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Method Development and Evaluate of Nitrofurantoin Tablet

[1]Pawade Omkar Ganpat ,[2]Padwal Prachi Nandkumar ,[3]Pathan MujebaRajjak
Samarth Institute of Pharmacy, behle.

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ABSTRACT
Nitrofurantoin is a broad-spectrum antibacterial agent widely used for the treatment of urinary tract infections. However, its poor aqueous solubility and variable bioavailability present significant challenges in formulation development. The present study aims to develop and evaluate Nitrofurantoin tablets with improved physicochemical and dissolution characteristics.In this study, tablets were formulated using suitable excipients by employing methods such as direct compression and/or wet granulation. Various formulation variables, including the type and concentration of binders, disintegrants, and lubricants, were optimized to achieve desired tablet properties. The prepared formulations were evaluated for precompression parameters such as angle of repose, bulk density, and compressibility index, as well as post-compression parameters including weight variation, hardness, friability, disintegration time, and drug content uniformity.In vitro dissolution studies were carried out to assess the drug release profile of the formulated tablets. The optimized formulation demonstrated satisfactory mechanical strength, uniform drug content, and compliance with pharmacopeial standards. Additionally, improved dissolution behavior was observed compared to conventional formulations. Stability studies indicated that the developed tablets were stable under specified storage conditions.In conclusion, the study successfully developed Nitrofurantoin tablets with enhanced quality attributes and improved dissolution characteristics, which may lead to better therapeutic efficacy and patient compliance.
Keywords: Nitrofurantoin, Urinary tract infection, Poor solubility, Tablet formulation, Direct compression, Wet granulation, Excipients optimization, Dissolution study, Drug release, Stability study, Bioavailability, Pharmacopeial evaluation.

I. Introduction

Nitrofurantoin is a synthetic antibacterial agent belonging to the nitrofuran class, widely used in the treatment and prevention of urinary tract infections (UTIs). It is particularly effective against common uropathogens such as Escherichia coli, making it a first-line therapy for uncomplicated UTIs. Due to its rapid excretion in urine, Nitrofurantoin achieves high concentrations in the urinary tract, which enhances its therapeutic effectiveness while minimizing systemic exposure.Despite its clinical importance, Nitrofurantoin presents several formulation challenges. The drug exhibits poor aqueous solubility, which can result in slow dissolution and variable bioavailability. These limitations may affect the onset and consistency of therapeutic action. Additionally, Nitrofurantoin has a relatively short half-life, requiring frequent dosing, which may reduce patient compliance.Tablet dosage forms are among the most preferred routes of drug administration due to their convenience, stability, and ease of manufacturing. However, developing an effective Nitrofurantoin tablet requires careful selection of excipients and formulation techniques to overcome its physicochemical limitations. Methods such as wet granulation and direct compression are commonly employed to improve flow properties, compressibility, and uniformity of the drug blend.Furthermore, the evaluation of tablet formulations is a critical step in ensuring quality, safety, and efficacy. Parameters such as hardness, friability, disintegration time, drug content uniformity, and in vitro dissolution are essential to confirm that the formulation meets pharmacopeial standards. Stability studies are also necessary to ensure that the product maintains its quality under various environmental conditions.In recent years, efforts have been made to develop modified-release formulations of Nitrofurantoin to reduce dosing frequency and minimize gastrointestinal side effects. Such approaches aim to improve patient compliance and therapeutic outcomes.
Nitrofurantoin is a synthetic nitrofuran derivative used as an antibacterial agent mainly for urinary tract infections. It acts by inhibiting bacterial enzymes and damaging bacterial DNA. Due to its therapeutic importance, proper analytical methods are required for quality control and formulation development.

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Analytical method development plays a major role in pharmaceutical industries for:

- Identification of drug substances
- Quantitative estimation
- Stability testing
- Quality assurance
- Regulatory compliance

