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**Research Paper**

# Quality Assessment of Momordica Diocia Tablet Formulation For Urolithiasis

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## ABSTRACT

Urolithiasis is one of the most common urinary tract disorders characterized by the formation of calculi in the kidney and urinary system. The recurrence of kidney stones and the adverse effects associated with conventional therapies have increased interest in herbal medicines as safer alternatives. The present study was aimed at the formulation and quality assessment of herbal tablets containing Momordica dioica extract for potential anti-urolithiatic activity.The extract of Momordica dioica was prepared and subjected to phytochemical investigation, which confirmed the presence of bioactive constituents such as flavonoids, saponins, alkaloids, tannins, and glycosides. Herbal tablets were formulated by direct compression technique using suitable excipients including binders, diluents, lubricants, and disintegrants. The prepared formulations were evaluated for pre-compression parameters such as angle of repose, bulk density, tapped density, Carr's index, and Hausner ratio. Post-compression evaluation included hardness, friability, thickness, weight variation, disintegration time, drug content uniformity, and in-vitro dissolution studies.The optimized formulation showed satisfactory physicochemical characteristics with acceptable hardness, low friability, uniform drug content, and effective drug release profile. Stability studies indicated that the formulation remained stable under accelerated storage conditions without significant changes in physical appearance and drug release behavior.The findings of the present investigation suggest that Momordica dioica herbal tablets may serve as a promising and effective herbal formulation for the management of urolithiasis. Further pharmacological and clinical studies are recommended to confirm its therapeutic efficacy and safety..

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## INTRODUCTION

### Quality Assessment

Quality assessment is a systematic process used to evaluate whether a product, research work, or process meets predefined standards, specifications, and user expectations. It ensures accuracy, safety, consistency, effectiveness, and reliability. Quality assessment helps in identifying errors, deficiencies, and areas requiring improvement, thereby supporting continuous enhancement. It is widely applied in pharmaceuticals, healthcare, education, manufacturing, and research for maintaining high standards and validating outcomes

### Urolithiasis

Urolithiasis is a common disorder characterized by the formation of stones in the urinary tract, including the kidneys, ureters, bladder, and urethra. It occurs due to supersaturation of urine with minerals such as calcium oxalate, uric acid, and cystine. Kidney stones are among the most prevalent urinary tract disorders and are associated with high recurrence rates. Historical evidence of urinary stones has been found in ancient Egyptian mummies and early Indian Sanskrit literature. Urolithiasis remains a significant cause of morbidity worldwide and is considered the third most common urinary tract disease after urinary tract infections and prostate disorders.acid, and cystine.[3,4]




**Figure1.1 :- urolithiasis (kidney stone)**

### Urolithiasis and Herbal Treatment

### Causes of Urolithiasis

Urolithiasis occurs due to the crystallization of concentrated substances in urine, leading to stone formation. Major causes include dehydration, high intake of sodium and oxalate-rich foods, obesity, metabolic disorders, urinary tract infections, and genetic factors.

### Types of Stones

- Calcium Oxalate/Phosphate Stones: Most common type, associated with high oxalate intake and low fluid consumption.
- Uric Acid Stones: Form in acidic urine and are linked with gout and metabolic syndrome.

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- Struvite Stones: Develop mainly due to chronic urinary tract infections.
- Cystine Stones: Caused by inherited disorders leading to excess cystine excretion.

**Herbal Formulations in Urolithiasis**

Herbal formulations are preparations containing medicinal herbs used for the prevention and treatment of diseases. In urolithiasis, herbal remedies help dissolve stones, reduce inflammation, increase urine output, and promote stone expulsion.

**Role of Momordica dioica**

is traditionally used in Ayurveda for kidney stone management. It possesses anti-urolithiatic, diuretic, and nephroprotective properties. Studies suggest that it aids in stone elimination, reduces recurrence, and protects kidney function by lowering urea and creatinine levels.

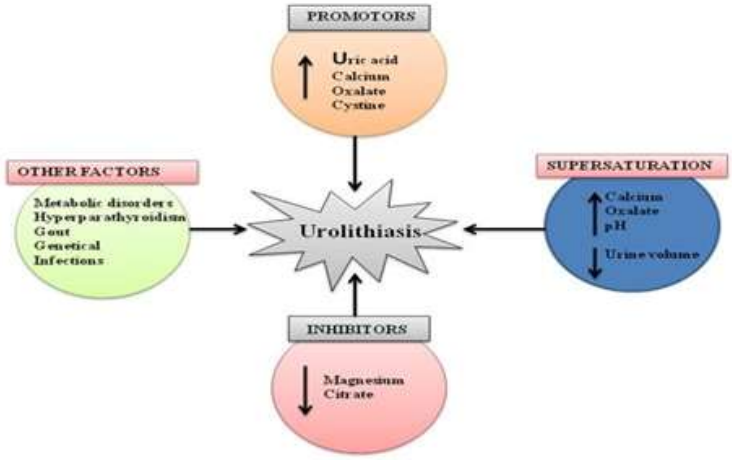



**Figure 1.3:- urolithiasis causes**

**Fruit and Pharmacological Activities of Momordica dioica**

The fruit of is the most widely used part for both nutritional and medicinal purposes. It is a green, spiny, ovoid fruit rich in flavonoids, saponins, phenolic compounds, and vitamin C. Traditionally, it is used for treating hypertension, skin disorders, asthma, and kidney stones. Fruit extracts exhibit diuretic, antioxidant, and antiurolithiatic properties, helping to reduce calcium oxalate stone formation



**Figure:- fruit of Momordica diocia**

**Pharmacological Activities**

- Antidiabetic Activity: Improves insulin secretion and glucose utilization.
- Antiurolithiatic Activity: Prevents calcium oxalate crystal deposition and kidney stone formt$^{n}$
- Hepatoprotective Activity: Protects the liver from chemical-induced toxicity.

