (8).

The extraction of *Moringa oleífera* leaves to obtain the extract using ethanol as the extracting solvent was expected to provide possible synergistic effect with the Lincomycin HCl (9).On the same defeat, the alcoholic method was used to obtain tomato fruit extract to obtain ripe tomatoes. The preliminary phytochemical screening and compatibility studies were decided to be balanced in focusing on a ratio of selected mixture between binary mixture as consequential of combining extract of *Oleifera moringa* and *Solanum lycopersicum* to yield a binary mixture (10).The idea was to determine whether or not the antimicrobial activity is likely to be enhanced when the combination gets incorporated with the Lincomycin HCl (11).Magnesium stearate to act as a friction reducing agent so that it becomes easier to fill up the capsule without much difficulty (12).

The glidant employed was aerosil 200 (colloidal silicon dioxide) that increases flow of the powder and reduces agglomeration of the particles to provide uniformity in the fill weight of the capsule (13). Lacticose monohydrate or microcrystalline cellulose diluents were optional to enhance volume properties, compressibility and overall flow properties of powder blend that could be taken orally.

Powder fill measured was appropriate in these capsules and they were within the blend developed. The bioactive extract of the plant materials was prepared with Ethanol (95%). When necessary in extraction and dilution process, pharmacopeial quality purified water was utilized. Other *In Vitro* studies had observed that the solubility and dispersion of plant extracts into the aqueous media was enhanced by the use of Tween-80, a non-ionic surfactant. All choice of formulation components selection was informed by literature available, compatibility factors and compatibility in an oral capsule formulation. Special intention was to use the plant extracts to test the potential synergistic antimicrobial effect in the presence of Lincomycin HCl when the In-Vitro

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consideration is conducted.

Methodology

Moringa oleífera and *Solanum lycopersicum* binary mixture in capsules, which were made of hard gelatin, were utilized along with Lincomycin Hydrochloride (HCl) that was in high quality with known suppliers (14).The pharmaceutical grade Lincomycin HCl was purchased in accordance with the recommendations that were established by the United States Pharmacopeia (U.S.P.), the British Pharmacopoeia (B.P.), and the European Pharmacopoeia (Eur. Ph.) (15).Analytical validation and quantification of assays were performed by the use of a certified reference standard of Lincomycin HCl. Mrollinga oleifera leaf extract Ethanol extract of authenticated foliage was used to extract bioactive phyto-chemicals which possess antimicrobial properties and also enhance the synergistic effect with Lincomycin HCl (16).The extract obtained is the *Solanum lycopersicum* fruit extract obtained as an alcohol extract of ripe tomatoes which was selected because of its antioxidant and antimicrobial properties. To create the binary mixture, a mix of these two extracts in some proportion that had been arrived upon based on the initial compatibility and phytochemical studies, Mg stearate was added as a lubricant to reduce friction between the inter-particles and equalize the mass of fill used to fill the capsules. Aerosil 200 (colloidal silicon dioxide) was incorporated as a glidant to inhibit agglomeration of powder and equalization of fill weight to fill the capsules. Microcrystalline cellulose or lactose monohydrate had been added as dispensable fillers or diluents to augment both compressibility and flow attributes of the powder blend. Oral route was chosen (size 0 hard gelatin capsules) which became appropriate in terms of fill weight (required) as well as in the mixture with the powder. They were extracted and diluted in a solvent, Ethanol, (95) which is the appropriate solvent to extract bioactive compounds off the plant materials as well as in their mixture with the powder. Where this data were In-Vitro studies, nonionic surfactant to solubilize plant extracts was added (tween-80). Individual materials were chosen based on compatibility tests done previously, literature and compatibility to oral capsule preparations. In order to test the hypothesis of synergistic action of the mixture of plant extracts and Lincomycin HCl in *In-Vitro* tests, both were mixed.

