iJRASET
International Journal For Research in Applied Science and Engineering Technology



INTERNATIONAL JOURNAL FOR RESEARCH

IN APPLIED SCIENCE & ENGINEERING TECHNOLOGY

Volume: 13 **Issue:** VIII **Month of publication:** August 2025

DOI: https://doi.org/10.22214/ijraset.2025.73580

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International Journal for Research in Applied Science & Engineering Technology (IJRASET)
ISSN: 2321-9653; IC Value: 45.98; SJ Impact Factor: 7.538
Volume 13 Issue VIII Aug 2025- Available at www.ijraset.com

Formulation and Evaluation of Osmotic Tablet of Lovastatin

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Abstract: ***Lovastatin is one of the antihypertensive drug used to control the high blood pressure. Osmotically Controlled release tablet of Lovastatin was performed for reducing dosing frequency and patient compliance. Elementary osmotic tablets of Lovastatin were developed using Sodium chloride as a key ingredient which gives osmogent property which provides driving force inside the core tablet and which leads to release of drug. Microcrystalline cellulose used as a release retardant material in the present work. These formulations were evaluated for, Hardness, Flow property, Thickness, Friability, Drug content and In-vitro drug release. Tablets were coated with a semipermeable membrane using 5% w/v cellulose acetate(CA) in acetone and PEG 400(1%) used as Plasticizer. Coated Elementary osmotic tablets were drilled for delivery orifice using standard micro drill of diameter size 0.8mm. Drug release rate was increased as the increase in the concentration of sodium chloride and release rate decreased on increasing the concentration of MCC. Drug release rate was directly proportional to delivery orifice size. SEM Study carried out for detection of diameter size of delivery orifice. The FTIR studies demonstrate that there was no interaction between polymer and drug. The optimized formulation was stable for 3 months of accelerated stability study.***
Keywords: Lovastatin Hydrochloride, Controlled release, Elementary osmotic Tablet, Semipermeable membrane, Cellulose Acetate.

I. INTRODUCTION

Oral drug delivery is the most accepted and used route of administration when compared to all the other routes that have been known for the delivery of drugs[1]. Conventional oral drug delivery systems release the drug immediately, in which its release of the drug cannot be controlled and cannot maintain effective concentration at the site of action or target for longer time[2]. These make the way forward for the development of other modified release drug delivery system. Most modified release delivery system classified into the followin categories:

- Delayed-release
- Extended-release
- Site-specific targeting
- Receptor targeting

All modified-release products improve the drug therapy over that achieved with their conventional counterparts.
There are several potential advantages of modified release systems over conventional dosage forms such as

- ✓ Increase patient compliance
- ✓ Employ less total drug

Sr. No.	Name of Chemical	Name of Supplier
	Lovastatin	Gift Sample from Vama Pharma (Nagpur)
	Aerosil	Shree Sadguru Hightech Pvt Ltd, Pune
	NaCl	Shree Sadguru Hightech Pvt Ltd, Pune
	Lactose	Shree Sadguru Hightech Pvt Ltd, Pune
	PVP K 30	Shree Sadguru Hightech Pvt Ltd, Pune
	Polyethylene oxide	Shree Sadguru Hightech Pvt Ltd, Pune
	Magnesium Stearate	Shree Sadguru Hightech Pvt Ltd, Pune
	Ethanol	Shree Sadguru Hightech Pvt Ltd, Pune