**Quantitative Analysis of Herbal Drugs**

Quantitative analysis of herbal drugs involves measuring active constituents using analytical chemistry techniques. Marker compounds are used as reference standards to ensure the quality, consistency, and therapeutic effectiveness of herbal formulations.

**Materials and Instruments**

**Chemicals and Materials :-**The study used along with analytical-grade chemicals such as formic acid, toluene, ethyl acetate, methanol, microcrystalline cellulose, PVP K-30, sodium starch glycolate, magnesium stearate, talc, carbopol, silica gel 60 F254 HPTLC plates, and saponin marker.

**Instruments:-**instruments used included an electronic weighing balance, UV cabinet, HPTLC system, rotary tablet punching machine, thickness tester, friability tester, hardness tester, dissolution apparatus, and double beam UV-visible spectrophotometer.

**Formulation Of Tablet:-**

The tablet was prepared by the direct compression method. In this process, the extract and excipients were passed through #40 or #60 mesh sieves to obtain uniform particle size. Accurately weighed ingredients were mixed thoroughly to achieve a homogeneous blend, followed by sieving through mesh no. 60 and retention on mesh no. 80. The blend was lubricated with magnesium stearate and talc, and finally compressed into tablets using a tablet punching machine. Direct compression is a simple, cost-effective, and efficient method that avoids the need for granulation

**N=F4**

**Table**:-Composition (Mg/Tablet) Of Different Compressed Table

*Selection Of Optimized Batch=F4*

| Ingredient (mg) | F1 | F2 | F3 | F4 | F5 |
|---|---|---|---|---|---|
| Momordica diocia | 250 | 250 | 250 | 250 | 250 |
| Microcrystalline cellulose | 225 | 200 | 190 | 200 | 180 |
| Polyvinylpyrrolidone (PVP K-30) | 10 | 20 | 15 | 30 | 45 |
| Sodium starch glycolate | - | 10 | 15 | 15 | 20 |
| Magnesium stearate. | 4 | 5 | 7 | 5 | 3 |
| Talc | 1 | | 3 | - | 2 |
| Carbapol | 10 | 15 | 20 | - | - |

**Evaluation Parameters**

The prepared tablets were evaluated for various quality control parameters.

**Organoleptic Properties**

Tablets were examined for general appearance, color, and taste. The tablets were brown in color with a bitter taste**.**

**Weight Variation Test**

Twenty tablets from each batch were individually weighed, and the average weight and percentage deviation were calculated to ensure uniformity.

**Thickness and Diameter**

Tablet thickness and diameter were measured using Vernier calipers to confirm dimensional uniformity.

**Hardness Test**

Tablet hardness was determined using a Monsanto hardness tester, and results were expressed in Kg/cm² to evaluate mechanical strength**.**

**Friability Test**

Friability was evaluated using a Roche friabilator operated at 25 rpm for 4 minutes. Percentage weight loss was calculated to assess tablet resistance to abrasion.

**In Vitro Dissolution Study**

Drug release studies were carried out using 0.1N HCl as dissolution medium maintained at 37 ± 0.5°C. Samples were withdrawn at predetermined intervals up to 12 hours, analyzed by UV-visible spectrophotometry at 279 nm, and cumulative percentage drug release was calculated to obtain the dissolution profile.In Vitro Dissolution Studies

**% Drug Release = (/) × Drug released at that time/Total drug in tablet ×100**

This process was continued at each time point, and the results were recorded to plot the drug release profile over time.

**Stability studies of tablet:-**

**Selection of batches**

The samples were selected randomly from all five batches. These samples were packed in the same container and closure system used for marketing.

**Storage condition**

The stability of tablets was studied by exposing the sample to elevated conditions of temperature and humidity.^{42} The filled packed containers were kept in oven at 40°C. The relative humidity (80%) was maintained in the desiccator by filling a saturated soln of sodium chloride. The desiccator was kept in oven at 40°C. The relative humidity was calculated with the help of digital thermo hygrometer (j412-cth)

**UV–Visible Spectrophotometry**

Momordica dioica extract (10 mg) was dissolved in distilled water and diluted to 100 mL to obtain a stock solution. Further serial dilutions (50–250 µg/mL) were prepared and analyzed using a Cary 100 Scan double beam UV–Visible spectrophotometer in the range of 200–400 nm. The maximum absorbance (λmax) was observed at 278 nm.