Reagents and Chemicals for Analytical Studies

In qualitative and quantitative analysis, chemicals and solvents used were of high purity and of analytical grade. These were hydrochloric acid, purified water, sodium acetate, glacial acetic acid, monobasic potassium phosphate, sodium hydroxide, phosphoric acid, 2methyl 2propanol, dipotassium hydrogen orthophosphate, tetrabutyl ammonium hydrogen phosphate, sodium edetate, and sodium metabisulfite. Certified suppliers were used to find all reagents, and only substances of an analytical-grade were utilized to ensure accuracy, predictability, and compliance with pharmacopeial standards (17).These reagents were primarily employed in the production of mobile phases, buffers and solutions required in high-performance liquid chromatography (HPLC), UV spectrophotometry of samples, dissolution testing, and Karl Fischer titrations of the moisture content. Amber volumetric flasks have been identified to minimize light degradation of Lincomycin HCl during solution preparation because it is sensitive to light (18).

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Equipment

The formulation and evaluation procedures were done in the presence of valid, accurately calibrated laboratory instruments. Reference standards, working standards, and sensitive reagents were stored in a refrigerator under controlled conditions to ensure they were not destroyed. Chromatographic separation, quantification, and purity determination of Lincomycin HCl was performed using the HPLC system with a stationary phase column (4.6 mm x 25 cm, 5 um, C8 type). The rapid drug content determination and establishing calibration curves to validate the methods of method validation were performed using a UV-Visible spectrophotometer. *In Vitro* release testing (USP Type I 12-basket assembly) was conducted to determine the dissolution behavior of the developed capsules in imitated gastrointestinal conditions. A Karl Fischer apparatus was used to measure moisture content of raw material and end product. Solutions have been prepared with great precision using high-quality laboratory glassware such as amber-colored volumetric flasks, beakers, and graduated pipettes. Every instrument was calibrated using standard operating procedures (SOPs) before it was used (19).

Pre-Formulation Studies

Before the actual formulation, pre-formulation research was conducted to investigate the drug physical and chemical properties of Lincomycin HCl and its responses with excipients. These were: Organoleptic evaluation, which worked in determining the appearance, color, and scent of the active pharmaceutical ingredient (API); solubility profiling, done in water and different buffer solutions to guide the development of dissolution testing methods; FTIR compatibility analysis between the API and the excipients (Magnesium Stearate, Aerosil-200) to determine whether any chemical interactions were present, and thus to determine whether the powder blend would be satisfactory when used as a filling in the capsules, and, lastly, the micromeritic tests, determining (20).

Formulation Development

Mixing and encapsulation preparation of the Lincomycin HCl capsules were done. Geometric mixing was carefully done in a clean, dry stainless steel vessel with measured portions of the active pharmaceutical ingredient (API), plant extracts and excipients. During the mixing process, the drug and extracts first were mixed with Aerosil-200, which enhances uniformity and flow but then the lubricant magnesium stearate is added in the last mixture. The uniform mixture was then poured into capsules of size #0 hard gelatin through a semi-automatic capsule filling apparatus. The capsules filled were put in amber-colored containers to ensure that they were not degraded due to light exposure.

Table# 01 Scale up of Tetracycline formulation Development:

Sr. No.	Raw Material	Role of Ingredient

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1	Lincomycin Hydrochloride (HCl)	Active Pharmaceutical Ingredient (API)
2	Binary Mixture Extract (*Moringa oleífera* + Solanum lycopersicum)	Herbal synergistic antimicrobial and antioxidant agent
3	Colloidal Silicon Dioxide	Glidant to improve powder flow and prevent agglomeration
4	Pregelatinized Starch (Corn)	Binder and flow enhancer for uniform blend
5	Empty Gelatin Capsule Shell #0 (Dark blue cap, light blue body)	Encloses and protects the formulated powder blend