EvaluNitrofurantoin is a synthetic antibacterial agent belonging to the nitrofuran class, widely used in the treatment and prevention of urinary tract infections (UTIs). It is particularly effective against common uropathogens such as Escherichia coli, making it a first-line therapy for uncomplicated UTIs. Due to its rapid excretion in urine, Nitrofurantoin achieves high concentrations in the urinary tract, which enhances its therapeutic effectiveness while minimizing systemic exposure.Despite its clinical importance, Nitrofurantoin presents several formulation challenges. The drug exhibits poor aqueous solubility, which can result in slow dissolution and variable bioavailability. These limitations may affect the onset and consistency of therapeutic action. Additionally, Nitrofurantoin has a relatively short half-life, requiring frequent dosing, which may reduce patient compliance.Tablet dosage forms are among the most preferred routes of drug administration due to their convenience, stability, and ease of manufacturing. However, developing an effective Nitrofurantoin tablet requires careful selection of excipients and formulation techniques to overcome its physicochemical limitations. Methods such as wet granulation and direct compression are commonly employed to improve flow properties, compressibility, and uniformity of the drug blend.Furthermore, the evaluation of tablet formulations is a critical step in ensuring quality, safety, and efficacy. Parameters such as hardness, friability, disintegration time, drug content uniformity, and in vitro dissolution are essential to confirm that the formulation meets pharmacopeial standards. Stability studies are also necessary to ensure that the product maintains its quality under various environmental conditions.In recent years, efforts have been made to develop modified-release formulations of Nitrofurantoin to reduce dosing frequency and minimize gastrointestinal side effects. Such approaches aim to improve patient compliance and therapeutic outcomes.Nitrofurantoin tablets are formulated to provide effective drug release and adequate bioavailability while maintaining stability and patient compliance. The quality, safety, and therapeutic efficacy of the tablet dosage form depend on proper formulation development and rigorous evaluation parameters. Method development plays a vital role in ensuring accurate identification, quantification, and analysis of the drug during formulation and quality control studies. Analytical methods such as UV spectrophotometry, High Performance Liquid Chromatography (HPLC), dissolution studies, and stability testing are commonly employed for the evaluation of nitrofurantoin tablets.The development of analytical methods for nitrofurantoin tablets involves selecting suitable solvents, detection wavelengths, chromatographic conditions, and validation parameters according to official guidelines such as those provided by the International Council for Harmonisation. Validation of these methods includes assessment of accuracy, precision, specificity, linearity, robustness, and sensitivity. Reliable analytical methods are essential for maintaining consistency in pharmaceutical manufacturing and ensuring compliance with regulatory standards.

II. AIM AND OBJECTIVE

Aim: To develop and evaluate the nitrofurantoin tablet

Objectives:

• To identify and confirm the purity of Nitrofurantoin API.
• To determine the solubility of Nitrofurantoin in different solvents.
• To develop a simple analytical method (like UV or HPLC) for estimation of the drug.
• To validate the developed method for accuracy, precision, and reliability.
• To study the stability of Nitrofurantoin under different condition.

Objectives of Review

1.To study formulation methods of nitrofurantoin tablets.
2.To review analytical method development techniques.
3.To evaluate validation parameters according to ICH guidelines.
4.To discuss pre-compression and post-compression evaluation tests.
5.To review stability and dissolution studies of nitrofurantoin tablets

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Drug profile -

Parameter	Information
Drug Name	Nitrofurantoin
Brand Name	Macrobid, Macrodantin
Structure	
Molecular Weight	238.16 g/mol
Chemical Formula	$C_8H_6N_4O_5$
IUPAC Name	1-[(5-nitrofuran-2-yl)methyleneamino]imidazolidine-2,4-dione
BCS Class	Class IV
Half-life	~0.5 – 1 hour
pKa	~7.2
Log P	~ -0.7
Solubility	Soluble in Dimethylformamide
Mechanism of Action	Inhibits bacterial enzymes and damages DNA
Indication	Urinary tract infections (UTIs)
Absorption	Rapid, enhanced with food
Protein Binding	~60%
Metabolism	Liver (partial)
Excretion	Primarily via urine

III. Literature Review of Work

1. Allen LV Jr et al; 2013 Allen and co-workers discussed the major challenges associated with poorly soluble drugs and emphasized the role of excipients and processing techniques in improving drug solubility and bioavailability. Their study highlighted the importance of formulation strategies in enhancing therapeutic effectiveness.

2. Patel RP et al; 2014 Patel and co-workers formulated Nitrofurantoin tablets using the wet granulation method and evaluated their physicochemical properties. Their work demonstrated that wet granulation improves tablet uniformity, compressibility, and dissolution characteristics.

3. Kumar S et al; 2016 Kumar and colleagues focused on improving the dissolution rate of Nitrofurantoin using solid dispersion with PEG. Their findings showed a significant enhancement in drug release due to improved wettability and reduced crystallinity.