**Preparation of Standard Curve**

Standard solutions of Momordica dioica (50–250 µg/mL) were prepared from the stock solution, and absorbance was measured at 278 nm. A calibration curve was constructed by plotting absorbance versus concentration according to Beer–Lambert's law.

**HPTLC Instrumentation and Chromatographic Conditions**

HPTLC analysis was performed using a CAMAG system equipped with Linomat V applicator, TLC Scanner III, twin-trough chamber, and WinCATS software. Precoated silica gel 60 F254 aluminium plates (20 × 10 cm) were used as the stationary phase. Samples were applied as 6 mm bands and developed with toluene:ethylacetate:formic acid (7:3:0.1 v/v/v) up to 80 mm. Densitometric scanning was carried out at 254 nm using a D2 lamp. Linear regression analysis was performed by plotting peak area against concentration of standard saponin.

**7.7.1 Preparation Of Stock Solutions Of Extracts Of MomordicaDiocia Fruits**

In the present study, water solvent was used to dissolve and prepare stock solution of All extracts of different parts of Momordica diocia plant. From the stock solution of fruits (1mg/ml), volumes were applied using CAMAG Linomat V sample applicator with the help of Hamilton syringe (100µL; Bonaduz, Switzerland)

**Stationary Phase** = precoated aluminium sheets of silica gel 60 F254 (20cm × 10 cm) (Merck, Germany).

**Mobile Phase** =toluen: ethyl acetate: formic acid (7:3:0.1))

**Analytical Method Validation parameters.**

**Accuracy:** Accuracy was determined as the closeness between the observed and true values using nine determinations over three concentration levels within the specified range.

**Precision:** Precision was evaluated based on the degree of agreement among repeated measurements and included repeatability, intermediate precision, and reproducibility studies. Repeatability was assessed using six replicates under the same operating conditions, while intermediate precision involved analysis by different analysts on different days and instruments. Reproducibility was evaluated between different laboratories.

**Specificity:** Specificity of the analytical method was established by its ability to accurately measure the analyte in the presence of excipients, degradants, sample matrix, and blank peaks without interference.

**Limit of Detection**:-

LOD can be expressed as LOD=3.3 SD/S

Where,

SD= standard deviation of response, S= Slope of calibration curve

**Limit Of Quantification:**

LOQ=10 SD/S

Where,

SD= standard deviation of response, S= Slope of calibration curve.

**Linearity:-**Linearity may be characterized as the capacity of an analytical technique to Produce outcomes which are directly related to the concentration of an analyte.

**Range**: It can be characterized as the interval amongst upper and lower quantities of analyte in the sample. Minimum of the specified range to be 80% to 120% of the test sample for the assay test.

**Robustness**: Ruggedness is the degree of measure of reproducibility under different situations such as in different laboratories, different analyst, different machines, environmental conditions, operators etc.

## RESULT AND DUSCUSSION

**Selection of Active Agent:-**

**Momordica Diocia**

Is widely used for the treatment of Diabetes, ,anti-inflammatory and anti-urolithiasis . The conventional tablet is administered 1or 2 Times a day .

**Herbal Extract**

Extracts used for the production of tablets obtained from suppliers as given in Table

| Sr.no | Extract | Supplier |
|---|---|---|
| 1 | Momordica diocia | zyrex ayurveda |

**Table :- Name Of Supplier Of Herbal Extract**

**Marker**:- Markers were used for analytical method development. The markers were purchased from different suppliers as given in Table

| Sr.no | Compound | Supplier |
|---|---|---|
| 1 | Saponin | Vishal Chem Pvt Ltd |

**Table :- Name Of Suppliers Of Marker Compound**

**Different Parameters For Raw Material Evaluation**

**Organoleptic Properties and Raw Material Evaluation of Momordica dioica Extract**

The Momordica dioica extract obtained from the supplier was evaluated for its organoleptic and physicochemical characteristics according to WHO guidelines and pharmacopoeial standards. The extract was observed as a brown-colored dry powder with a characteristic odor. Identification by HPTLC confirmed the authenticity of the extract by matching standard peaks. Phytochemical characterization showed that total ash, acid insoluble ash, water-soluble extractive value, and total bitter principles were within prescribed limits. Heavy metal analysis for arsenic, lead, and mercury complied with permissible limits. Microbial evaluation revealed that total plate count, yeast and mold count were within acceptable limits, while pathogenic organisms such as E. coli, Salmonella, and Staphylococcus aureus were absent. These findings confirmed the quality, purity, and safety of the Momordica dioica extract for herbal tablet formulation.