Elementary method

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The osmotic core tablets of Lovastatin were prepared by Wet granulation method. Required amount of Lovastatin, Aerosil, Sodium Chloride, Lactose and Polyethylene oxide were weighed accurately. It was blended in blender and then passed through sieve #85. IPA was used as granulating agent. It was added slowly during the granulation process to get proper granules. PVP K-30 was used as a binder. The granules were dried in Tray drier at 50ºC
for 20-25 minutes. Then they were passed through sieve #30 to get uniform sized granules and blended with magnesium stearate and talc as a lubricant and glidant respectively. Then desired amount of granules compressed into tablets having an average weight of 200 mg using a multistation tablet-punching machine fitted with 7.2 mm standard convex punches.
The tablets were coated by conventional pan coating method. Cellulose acetate was selected as semi permeable, pH independent polymer. Coating solution was prepared by dissolving cellulose acetate in a solution of Ethanol: Acetone (50:50). PEG 400 was added as a plasticizer. The coating was carried out by a conventional pan coater. The operating condition was maintained as follows: pan size 6 inch, pan speed 30-35 rpm, spray rate 8-10 ml/min, air temperature 20–25°C, and atomization air pressure 1-1.5 bar. The coated tablets were dried at 35–40°Cfor 4 hours. The formulated coated tablets, a small orifice were drilled through one side of each coated tablet by standard mechanical drilling technique using 0.8 mm needle to obtain uniform orifice.

Table 6.3: Formula of Lovastatin Osmotically Controlled Release Tablet

Ingredient (mg)	1	2	3	4	5	6	7	8	9
Lovastatin	20	20	20	20	20	20	20	20	20
Aerosil	80	80	80	100	100	100	120	120	120
NaCl	5	10	15	5	10	15	5	10	15
Lactose	60	55	50	40	35	30	20	15	10
PVP K 30	15	15	15	15	15	15	15	15	15
Polyethylene oxide	15	15	15	15	15	15	15	15	15
Magnesium Stearate	2	2	2	2	2	2	2	2	2
Talc	3	3	3	3	3	3	3	3	3
Total Weight	200	200	200	200	200	200	200	200	200

II. COATING SOLUTION

Table 6.4: Formula of Coating Solution

Sr. No.	Ingredient	Quantity
1	Cellulose acetate	35 mg
2	PEG 400	15 mg
3	Ethanol : Acetone	50:50

A. Micromeritic Studies of Lovastatin Tablets

Different Parameters like Angle of repose, Density (Tapped and Bulk), flow property, Carr's compressibility Index, Hausner's ratio, Percentage yield (i.e., recovery) of Lovastatin Tablets formed were studied.

B. Post Compression Evaluation of Lovastatin Tablets

Pre-compressional parameters of the prepared tablets (bulk density, tapped density, carr's index, and angle of repose) were in the range of given in official standard, indicates that the physical mixture were found to be free flowing. The post-compressional parameters of the tablets were found to be within the limits. The optimized formulation was selected for SEM and FTIR studies did not show any interaction between the drug, polymer and excipients.

C. In-Vitro Dissolution Studies

In Vitro dissolution study of formulation containing Lovastatin with different concentration of the osmogent and the polymer concentration was discussed. F6 was found to be satisfactory, where the release of the drug was found to be 96±2.08 % at24 hrs.

D. Stability Studies

Stability studies on selected formulations were carried out for 3 months as per ICH guidelines, ICHQ1AR: "Stability testing of new drug substances and products", 40±2°C / 75±5% RH Testing frequency: Samples were evaluated at the intervals of 0, 1, 2 and 3 months. Stability studies of the optimized formulation revealed that the selected parameters of drug content and drug release showed insignificant difference in the variation. The results revealed that the prepared formulation is stable. Hence, we can formulate the drug in different dosage forms by using these excipients in proper ratios. The selected method, i.e., Elementary method was highly suitable for formulating Lovastatin osmotic release tablet.

III.RESULT AND DISCUSSION

A. Drug and Polymer Compatibility Study by FT-IR

In FTIR spectra the peaks of physical mixture was compared with the original spectra. Same peaks were observed, there is no possible molecular interaction between the drug and the polymer.

