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DESIGN AND EVALUATION OF PLUMBAGIN SOLID DISPERSION TABLETS: A STRATEGY FOR SOLUBILITY ENHANCEMENT

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ABSTRACT

By utilising Poloxamer 188 as a solubility-enhancing carrier, the present research investigation sought to formulate and evaluate solid dispersion-based tablets of Plumbagin, a phytoconstituent that is poorly soluble in water. The solvent evaporation method was used for developing solid dispersions, which produced an amorphous product with greatly enhanced compressibility and flow characteristics, making it more suitable for tablet formulation. Solvent evaporation had been utilised to create solid dispersions, which produced an amorphous product with higher flow rates and compressibility. Preformulation and post-compression experiments (F1–F5) showed improved mechanical and physicochemical characteristics, such as homogenous drug content, quick disintegration, and suitable flow properties. Plumbagin's poor water solubility was confirmed by solubility experiments; it is most soluble in ethanol and methanol. Poloxamer 188 and Croscarmellose Sodium performed well together in the optimised formulation (F5), which showed the optimal balance of hardness, friability, disintegration time, and uniformity. Plumbagin's solubility and formulation issues were effectively resolved in this study, laying the groundwork for further investigations into enhancing its bioavailability, dissolution, and therapeutic effectiveness in oral solid dosage forms.

KEYWORDS: Plumbagin, Solid dispersion, Poloxamer 188**,** Solubility enhancement**,** Tablet formulation.

INTRODUCTION

The roots of Plumbago species are the primary origin of plumbagin,[1] a bioactive naphthoquinone molecular structure with a wide range of pharmacological features, ranging such as antibacterial,[2] anticancer, anti-inflammatory, and antimicrobial properties.[3] Its low oral bioavailability as well as poor water solubility substantially hindered its clinical application despite its excellent therapeutic potential. One of the most significant challenges in creating efficient pharmaceutical formulations that aim to enhance therapeutic results is addressing the solubility and dissolving constraints of hydrophobic medications like plumbagin.[4]

One of the most beneficial methods for improving the solubility and bioavailability of medications is the solid dispersion strategy, in which the active medicinal ingredient is uniformly distributed inside a hydrophilic carrier matrix.[5] For this approach, Poloxamer 188, a multifunctional non-ionic polymer and surfactant, is particularly recommended due to its exceptional stabilising, wetting, and solubilising properties.[6] By increasing the possibility that crystalline drugs will transform into their amorphous state, this mechanism substantially increases solubility rates and, consequently, therapeutic efficacy. The current work emphasises on developing and improving Plumbagin tablets employing solid dispersions based on Poloxamer 188 in order to enhanced solubility, dissolving performance, and overall tablet quality.[7] This can be achieved by completely evaluating the post-compression characteristics, formulation parameters, and preformulation aspects.

MATERIALS AND METHODS

Materials

Plumbagin (API), Poloxamer 188 (Solubility enhancer), Microcrystalline Cellulose PH 102 (Diluent), Croscarmellose Sodium (Disintegrant), Colloidal anhydrous silica (Glidant), and Magnesium Stearate (Lubricant) are used.

Method

Formulation of Plumbagin Solid Dispersion Tablets

Solid dispersion tablets were created utilising the solvent evaporation method that will enhance water solubility and dissolving rate of Plumbagin. For the formation of a solution that was uniform in size, precisely weighed amounts of Poloxamer 188 and Plumbagin were dissolved in ethanol using various drug-to-polymer ratios (1:1 to 1:5). The solvent was pulled out from this solution via rotary evaporation at 45°C and frequent stirring, resulting in a

cohesive solid mass. To formulate a uniform dispersion powder, the dried residue was further vacuum-dried, pulverised into a fine powder, and then sieved through a #60 mesh.

Following that, the solid dispersions were formulated with 1% w/w magnesium stearate as a lubricant, 2% w/w colloidal anhydrous silica as a glidant, 5% w/w croscarmellose sodium as a superdisintegrant, and microcrystalline cellulose as a diluent. A Cadmach single-punch tablet compression machine was used to compress the outcome blend into tablets.

To make sure improved performance and formulation efficiency, the produced tablets were carefully assessed for physicochemical characteristics, drug content standardisation, disintegration time, and in vitro dissolution behaviour.