**Pre-Formulation Study:-**

**Table :-Pre Compression Study Of All Batch**

| Batch Code | Tapped Density (g/cm³)±SD | Bulk Density (g/cm³)±SD | Carr's Index (%)±SD | Hausner Ratio ±SD | Angle of Repose ±SD |
|---|---|---|---|---|---|
| **F1** | 0.561 ± 0.012 | 0.485 ± 0.011 | 13.54 ± 0.45 | 1.15 ± 0.02 | 25.86 ± 0.55 |
| **F2** | 0.565 ± 0.011 | 0.491 ± 0.010 | 13.91 ± 0.45 | 1.10 ± 0.01 | 26.45 ± 0.52 |
| **F3** | 0.552 ± 0.010 | 0.495 ± 0.011 | 14.49 ± 0.46 | 1.15 ± 0.01 | 27.23 ± 0.58 |
| **F4** | 0.549 ± 0.010 | 0.466 ± 0.009 | 15.11 ± 0.47 | 1.09 ± 0.02 | 25.64 ± 0.56 |
| **F5** | 0.552 ± 0.010 | 0.511 ± 0.012 | 14.41 ± 0.49 | 1.13 ± 0.02 | 29.76 ± 0.50 |

**Discussion**

Pre-compression evaluation of the tablet formulations (F1–F5) showed satisfactory flow and compressibility characteristics. Bulk density values ranged from 0.466 ± 0.009 to 0.511 ± 0.012 g/cm³, indicating moderate variation in powder packing. Tapped density values ranged between 0.552 ± 0.010 and 0.565 ± 0.011 g/cm³, suggesting good compressibility of the blends. Carr's Index values (13.54 ± 0.45% to 15.11 ± 0.60%) indicated good to excellent flow properties, particularly for formulation F4. The angle of repose ranged from 25.64 ± 0.56° to 29.76 ± 0.50°, confirming acceptable flow behavior for all batches.

**Formulation Of Tablet:-**

**Evolution Parameter Used :-**

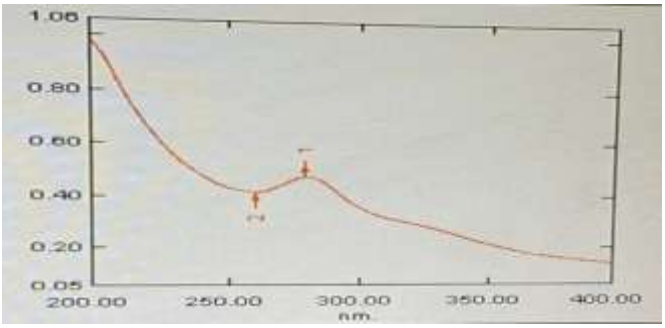
**Table :-Post Compression Study Of All Batch**

| Formulation Batch | Thickness (mm) ±SD | Diameter (mm) ±SD | Hardness (kg/cm²)±SD | Friability (%)±SD | WeightVariation (mg) ±SD |
|---|---|---|---|---|---|
| **F1** | 4.5± 0.02 | 10 | 4.1 ± 0.1 | 0.45 ± 0.02 | 502.5 ± 1.5 |
| **F2** | 4.5± 0.02 | 10 | 4.3 ± 0.1 | 0.43 ± 0.02 | 504.0 ± 1.7 |
| **F3** | 4.5± 0.02 | 10 | 4.6 ± 0.1 | 0.37 ± 0.02 | 504.5 ± 1.5 |
| **F4** | 4.5± 0.02 | 10 | 4.9 ± 0.1 | 0.40 ± 0.02 | 500.0 ± 1.4 |
| **F5** | 4.5± 0.02 | 10 | 4.2 ± 0.1 | 0.38 ± 0.02 | 501.2 ± 1.3 |

## DISCUSSION

Post-compression evaluation of formulation batches (F1–F5) demonstrated satisfactory tablet characteristics. Tablet thickness remained uniform at 4.5 ± 0.02 mm, while the diameter was consistently 10 mm for all batches, indicating proper die filling and compression behavior. Hardness values ranged from 4.0 ± 0.1 to 4.9 ± 0.1 kg/cm², with formulation F4 showing the highest mechanical strength. Friability values (0.37 ± 0.02% to 0.45 ± 0.02%) were below the pharmacopeial limit of 1%, confirming good tablet integrity and durability. Tablet weight variation ranged from 500.0 ± 1.4 mg to 504.5 ± 1.5 mg, demonstrating excellent uniformity and consistent powder flow during compression.

**Determination of λ max:-**

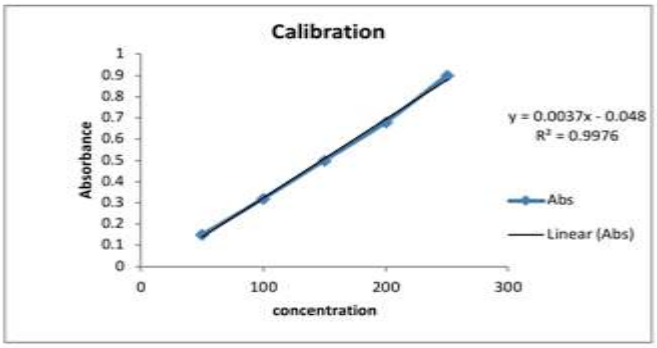



This is a confirmatory analytical test for the drug, which showed UV spectrum as described in reference book and the absorption curve showed characteristic absorption maxima at λ max 278 nm for Momordica diocia,

**Standard Calibration Curve Of MomordicaDiocia:-**

**Table :- Standard Calibration Curve Of MomordicaDiocia In Water At 278**

| Sr.no | Concentration | Absorbance |
|---|---|---|
| 1 | 50 | 0.15 |
| 2 | 100 | 0.32 |
| 3 | 150 | 0.50 |
| 4 | 200 | 0.68 |
| 5 | 250 | 0.90 |