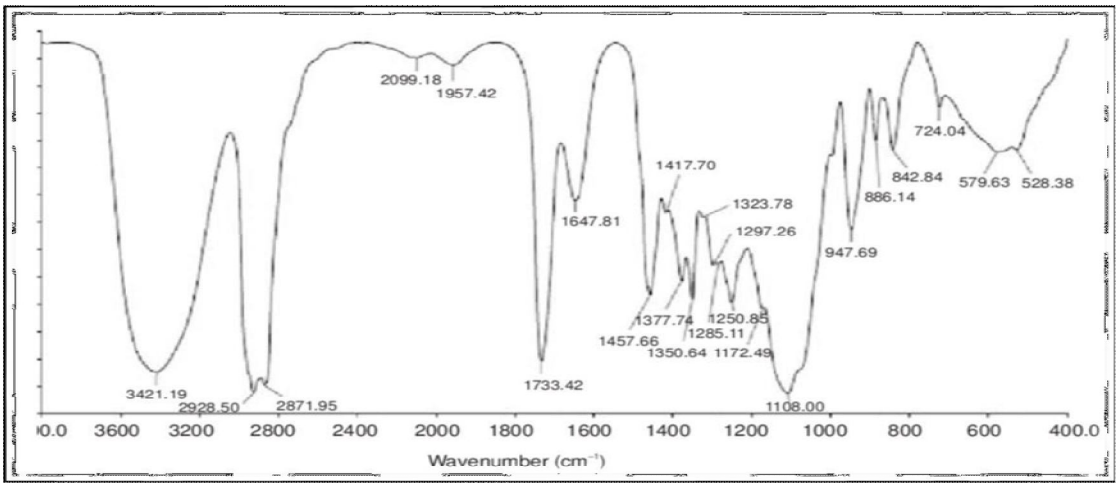


Figure No.7.3: FTIR Spectra of Lovastatin

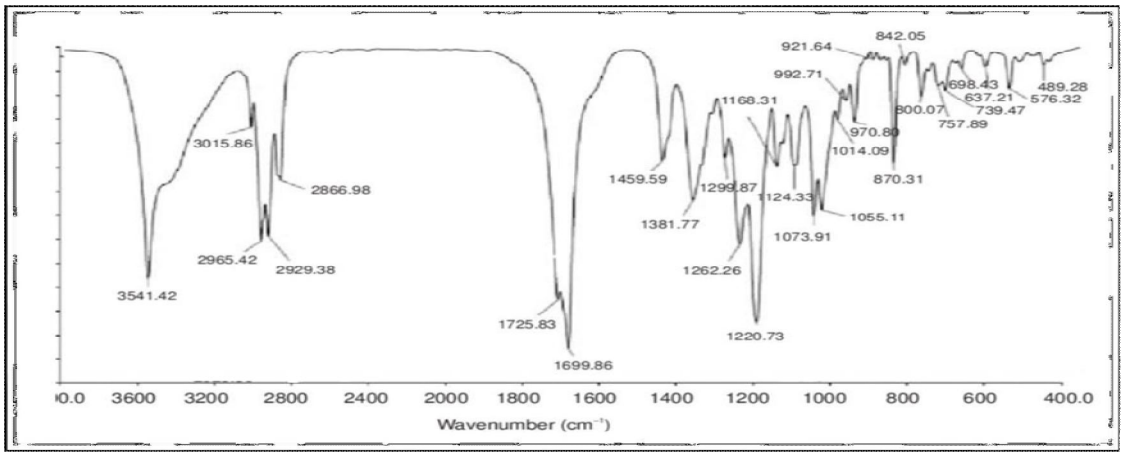


Figure No.7.4: FTIR Spectra of Lovastatin with excipients

Pure drug of Lovastatin complies with the reference sample and the combination of API with different excipients show no deviation from pure drug. Hence there was no compatibility problem between API and excipients.

B. Evaluation of Granules

The granules of different formulations were evaluated for angle of repose, bulk density, tapped density, compressibility index, Hausner's ratio.