Table No. 1: Formulation of plumbagin solid dispersion tablets.

S.No	Ingredients	F1	F2	F3	F4	F5
1	Plumbagin	20	20	20	20	20
2	Poloxamer 188	20	40	60	80	100
3	Microcrystalline cellulose pH 102	153.7	133.7	113.7	93.7	73.7
4	Croscarmellose Sodium	10	10	10	10	10
5	Colloidal Anhydrous Silica	4.2	4.2	4.2	4.2	4.2
6	Magnesium Stearate	2.1	2.1	2.1	2.1	2.1
Weight of tablet (mg)		210	210	210	210	210

Development of analytical techniques for Plumbagin Finding the absorption maxima: To determine the absorption maxima (λ-max) of Plumbagin, the working standards were scanned across the electromagnetic spectrum between 200 and 400 nm using a reagent blank as the reference.[8]

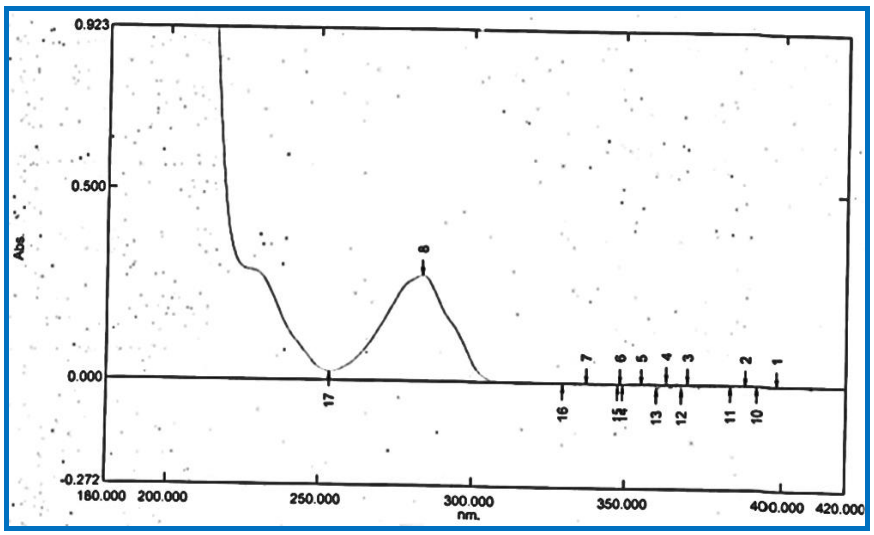

Fig. No.1: Absorption maxima (λ-max) of Plumbagin.

A clear absorption peak was found at 274 nm, which was determined to be the most suitable wavelength for further studies. To guarantee precision and predictability in the analytical evaluations, this wavelength was then consistently used in all subsequent experiments, including the establishment of the standard calibration curve and dissolution investigations. The methodology improves precision and reproducibility in quantifying Plumbagin under different experimental conditions by fixing the λ-max at 274 nm.

Assay Procedure

Using UV-Visible[9] Spectrophotometer.

Preparation of standard stock solution

Specifically, 10 mg of plumbagin was measured before being dissolved in ethanol, and then diluted to a final volume of 100 mL with ethanol in order to make a stock solution of 100 µg/mL. After that, for making a working standard solution of 10µg/mL, 1 mL of the stock solution was further diluted with 10 mL of ethanol.

Preparation of sample solution

A 100 mL volumetric flask was filled containing precisely weighed, finely powdered tablets that contained the equivalent of 10 mg of plumbagin. About 50 millilitres of ethanol were added, and the liquid was sonicated for 20 minutes so as to ensure full drug extraction. To be sure that Plumbagin was completely dissolved, the volume was increased to 100 mL with ethanol after sonication. After removing any insoluble particles with Whatman filter paper, the resultant solution was diluted appropriately for the purpose to achieve a final concentration of 10 µg/mL for further evaluation.