**Discussion**

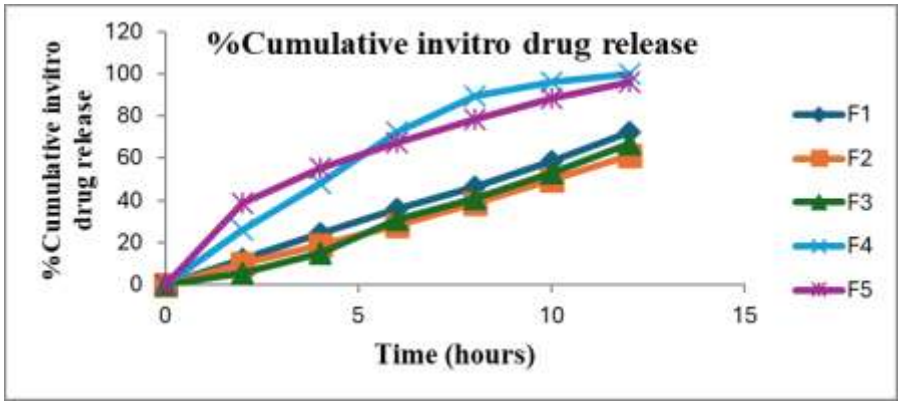
From the standard curve, it was observed that the drug obeys Beer's law in concentration range of 50-250µg/ml in water. Drug shown good linearity with regression of coefficient ($r^2$ = 0.9976) and equation for this line obtained was found to be y = 0.0037x-0.048 which is used for the calculation of amount of drug and dissolution study.

**In Vitro Drug Release Study:-**

**Table :-In Vitro Drug Release Study of all Batch Synthetic Polymers**

| Time(hr) | F1 | F2 | F3 | F4 | F5 |
|---|---|---|---|---|---|
| 0 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 |
| 2 | 12.4±0.23 | 10.2±0.23 | 5.5±0.38 | 25.8±0.56 | 38.6±0.18 |
| 4 | 24.1±0.43 | 18.5±0.32 | 15.1±0.32 | 48.2±0.45 | 55.4±0.23 |

| | | | | | |
|---|---|---|---|---|---|
| **6** | **35.8±0.27** | **28.3±0.15** | **31±0.23** | **72.1±0.55** | **67.1±0.43** |
| **8** | **46.2±0.32** | **38.9±0.28** | **40.7±0.44** | **89.4±0.32** | **78.5±0.37** |
| **10** | **58.5±0.13** | **49.6±0.72** | **52.8±0.65** | **96.2±0.16** | **88.5±0.72** |
| **12** | **72.1±0.33** | **61.4±0.19** | **66.7±0.75** | **100.0±0.13** | **96.07±0.35** |




**Graph :- %Cumulative In Vitro Drug Release Study**

## Discussion

The in vitro drug release study of formulations F1–F5 demonstrated a sustained release pattern over 12 h, influenced by formulation composition and matrix characteristics. Initial drug release at 2 h ranged from 5.5 ± 0.38% to 38.6 ± 0.18%, with F4 showing the highest burst release, indicating rapid matrix hydration and swelling. Other formulations exhibited a more controlled initial release profile.By the 4th h, cumulative drug release ranged between 15–55%, suggesting diffusion-controlled release from the matrix system. Formulations F4 and F5 showed improved release behavior, possibly due to optimized polymer concentration and enhanced erosion mechanisms. At 6 h, drug release was observed in the range of 28–72%, where F4 displayed faster release while F3 maintained a slower and sustained release profile suitable for prolonged drug delivery.After 12 h, cumulative drug release ranged from 61% (F2) to 100% (F4). Formulations F4 and F5 achieved near-complete drug release (>90%), indicating effective swelling and matrix disintegration properties responsible for sustained diffusion.

## Stability Studies Of Tablet.

### Selection of batches

The samples were selected randomly from all five batches. These samples were packed in the same container and closure system used for marketing.

### Physical Parameters

To check the physical stability of the tablets, at accelerated stability conditions (listed in Table) were evaluated at the different period. For a period of 3 months. Samples were withdrawn at predetermined intervals of 0, 1, 2, and 3 months and evaluated for various parameters such as appearance, hardness, friability, weight variation, disintegration time, drug content, and in-vitro dissolution study Therefore, the optimized formulation F4 was found to be stable

**Table : Physical Parameters Of Tablets Under Accelerated Conditions**

| Parameters | Initial | 1 Month | 2 Months | 3 Months |
|---|---|---|---|---|
| **Appearance** | Greenish brown tablet | No change | No change | No change |
| **Average weight (mg)** | 500 ± 3 | 500 ± 2 | 501 ± 3 | 500 ± 2 |
| **Hardness (kg/cm²)** | 4.9 ± 0.2 | 4.8 ± 0.3 | 4.8± 0.2 | 4.9± 0.2 |
| **Friability (%)** | 0.48 | 0.50 | 0.54 | 0.58 |
| **Disintegration time (min)** | 14.2 ± 0.5 | 14.5 ± 0.4 | 14.8 ± 0.6 | 15.0 ± 0.5 |
| **Drug content (%)** | 99.2 ± 0.4 | 98.8 ± 0.5 | 98.4 ± 0.6 | 97.9 ± 0.5 |
| **Drug release after 12 h (%)** | 98.4 ± 0.5 | 97.9 ± 0.6 | 97.2 ± 0.5 | 96.8 ± 0.7 |

**Qualitative identification of Momordica diocia extract.**

**Sample Preparation Of Momordica Diocia Extract**

An accurately weighed quantity of 10 mg of extract was dissolved in water (7 ml) and refluxed for 30 min. The volume was made up to 10 ml with water to produce a final concentration of 1000µg/µl.