Post-Formulation Assessment

The Lincomycin Hydrochloride (HCl) capsules prepared using binary extract mixture of *Moringa oleífera* and *Solanum lycopersicum* passed through various physicochemical tests to check the compliance with pharmacopeial standards as well as test the quality and stability of the formulation. Weight Variation Test: To test the conformity to pharmacopeial standards; twenty capsules were randomly selected and weighed both individually and as a group. The weight average was computed and the weight was measured against that of the capsule to verify whether it adhered to the official pharmacopeial standards. Disintegration Test: Uniformity in filling capsules and assay of disintegration in a clean purified water at 37 alone as 0.5 was carried out through standard disintegration apparatus. The time of complete disintegration was measured (21).Findings indicated that the capsules dissolved within the pharmacopeial dissolution limits, which indicated that they were appropriate to be administered orally and that they successfully released both the active pharmaceutical ingredient (API) and the herbal extracts. Dissolution Testing: Dissolution tests were performed at the controlled temperature of 37 + o.5 o C using the USP Dissolution Apparatus I (basket method). Dissolution medium: A demerit, The dissolution medium was low based on pretested solubility tests. Samples: The samples used were withdrawn at pre-programmed time points, and analyzed using a validated HPLC method or UV- Visible spectrophotometric analysis. Drug Content Uniformity: Individual capsules were analysed via validated HPLC method to determine homogeneity of the drug Lincomycin HCl in the formulation. Findings were presented as a percentage of the weight labelled and compared to pharmacopeial standards to verify the consistency and accuracy of dosage levels. Moisture Content Determination: Photometric determination of moisture was done by using Karl Fischer titration (22).Validity of Analysis: High-Performance Liquid Chromatography (HPLC) was used to analyze and ensure that the water content levels of the capsules containing Lincomycin Hydrochloride (HCl) stayed within pharmacopeial-acceptable limits, which does not cause Lincomycin Hydrochloride (HCl) to degrade, and maintains stability of the plant extracts incorporated. To precisely determine the active pharmaceutical ingredient (API) as well as the plant extracts, chromatographic separation was optimized using a C8 column and good mobile phase (23).

Validity The process was confirmed according to ICH guidelines as follows: Linearity It was tested during a specific range of concentrations, making standard Lincomycin HCl solutions. Calibration curves were drawn up and correlation coefficients

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determined to ensure linearity.- Accuracy and Precision: Accuracy was evaluated by means of recovery studies at different levels of concentration. Accuracy was measured through the repeatability (intra-day) and intermediate precision (inter-day) tests. Percentage recovery, and relative standard deviation (RSD) were reported as results to show the reproducibility.- Specificity: It was tested to determine that excipients, *Moringa oleífera* and *Solanum lycopersicum* extracts and any possible degradation product did not interfere with the ability of the method to detect or quantify Lincomycin HCl.- Robustness and Ruggedness: Robustness was assessed by deliberately changing the parameters of analysis, i.e., flow rate, mobile phase composition, and detection wavelength. Ruggedness was established through analysis of samples in various conditions and analyses performed by different analysts aiming at establishing the reliability of the analytical method applied in the formulated capsules. Complementary UV-Visible Spectrophotometric Analysis: A complementary UV-Visible spectrophotometric analysis was done to the samples in various conditions and by different analysts; hence establishing reliability of the analysis method used in formulated capsules.

RESULTS AND DISCUSSION

The volume of Lincomycin Hydrochloride (HCl) was altered according to its certified strength. The change in the required amount of the active pharmaceutical ingredient (API) after compensation at the potency was corrected by changes in the amount of Colloidal Silicon Dioxide in order to maintain the constant weight of capsules in the formulation of the combination of extracts of *Moringa oleífera* and *Solanum lycopersicum*.
The results are shown in the table below.

Table 02 Formulation Development

Sr. #	Raw Material	Role of Ingredient	Percentage per Capsule	Scale (mg/capsule)
1	Lincomycin HCl	Active Pharmaceutical Ingredient (API)	97.5%	585.0
2	Colloidal Silicon Dioxide	Glidant	1.2%	7.2
3	Pregelatinized Starch (Corn)	Lubricant	0.5%	3.0
4	Stearic Acid	Dissolution Enhancer	0.3%	1.8
5	Empty Gelatin Capsule Shell #0 (Dark Blue Cap, Light Blue Body)	To enclose medicine	---	102
Total weight of Contents/ capsule				600mg
Total weight of capsule with shell				702mg

The pictorial view of the working is elaborated as:
Step1

Annual Methodological Archive Research Review
http://amresearchreview.com/index.php/Journal/about
Volume 4, Issue 3 (2026)