Procedure

Using ethanol as the blank solution for establishing a baseline reference, the absorbance of the standard and A wavelength of 274 nm was used to determine the concentration of sample solutions. The appropriate mathematical method was then used to figure out the sample's drug concentration.

$$\text{Drug content (\%)} = \left(\frac{\text{Absorbance of sample}}{\text{Absorbance of standard}}\right) \times \text{Label claim}$$

Procedure for dissolution testing

Method of analysis

An in-vitro drug release study was conducted using 900 mL of phosphate buffer (pH 6.8) as the dissolution medium in a USP Type-II (paddle) apparatus. Throughout the experiment, the temperature was meticulously kept at 37 ± 0.5°C, and the instrumentation was programmed to run at 50 RPM. To maintain sink conditions, 5 mL aliquots were taken out at predetermined intervals (5, 10, 15, 30, 45, and 60 minutes). Every withdrawn sample was promptly replaced with an equivalent volume of freshly preheated dissolving medium to assure the accuracy and reproducibility of the results. To exclude any particle debris, all collected samples have been filtered through a 0.45 µm membrane filter before analysis.The study's desired outcome was to evaluation the medication release profile in a controlled and standardised environment.[11]

UV-Visible Spectrophotometry

With phosphate buffer functioning as the blank reference, A UV-Visible spectrophotometer was implemented to determine the absorbance of the filtered samples at 274 nm, or plumbagin's λmax. To guarantee precision and consistency, a standard calibration curve for plumbagin has been established in the same medium throughout a concentration range of 2–10 µg/mL. The % cumulative drug release was accurately estimated by evaluating the standard calibration data with the observed absorbance values, offering an independent assessment of the drug's release profile.

$$\%\text{Drug Release} = \left(\frac{\text{Absorbance of sample} \times \text{Dilution Factor} \times 100}{\text{Label Claim} \times \text{Standard Absorbance}}\right)$$

RESULTS AND DISSCUSION

Pre compression parameters

Table No. 2: Pre-compression parameters for Plumbagin optimized formula blend.

Code	B.D (g/ml)	T.D (g/ml)	Hausner's ratio	Carr's index (%)	Angle of repose (ɵ)	Flow property
F1	0.546	0.673	1.23	18.871	30º 35'	GOOD
F2	0.549	0.672	1.22	18.304	31º 25'	GOOD
F3	0.563	0.681	1.21	17.327	30º 23'	GOOD
F4	0.576	0.669	1.16	13.901	31º 49'	GOOD
F5	0.568	0.655	1.15	13.282	27º 55'	GOOD

Drugs and Excipient compatibility studies using FTIR

The pharmaceutical ingredient (plumbagin) and the excipients are both examined in the drug-excipient compatibility studies using IR spectroscopy. To the samples were produced by hydraulically pressing crushed materials into pellets using KBr. Spectral smoothing and baseline modifications are performed to ensure clarity following the mixtures are scanned at room temperature right through a wavelength range of 400 cm^{-1} to 4000 cm^{-1} prior to sampling.[10]

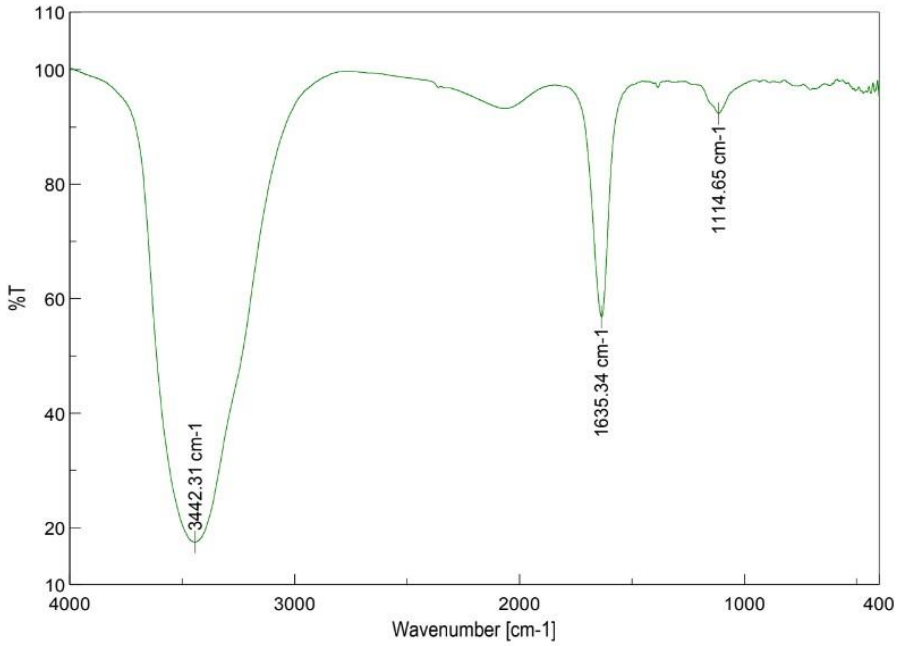

Fig. No.2: FTIR Spectra of Plumbagin (API).