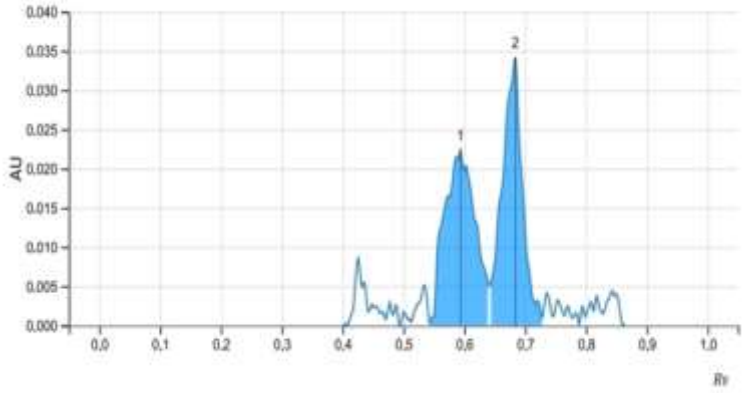



**Figure 8.1 :- Fingerprint Of Momordica Diocia**

**HPTLC Instrumentation and Chromatographic Conditions:-**

The stock solution of Momordica dioica extract (1 mg/mL) was prepared using water as solvent. Samples were applied on HPTLC plates using a CAMAG Linomat V sample applicator fitted with a 100 µL Hamilton syringe (Bonaduz, Switzerland).

The standard stock solution of saponin (1 mg/mL) was prepared in water. Different concentrations ranging from 2–14 µg/spot were applied as 8 mm bands using the CAMAG Linomat V applicator. Calibration curves were constructed by plotting peak area against corresponding saponin concentration, followed by linear regression analysis.

Linearity of the developed HPTLC method was evaluated in the concentration range of 8–14 µg/spot. The calibration curve showed a strong linear relationship between concentration and peak

area with a correlation coefficient ($R^2$) of 0.998,
indicating excellent method linearity..

**Linearity Data**

| Concentration (µg/spot) | Peak Area (AU) | Y=X |
|---|---|---|
| 8 | 2.13x10-² | 2.13x10-² |
| 10 | 2.97x10-² | 2.97x10-² |
| 12 | 3.79x10-² | 3.79x10-² |
| 13 | 4.16x10-² | 4.16x10-² |
| 14 | 4.54x10-² | 4.54x10-² |