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http://amresearchreview.com/index.php/Journal/about

Figure 02. Lincomycin (Final Mix)

Step-2

Figure-03 Lincomycin formulation development (Active Raw Material/ API) Step-3

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Volume 4, Issue 3 (2026)

Online ISSN 3007-3197
Print ISSN 3007-3189

http://amresearchreview.com/index.php/Journal/about

Figure-04 Lincomycin formulation development (at Intermediate/ After Encapsulation) Step-4

Figure-05 Lincomycin Finished Pharmaceutical Product (After Packaging) Packed in Alu-Pvc Foil

Adjustment and their outcomes in Analytical method Development (Contents By HPLC)

In 12.0 g of Sodium hydroxide pellets in 100 mL volumetric flasks and dilute up to the mark with water. As a mobile phase, add 9.0 mL of Phosphoric Acid in 650 mL of water and adjust with ammonium hydroxide to a pH of 6.2.Buffer solution: 520 mL
Acetonitrile: 105 mL
Methanol: 105 mL.Mix, shake well and degas by sonication and filter it through 0.45 µm membrane filter.

Chromatographic Conditions: Column: L7/C8 (4.6 mm × 25 cm),Detector λ: 220 nm,Flow rate: 1.0 mL/min,Injection volume: 30 µL,Column temperature: 47 ºC.
Introduction of the standard and sample solution into the chromatograph Using a 0.45 µm disc filter, add equal volumes of the standard and sample solution to the chromatograph and record the responses of the main peaks. The rel standard deviation of repeated injection of the standard solution is not to be more than 2.0 percent and the

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http://amresearchreview.com/index.php/Journal/about

tailing factor should not be greater than 1.3. Identify the percentage of Lincomycin HCl through a comparison of the main peak responses of both solutions of the standard and sample. To do this calibration, a solution was prepared by adding 2.0 mL of hydrochloric acid (usually 37%) to 45 mL of water and diluted to 500 mL with water. A reference solution (commercial product of Lincomycin HCl) was also prepared to use in this calibration.

Tablet # 04 Product Description for In-Vitro study both reference and test product

Description	Reference / Comparator Product	Test Product
Product Name	Novelink 500mg Capsule	Lecin 500mg Capsule
Composition	Each hard capsule contains: Lincomycin (U.S.P):…… 500 mg	Each hard Capsule Contains: Lincomycin (U.S.P):…… 500 mg
Lot #	NL-3542	T-001

Figure-08 Reference Product used for In-Vitro Study/Bioequivalenc

Results in chromatogram are sequentially elaborated as further:

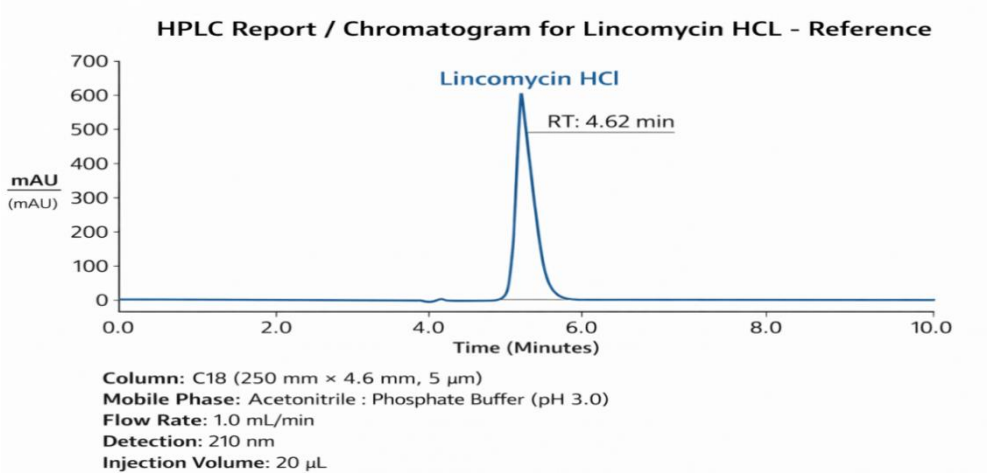

Figure-06 HPLC Report/ Chromatogram for Lincomycin HCl Reference

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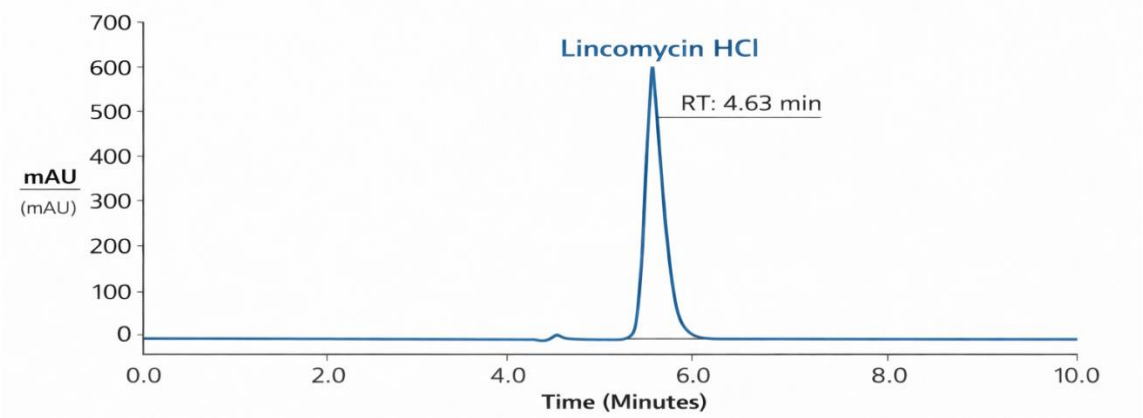

Figure-07 HPLC Report/ Chromatogram for Lincomycin Test Sample

Results of Comparative Dissolution Profile are as under:

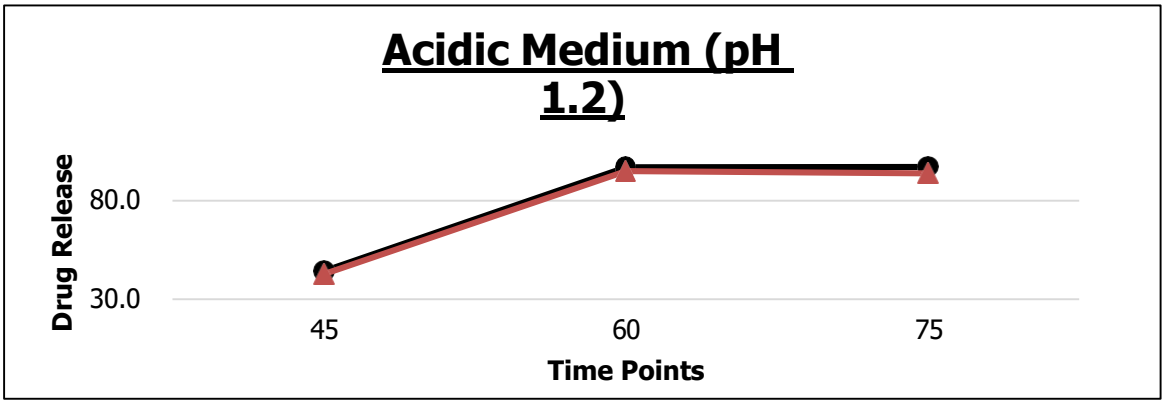

Figure-9 Graphically representation of CDP for reference and test product (pH 1.2)