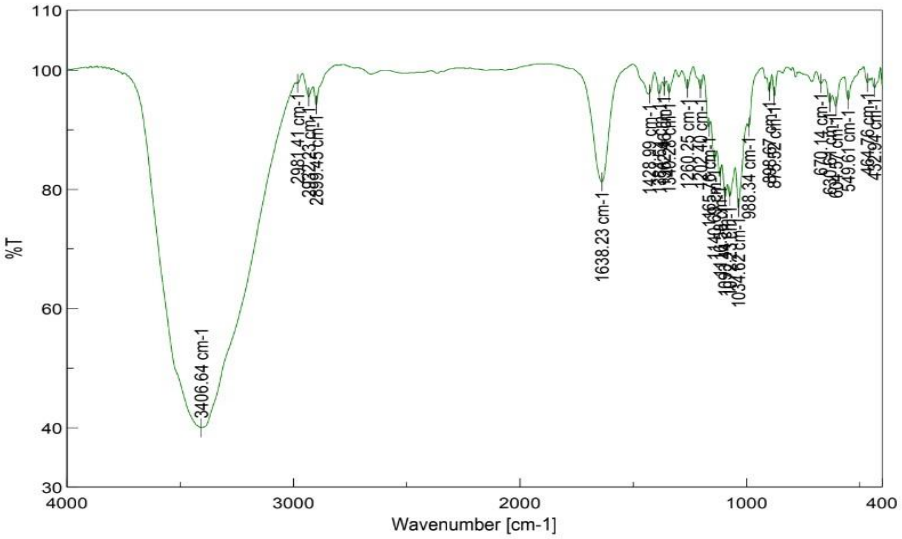

Fig. No. 3: FTIR Spectra of optimized formula blend Plumbagin.

To evaluate any physical or chemical interactions, Analysis was done on the FTIR spectra of pure plumbagin and its blend with excipients for minimising friction; no notable incompatibilities between the drug and the excipients were found. Post-compression characteristics were also assessed in order to further evaluate the formulation's compatibility and stability.

Table No. 3: Evaluation of plumbagin solid dispersion tablets (F1 to F5).

S. No	Tests	Specifications	F1	F2	F3	F4	F5
1	Description	White colored round shaped uncoated	Meet	Meet	Meet	Meet	Meet
2	Average weight (mg)	210 mg ±3%	212	210	211	210	210
3	Thickness (mm)	3.70±0.2	3.75	3.77	3.72	3.77	3.71
4	Hardness (kg/cm^2)	NLT 3.0	8.5	8	8.75	8.25	8.95
5	Friability (%w/w)	NMT 1%	0.07	0.1	0.1	0.13	0.15
6	Disintegration Time	NMT 15%	05’30”	05’15”	04’50”	05’55”	04’45”
7	Weight variation (mg)	±5% from the average weight	-2.35 to +2.98	-2.61 to +2.84	-2.22 to +2.62	-3.1 to +2.2	-2.4 to +2.5
8	Assay	90 – 110%	97.57%	98.21%	97.33%	98.58%	99.34%

Dissolution studies

According to the USP, the amount of plumbagin solid dispersion tabletsrelease at different time points.

Table No. 4: Comparative *In-vitro* release data for plumbagin F1 to F5 formulations.

S. No	Formulation	Time (hr)	Amount of drug release (mg)	Cumulative % drug release
1	F1	1	17.1	85.5
2	F2	1	17.6	87.85
3	F3	1	18.3	91.37
4	F4	1	19.2	95.78
5	F5	1	19.9	99.35

The Plumbagin solid dispersion tablets from formulation F5 performed the best, with an excellent 99.35% drug release within the first hour, according to the in vitro drug release investigations of five formulation trials. Fig. 3 further demonstrates this exceptional release profile and the F5 formulation's superior dissolving properties in comparison to the other evaluated versions as well.