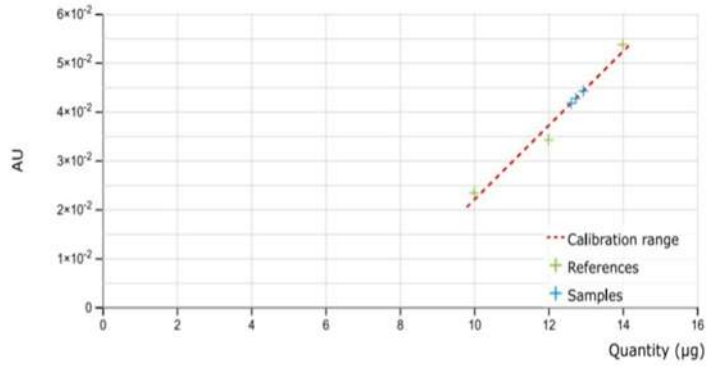



**Table -**Calibration Curve Of drug At 254 nm

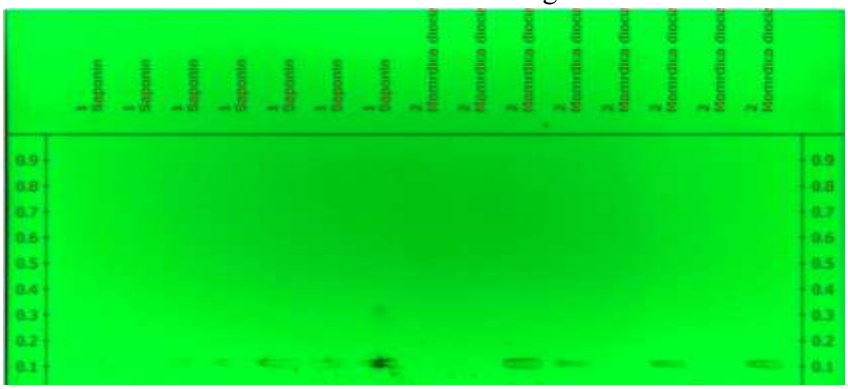


**Figure :- Photograph at 254nm UV light**

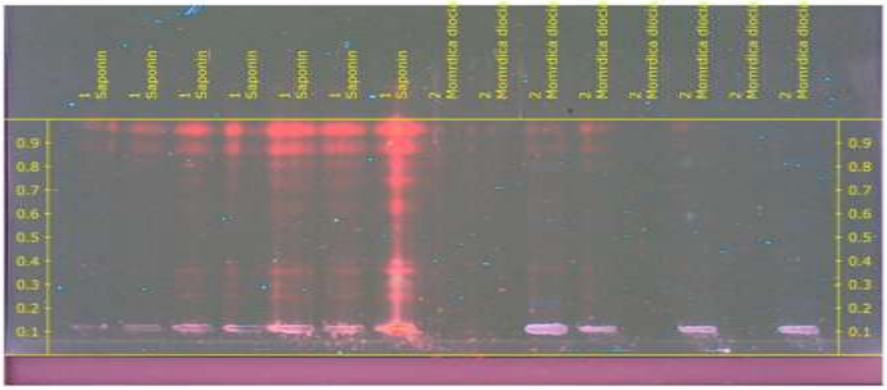


**Figure:- Photograph at 366nm UV light**

**Calibration curve**

For proving linearity, five calibration points were analyzed over the range of 2 to 14 µgband-1of quercetin. The data were analyzed by linear regression least square model and showed a good linear relationship evidenced by r2 =0.9866 and the linear regression equation for quercetin was **$y= 7.576\times10^{-9}x–5.387\times10^{2}$**

Where, y is the response as peak area and ,x is the concentration in µg.

No significant difference was observed in the slopes and intercepts of standard curves.the HPTLC chromatograms (254nm) of saponin and the methanol extracts fruits of Momordica.D

**Table:-**Linear regression parameters

| **Linear regression parameters** | |
|---|---|
| Linearity range | 2-14µg |
| RF | 0.52 ± 0.02 |
| Linear regression equation | $7.576\times10^{-9}x–5.387\times10^{-2}$ |
| Correlation factors ($R^2$) | 0.9866 |
| Confidence limit of slope | $7.576 \times 10^{-3} \pm 0.0002$ |
| Confidence limit of intercept | $–5.387 \times 10^{-3} \pm 0.0005$ |
| LOD (µg band -1) | 0.052 µg |
| LOQ (µg band -1) | 0.159 µg |

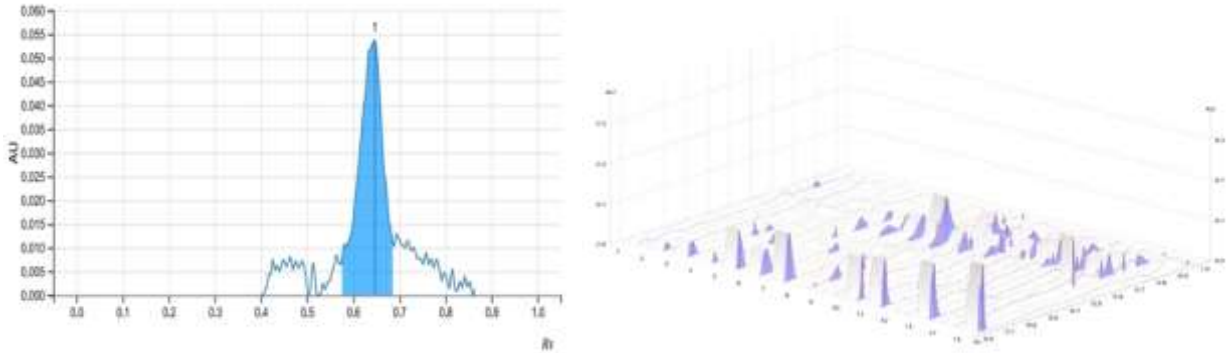


**Figure:- HPTLC Densitograms Of Saponin (14.0 µg band-1), 3D Display Of HPTLC Chromatograms Saponin Along With Methanol Extracts Of Momordicadiocia Fruits**

**Method Validation**

The developed HPTLC method was validated in terms of linearity, precision (intra-day and inter-day precision), robustness or variability of the method, accuracy or recovery studies, specificity, and limits of detection and quantification according to the guidelines [(ICH guideline, (Q2R1)].

Recovery studies were carried out by standard addition method. The pre-analyzed samples were spiked with extra 80, 100 and 120% of saponin , and the recovery of saponin at different levels in the extracts was performed. Results showed that the percent recoveries for quercetin were in the range of 989.5% respectively, as shown in Table

**Accuracy:-**

**Table:- Recovery studies of saponin by addition of 9.6,12,14.4(µg band -1) quantities By the proposed HPTLC method.**

| Level (%) | Amount Added (µg/spot) | Amount Found ( µg /spot) | % Recovery | Mean % Recovery |
|---|---|---|---|---|
| 80 | 9.6 | 9.49 | 98.85 | 99.5 % |
| 100 | 12 | 12.01 | 100.08 | |
| 120 | 14.4 | 14.34 | 99.58 | |

**Discussion** : The % recovery values are within the Acceptable range of 98-102%, indicating

**Precision:-**Repeatability of sample application and measurement of peak area were carried out Using six five replicates of the same band (9ug, 12ug and 14ug of saponin). It was expressed in terms of percent relative standard deviation (%RSD). The intra-and Inter-day variation for the determination of saponin was carried out at three different Concentration levels of 9.6, 12ug and 14ug band-1.