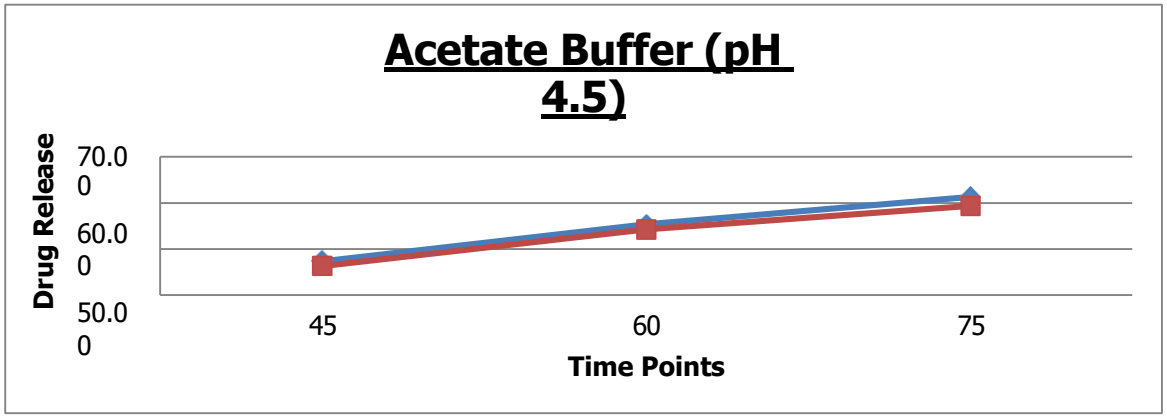

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Figure-10 Graphically representation of CDP for reference and test product (pH 4.5)

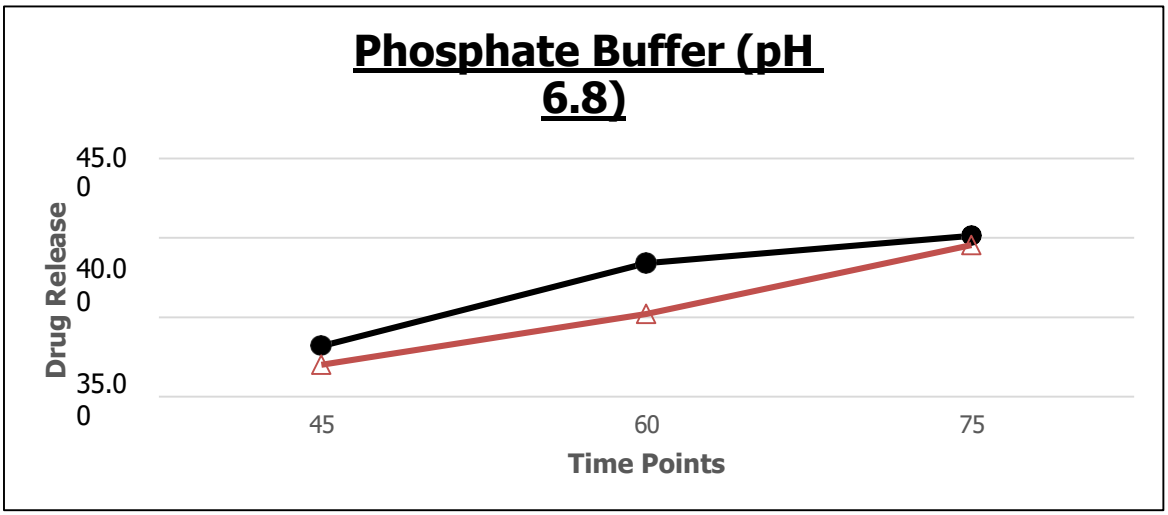

Figure-11 Graphical representation of CDP against reference and test product (pH 6.8)
The study included a comparative dissolution analysis in between the test product, Lincomycin HCl 600 mg Capsules with extraction of *Moringa oleífera* and *Solanum lycopersicum* and a reference one, Lincomycin HCl 600 mg Capsules (commonly available brand). The difference factor (f1) was observed to be 4.12% as well as the similarity factor (f2) of 75.46%. These values do not exceed the accepted regulatory limits (f1 less than 15 and f2 more than 50), which means that the dissolution profiles of the two products are highly similar. The test and the reference formulations mobilized over 80% of the drug within 70 minutes in an acidic medium, which is the necessary requirements of the immediate-release formulations. Moreover, the trend of dissolution showed a similarity between acetoate buffer (pH 4.5) and phosphate buffer (pH 6.8), which showed a uniform release of the drug at various physiological pH conditions.These findings can be seen as a confirmation that the test product meets the regulatory standards of similarity in its dissolution profile, thus providing strong evidence of *In Vitro* bioequivalence. As a result, the Lincomycin HCl capsules prepared using Moringa oleiciterra and *Solanum lycopersicum* extracts will have the same behavior concerning dissolution as the reference product and can be considered pharmaceutically identical (24).