Evaluation data of granules

Formulation	Angle of Repose	Bulk Density (g/ml)	Tapped density (g/ml)	Compressibility Index (%)	Hausner's ratio
F1	25.71±0.14	0.414±0.86	0.487±0.58	16.05±0.11	1.18±0.18
F2	24.78±0.17	0.425±0.31	0.478±0.96	12.50±0.46	1.14±0.36
F3	26.57±0.16	0.426±0.07	0.502±0.19	16.40±0.39	1.19±0.20
F4	27.48±0.19	0.408±0.74	0.479±0.26	15.85±0.35	1.18±0.47
F5	24.31±0.29	0.409±0.74	0.477±0.26	13.85±0.35	1.18±0.47
F6	26.57±0.27	0.419±0.21	0.517±0.62	10.02±0.91	1.24±0.50
F7	26.48±0.14	0.428±0.57	0.525±0.80	18.16±0.44	1.23±0.16
F8	23.97±0.89	0.404±0.43	0.509±0.69	19.42±0.10	1.27±0.09
F9	25.77±0.93	0.399±0.36	0.464±0.78	15.43±0.96	1.17±0.87

IV. DISCUSSION

The results of angle of repose and compressibility index (%) ranged from 23.97 ± 0.89 to 27.48 ± 0.19, and 10.02 ± 0.91 to 19.42 ± 0.10, respectively. The results of Bulk Density and Tapped Density ranged from 0.399 ± 0.36 to 0.428 ± 0.57 and 0.464± 0.78 to 0.525 ± 0.80, respectively. Hausner's found that this ratio was related to interparticle friction and, as such, could be used to predict powder flow properties. Generally a value less than 1.25 indicates good flow properties, which is equivalent to 20% of Carr's index.

The results of angle of repose (<30) indicate good flow properties of the granules. Generally, compressibility index values up to 15 % result in good to excellent flow properties. Bulk densities of granules prepared by using water alone as a granulating agent (F-1 to F-9) were found to be quite higher than those of other granules. This may be due to the presence of more fines in the granules, as water alone could not provide sufficient binding to the granules. In addition, granule density may influence compressibility, tablet porosity, dissolution and other properties. All these results indicate that the granules possessed satisfactory flow properties, compressibility.

A. Evaluation of Uncoated Tablet of Lovastatin

Formulat ion code	Average weight (mg)	Thickness (mm)	Friability (%)	Hardness (kg/cm^2)	Uniformity of Content (%)	Porosity (%)
F1	200±3.19	2.00±0.06	0.34	3.8±0.08	95.40 ±1.18	13.34
F2	200±3.21	2.01±0.12	0.3	3.6±0.11	94.50 ±1.29	12.65
F3	200±3.37	2.01±0.15	0.47	3.2±0.20	97.90 ±1.04	16.32
F4	200±2.27	2.03±0.06	0.32	3.6±0.29	94.90 ±1.10	14.55
F5	200±2.57	2.01±0.1	0.33	3.3±0.15	93.80 ±1.47	17.57
F6	200±3.06	2.01±0.06	0.32	3.5±0.26	98.00±1.28	18.40
F7	200±2.75	2.02±0.12	0.58	3.4±0.16	95.20±1.58	15.23
F8	200±2.75	2.02±0.08	0.8	3.5±0.16	93.8 ±1.49	13.24
F9	200±2.76	2.02±0.08	0.95	3.3±0.27	95.7 ±1.16	14.87

All the formulations pass weight variation test as per IP. The range of weight variation is 200±2.27 mg to 200±3.21mg. All the osmotic tablet system had acceptable friability as none of the tested formulae had percentage loss in tablets weight exceed 1%. Friability below 1% is an indication of the good mechanical resistance of the tablets. Friability of all formulations ranges from 0.3 % to 0.95 %. This ensures that tablets could withstand to the pressure, shocks during handling, transportation and shifting processes.

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B. Evaluation of Osmotic Tablets of Lovastatin

After coating osmotic tablets were evaluated for Thickness of tablet, Thickness of film, weight uniformity, and dissolution test of prepared formulations.