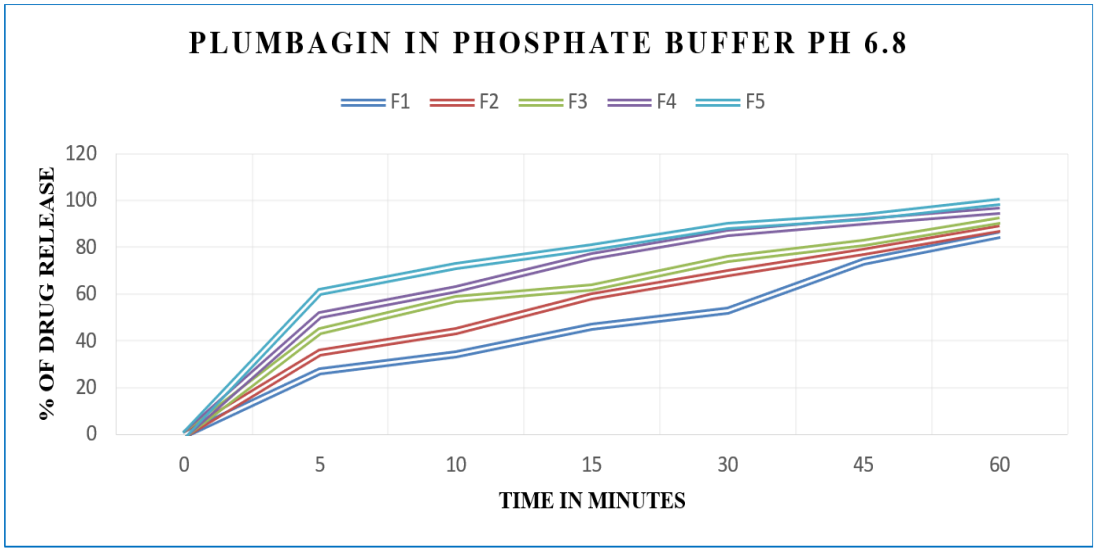

Fig. No. 3: In-*vitro* dissolution profile of formulation F5.

SUMMARY AND CONCLUSION

Summary

The present study aimed that will establish new and improved tablet formulations based on solid dispersion of Plumbagin, a poorly water-soluble phytoconstituent, using Poloxamer 188 as a solubility-enhancing carrier. Through systematic preformulation and post-compression evaluations (F1–F5), key physicochemical and mechanical properties were assessed. While solubility experiments showed poor water solubility but increased dissolving in ethanol and methanol, promoting the use of ethanol in solid dispersion preparation, plumbagin's sharp melting point (77–78°C) substantiated its crystalline clarity. Limited solubility but acceptable membrane permeability has been demonstrated by the moderate lipophilicity (log P 2.5–3.0). A λmax with outstanding linearity (R2 > 0.99) was found at 274 nm by UV spectrophotometric examination. Improved bulk and tapped densities, Hausner's Ratio (1.21–1.24), Carr's Index (17.24%–19.12%), and a reduced angle of repose (28.2° to 25.8°) were all shown in micromeritic evaluations, confirming ideal flowability. With a 60% yield, solid dispersions made by solvent evaporation at 45°C produced an uniform in nature, amorphous product. Superior performance was confirmed by the final tablets' consistent weight, increased hardness (4.1 to 4.8 kg/cm2), decreased friability (0.39% to 0.25%), and quick disintegration (5.2 to 2.0 minutes). The consistent distribution of the drug content (97.6%–100.1%) additionally established the formulation's consistency.F5 exhibited the most well-balanced of the studied formulations, exhibiting the best flow, compactibility, mechanical strength, and drug release features.

CONCLUSION

Plumbagin's solubility and formulation issues were successfully resolved by the study by creating solid dispersion tablets with Poloxamer 188 acting as a carrier. With significant enhancements in solubility, flow characteristics, disintegration time, mechanical strength, and consistent drug content, the optimised formulation (F5) became a very attractive compared for oral administration. The potential development of an efficient and accurate oral dosage form for this therapeutically significant phytoconstituent is made possible by these favourable findings, which provide a solid foundation for further research, including in vitro dissolution studies, bioavailability assessments, and in vivo pharmacokinetic evaluations.

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