Excipient compatibility study
A Description of the Drug-Excipient Samples is as under:

Table-05 Description of Tetracycline formulation under the compatibility study

Sr, #	RAW MATERIALS	Role of Ingredients	Percentage of Ingredients/cap.	Scale mg/capsule
1	Lincomycin HCl	**API**	98.33%	590.0*

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2	Colloidal silicon dioxide	Glidant	1.0%	6.0**
3	pregelatinized starch (corn)	Lubricant	0.33%	2.000
4	stearic acid	Dissolution Enhancer	0.33%	2.000
	Empty Gelatin Capsule shell#0 (Dark blue Cap and Light blue body)	To enclose medicine	----	100
Total weight of Contents/ capsule				600mg
Total weight of capsule with shell				700mg

Drug Substance-Excipient Compatibility Study:

Table 1 then prepared samples of the drug substance and excipients and stored at accelerated conditions (45 +/-2 C and 80 +/-5 relative humidity and one month) at the same time. HPLC analysis of the solid-state mixtures assessed drug-excipient compatibility and the findings are summarized in the Compatibility Study Report (Table 5). These compatibility results and past formulation experience were used to choose excipients. Moreover, the grades and suppliers of excipients were selected in accordance to their known stability in accepted oral dosage preparations.The active pharmaceutical ingredient, Lincomycin HCl, was found to be compatible with extensively used capsule excipients. Thus, functionally suitable pharmacopeial excipients were used in the formulation (25).The designation of all excipients in final formulation has been confirmed to be compatible, and are commonly employed in oral dosage formulations.Figures 7, 8, and 9 present major features of the development of Lincomycin HCl 600 mg oral dosage capsules of binary mixture extracts of *Moringa oleífera* and Solanum lycopersicum. The formulation was made in such a way that it was to provide uniform drug behavior, stability, and patient compliance. In general, the systematic formulation plan was utilized to maximize the choice of excipients, to guarantee consistency in filling the capsules, and to form reproducible manufacturing parameters that guarantee both the safety, quality, and stability of the end product.On the whole, the formulation plan and analytical validation show a scientifically valid process of development that leads to the safety, quality and stability of the final product. The information provided in the figures supports the argument that the formulated capsules were always up to the quality requirement.

Table-6 Excipients compatibility study results After one month storage at accelerated conditions

Excipient Compatibility Study After One Month (Temperature: 40°C±2°C, relative humidity 75%±5%).							
Sr. #	**Composition**	**Theoretical Contents**	**Concentration (mg/mL)**		**Area**		**%Age Of Contents**
			STD.	SPL.	Ave. Ref.	SPL.	
1.	Standard API	100%	0.30	0.30	2250000.0	2255000	100.03
	Standard						

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Online ISSN 3007-3197
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http://amresearchreview.com/index.php/Journal/about

2.	API + Colloidal silicon Dioxide	100%	0.30	0.30	2250000.0	2229000	99.74
3.	Standard API+ Starch (Corn)	100%	0.30	0.30	2250000.0	2224500	99.63
4.	Standard API + citric Acid	100%	0.30	0.30	2250000.0	2231000	99.9
5.	Standard API + Capsule Shell	100%	0.30	0.30	2250000.0	2256000	100.27