Table No.7.8 : Post coating evaluation parameters of Lovastatin osmotic tablet

Formulation Code	Average Weight (mg) (n=20)	Thickness of coated tablet (mm) (n=10)	ess of Film (mm)
F1	250.8 ± 0.4163	2.52 ± 0.17	0.2286 ± 0.004
F2	250.4 ± 0.4988	2.51 ± 0.15	0.2953±0.005
F3	250.5 ± 0.6046	2.53 ± 0.19	0.2468 ± 0.007
F4	250.1 ± 0.5467	2.55 ± 0.13	0.1976 ± 0.006
F5	250.9 ± 0.6904	2.52 ± 0.24	0.2104 ± 0.004
F6	250.1 ± 0.500	2.56 ± 0.08	0.1860 ± 0.004
F7	250.2 ± 0.4163	2.53 ± 0.26	0.2495 ± 0.006
F8	250.6 ± 0.4760	2.54 ± 0.22	0.2428 ± 0.008
F9	250.4 ± 0.6531	2.53 ± 0.16	0.2485 ± 0.004

All the formulations passes weight variation test. The range of weight variation is 250.1 ± 0.500 to 250.9 ± 0.6904. This ensures that tablets could withstand to the pressure, shocks during handling, transportationand shifting processes.

C. In vitro drug release study of Lovastatin

In vitro release rate was tested using (USP-II) paddle type dissolution apparatus, using 900 ml of pH 7.5 phosphate buffers as dissolution medium at temperature 37 ±2ºC. Samples were withdrawn at time intervals of 1, 2, 4, 8 and 16 hours and up to 24 hrs analyzed spectrophotometrically. For the final optimized formulation, the pre- compression parameter density and particle size distribution mentioned in pre- formulation studies were carried out.