**Table 8.12 :- Inter- And Intra-Day Precision Of The HPTLC Method For Saponin**

| Level (%) | Concentration (ug/spot) | Repeatability (Intra-day) | | |
|---|---|---|---|---|
| | | Mean Peak Area (AU) | SD | %RSD |
| 80 | 9.6 | 2.8lx10-² | 0.00011 | 0.39 |
| 100 | 12 | 3.79x10-² | 0.00016 | 0.42 |
| 120 | 14.4 | 4.56x10-² | 0.00020 | 0.44 |
| **Level (%)** | **Concentration (ug/spot)** | **Intermediate Precision (Inter-day)** | | |
| | | **Mean Peak Area (AU)** | **SD** | **%RSD** |
| 80 | 9.4 | 2.84x10-² | 0.00011 | 0.42 |
| 100 | 12 | 3.81x10-² | 0.00015 | 0.39 |
| 120 | 14.4 | 4.58x10-² | 0.00019 | 0.41 |

**Specificity**

The specificity of the proposed HPTLC method was determined by saponin, and the methanolic extract of Momordica diocia. The band for saponin in the sample were confirmed by comparing the RF and peaks with that of the compound. The peaks were compared at three different positions: the peak start, peak centre, and peak end. Saponin peaks were well resolved indicating there was no interference from the other component present.

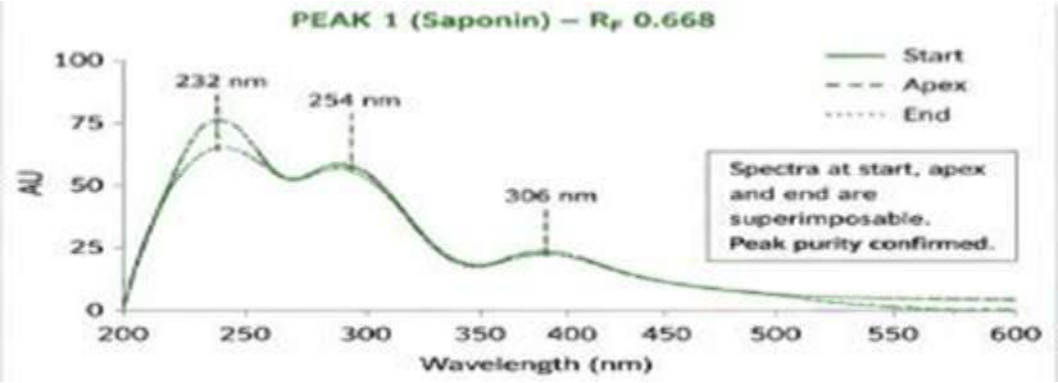



**Figure:-Overlaid spectra of saponin along with Momordica diocia parts (fruits) at254**

**Limit of Detection and Limit of Quantification.**

| Parameter | Formula | Value |
|---|---|---|
| LOD | 3.3×σ/S | 0.052ug |
| LOQ | 10×σ/S | 0.159 |

**Robustness or variability of the method:-**

**Table :-Robustness study of the proposed HPTLC method for saponin**

| Parameter(s) | Change Parameters | Mean peak area | SD | %RSD |
|---|---|---|---|---|
| Minor changes mobile phase (toulen:ethylacetate:formicacid) | 7:3:0.1 | 3.79×10-² | 0.00016 | 0.42% |
| | 8:1:1 | 3.76×10-² | 0.00021 | 0.56% |
| | 6:4:0.1 | 3.78×10-² | 0.00019 | 0.50% |
| | Overall | 3.777×10-² | 0.00021 | **0.55%** |
| Scanning wavelength (nm) | 278 | 3.79×10-² | 0.00016 | 0.42% |
| | 276 | 3.80×10-² | 0.00018 | 0.47% |
| | 280 | 3.77×10-2 | 0.00021 | 0.56% |
| | Overall | 3.786×10-² | 0.00020 | **0.50%** |

## CONCLUSION

The present study successfully formulated and evaluated tablets for the management of urolithiasis. Pre-formulation studies showed good flow and compressibility properties of the powder blend. The prepared tablets demonstrated satisfactory physicochemical characteristics, including acceptable hardness, friability, weight variation, thickness, and stability within pharmacopoeial limits.Among all batches, formulation F4 exhibited the best controlled and sustained drug release over 12 hours and remained stable during accelerated stability studies. UV spectroscopic analysis confirmed good linearity following Beer-Lambert's law, while HPTLC studies verified the presence of active phytoconstituents such as saponins

Overall, the formulated herbal tablets showed promising antiurolithiatic potential with good quality, stability, and sustained release characteristics. Further in vivo and clinical studies are required to confirm their therapeutic efficacy and safety.

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