The chosen excipients in the solid oral preparation (Lincomycin HCl, which is identical to 600mg Lincomycin, mixed with extracts of *Moringa oleífera* and Solanum lycopersicum) were determined to be compatible as they did not react with each other negatively in one month under accelerated conditions (42 0 C -2 C, 78 percent RH -5 percent). Validation The analytical procedure to be applied to the capsules was confirmed to fulfill the requirements of ICH Guideline Q2 (R1), November 2005, by verifying its suitability in regular quality assurance. System suitability parameters such as, %RSD(1.8%), tailing factor (1.25), and theoretical plates (3600), were all under the acceptance parameters, which means that this system was precise in its operations and efficient in chromatography (26).The technique proved to be very specific and there was no interference due to placebo or blank samples with the retention time of the active ingredient in the test and standard solutions. Recovery studies were used to validate its accuracy, and the recovery was between 99.50% and 101.40, which is within acceptable limits. The test of robustness demonstrated that the method was not volatile during the period of 5 hours, including some slight fluctuations in pH, as the chromatographic behavior remained constant. High precision was also observed in the method with a repeatability and intermediate precision of 0.30% and 0.48% RSD, respectively. Moreover, it satisfied the criteria of linearity and range which strengthened its dependability. Overall, the approach was found to be correct, precise, specific, robust, and applicable in the intended analysis in the routed Lincomycin HCl capsules containing Moringa and Solanum extracts.

Discussion

Lincomycin HCl 600 mg Capsules is the development of the Lincomycin-HCl equivalent 600 mg of Lincomycin HCl infrastructure with binary extracts of Moringa olei and Solanum lycopersum that presented a robust formulation design with adequate analytical and stability information. The selected excipients met pharmacopeial requirements and were also authenticated in pre-formulation and accelerated compatibility analyses which guaranteed the stability and safety of the product.Relative dissolution testing demonstrated a high extent of analogicality to the reference product, Lincomycin HCl 600mg (commercial brand), bearing a difference factor (f1) of 4.12

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percent and a similarity factor (f2) of 75.46, as well as indicating identical dissolution profiles in various media that in *In Vitro* bioequivalence. The suitability of the systems under analysis, validated first by implementing the ICH Q2(R1) guidelines, was verified to be specific, accurate (with recovery rates of 99.50% to 101.40%), precise (repeatability and intermediate precision with a percentage deviation of less than 0.5%), robust, and linear, which guaranteed the reliability of the method in routine quality control. The stability tests conducted under the ICH-approved accelerated conditions (42 ° C ± 2 ° C / 78% RH ± 5) with a period of six months under the conditions indicated that the formulation remained physically and chemically stable with no significant alterations or interactions observed especially when packed my ALU-ALU blister packs. Comprehensively, these results prove the quality, safety, and adherence to legal requirements of the formulation to the success of its market authorization as a stable and effective oral dosage of Lincomycin HCl with attrition by *Moringa oleífera* and *Solanum lycopersicum* extracts **(27)**.

CONCLUSION

The creation of the Lincomycin HCl 600 mg Capsules, Lincomycin (synonymous to Lincomycin HCl 600mg) complemented by binary extracts of *Moringa oleífera* and *Solanum lycopersicum* presented an excellent formulation design that was backed by good data of analytical and stability.The selected excipients were pharmacopeial and underwent the pre-formulation and accelerated compatibility tests; these tests were necessary to assure that the product would be stable, effective, and safe. Similarity to the reference product, Lincomycin HCl 600 mg (commercial brand), was observed with comparison of dissolution degree of 4.12 percent and similarity factor (f2) of 75.46 per cent confirming the similar dissolution profile in various media hence the *In Vitro* bioequivalence. The test product and reference product both liberated more than 80% of the drug within 70 minutes, thus qualifying as an immediate-release product and exhibiting similar action in acidic and buffered conditions.System suitability, specificity, accuracy (with a recovery of 99.50% to 101.40%), precision (repeatability and intermediate but linear), and robustness, as well as linearity, were ensured by validation of the analytical method, as per the instruction to ICH Q2(R1), and reliability of the method in daily quality control of the capsules. One month stability tests at an accelerated condition (42f C +2f C / 78percent RH +5 percent) showed that the formulation was stable both physically and chemically, and no noticeable changes or interactions were reported. Light and moisture sensitiveness in the ALU-ALU blister packs added extra protection to the product quality in the storage. In general, these results affirm the formulation as quality, safe, and regulatory; thereby making the Lincomycin HCl 600 mg Capsules with *Moringa oleífera* and *Solanum lycopersicum* extracts a scientifically sound and market-ready oral dosage form with demonstrated *In Vitro* bioequivalence.

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