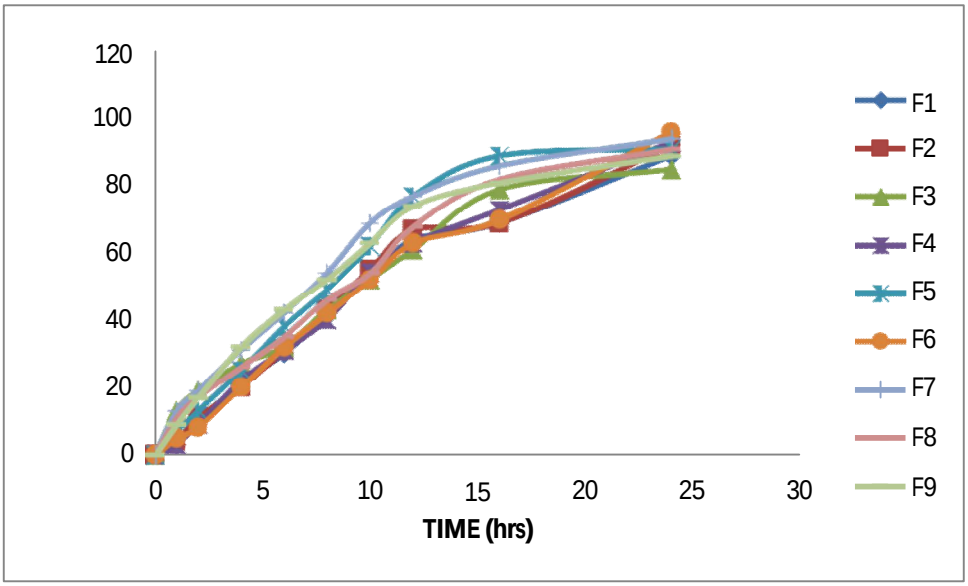


Figure No. 7.6: In vitro release profile of Lovastatin Osmotic release tablet

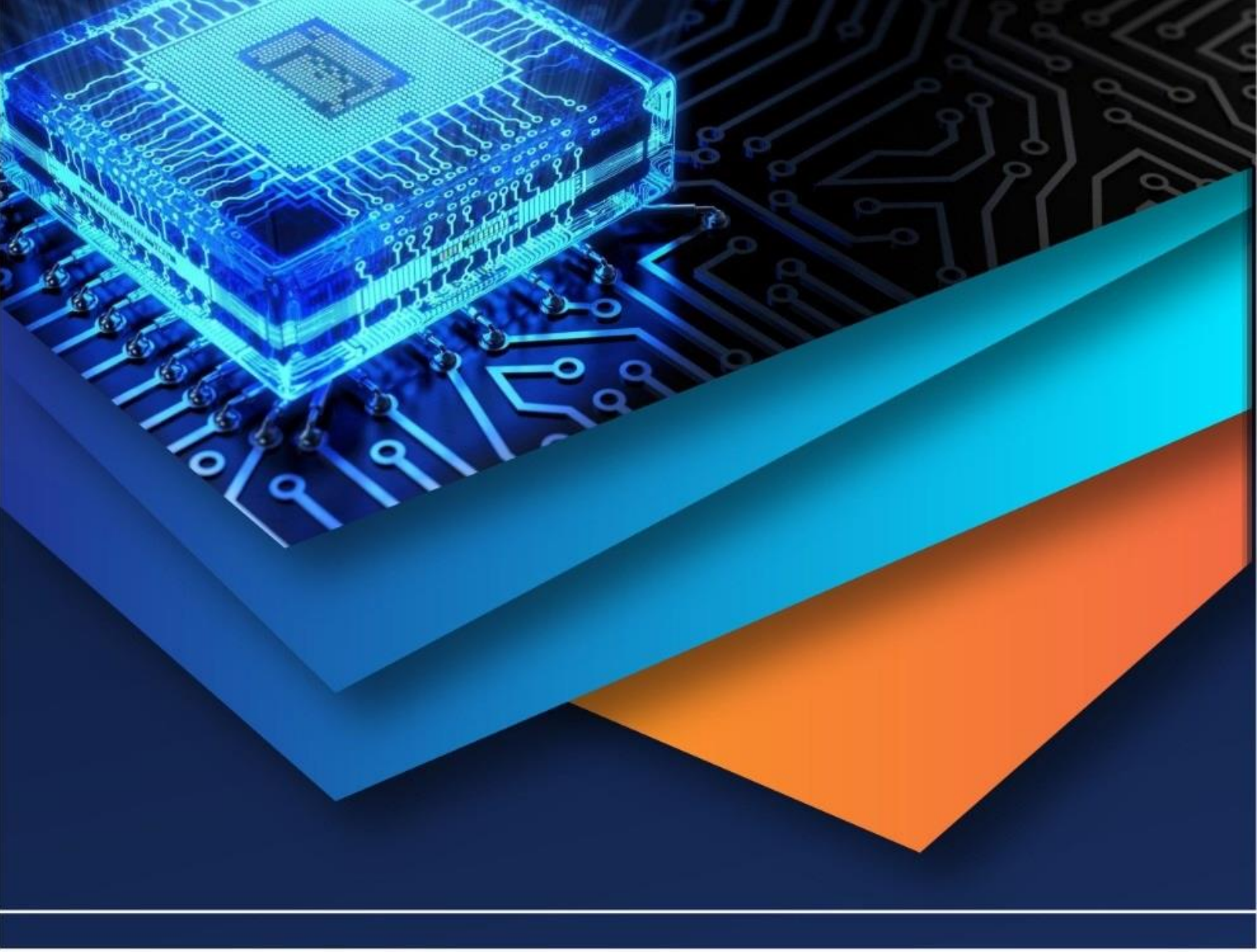
V. CONCLUSIONS

The results of osmotic tablet studies of Lovastatin tablets proved that the granules of Lovastatin showed good flow properties, tablet evaluation tests are within the acceptable limits, IR spectral analysis proved that there was no drug-excipients interaction, the kinetic studies revealed that optimized formulation followed First order release kinetics and stability studies revealed that all the formulations were found to be stable after storing at temperature of 45ºC ± 2ºC, 75% ± 5% relative humidity for 3 months. Thus the results of the above study clearly indicated that Developed Osmotically controlled release tablet of Lovastatin provide release of drug at a predetermined rate and for a predetermined time in controlled manner.

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