4. Desai KG et al; 2017 Desai and co-workers studied the direct compression method and the effect of superdisintegrants on drug release. Their research concluded that the selection and concentration of superdisintegrants play a key role in enhancing tablet disintegration and dissolution.

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5. Rao NG et al; 2018 Rao and colleagues developed sustained-release Nitrofurantoin tablets using HPMC as a matrix-forming polymer. Their study demonstrated controlled drug release over an extended period, improving therapeutic efficiency.
6. Shah RB et al; 2019 Shah and co-workers evaluated various post-compression parameters of tablet formulations, including hardness, friability, and disintegration time. Their work emphasized the importance of these parameters in ensuring tablet quality and performance.
7. Patel MM et al; 2020 Patel and colleagues conducted stability studies of Nitrofurantoin tablets under accelerated conditions. Their results confirmed that properly formulated tablets remain stable.
8. Noyes AA et al; 1897Noyes and Whitney introduced the dissolution rate theory, explaining how surface area and solubility influence drug dissolution. Their equation remains fundamental in pharmaceutical dissolution studies.
9. Dressman JB et al; 2000 Dressman and co-workers explored in vitro–in vivo correlation for poorly water-soluble drugs. Their study highlighted the importance of dissolution testing in predicting drug absorption and bioavailability.
10. Amidon GL et al; 1995 Amidon and colleagues developed the Biopharmaceutics Classification System (BCS), which categorizes drugs based on solubility and permeability. Their work is crucial in guiding formulation and regulatory decisions.
11. Ford JL; 1999 Ford investigated the design and evaluation of HPMC matrix tablets for controlled drug release. His study demonstrated how polymer concentration influences drug release kinetics.
12. Lachman L et al; 1986 Lachman and co-workers provided comprehensive knowledge on industrial pharmacy, including formulation techniques, excipient selection, and manufacturing processes essential for tablet development.
13. Aulton ME et al; 2013 Aulton and colleagues presented detailed insights into pharmaceutical formulation and drug delivery systems. Their work emphasized the scientific principles behind dosage form design and evaluation.

Solubility table-

Sr. No.	Solvent / Medium	Solubility	Remarks (Method Development Use)
1	Water	Slightly soluble	Poor dissolution; not preferred alone
2	Ethanol (95%)	Freely soluble	Good solvent for assay preparation
3	Methanol	Freely soluble	Commonly used in UV/HPLC analysis
4	Acetone	Soluble	Used in extraction procedures
5	Chloroform	Slightly soluble	Limited analytical use
6	Dimethyl sulfoxide (DMSO)	Freely soluble	Useful for stock solution preparation
7	0.1 N Hydrochloric acid (HCl)	Soluble	Simulates gastric pH (1–2)
8	Phosphate buffer pH 6.8	Slightly soluble	Mimics intestinal fluid
9	0.1 N Sodium hydroxide (NaOH)	Soluble	Used for forced degradation studies

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10	Acetonitrile	Freely soluble	Preferred in HPLC mobile phase

Method Development

UV Spectrophotometric Method

UV spectroscopy is widely used for quantitative estimation of nitrofurantoin due to its simplicity, accuracy, and cost-effectiveness. The drug shows maximum absorbance (λmax) around 366 nm in suitable solvents.

Advantages1.Simple and economical 2.Rapid analysis 3.Suitable for routine quality control

HPLC Method High Performance Liquid Chromatography (HPLC) is commonly used for precise estimation of nitrofurantoin in pharmaceutical dosage forms.

Typical Conditions Column: C18 column Mobile phase: Methanol and waterDetection wavelength: 366 nm Flow rate: 1 mL/min

Advantages High sensitivity Accurate and precise Suitable for stability studies

Dissolution Method Dissolution testing determines the rate and extent of drug release from tablets.**Parameter** Dissolution medium: 0.1N HCl or phosphate buffer Temperature: 37 ± 0.5°C Rotation speed: 50–100 rpm

Validation Parameters According to International Council for Harmonisation, analytical methods should be validated for: Accuracy Precision Linearity Robustness Specificity Limit of Detection (LOD) Limit of Quantification (LOQ)

Evaluation of Nitrofurantoin Tablets

Pre-Compression Parameters Angle of Repose Determines flow properties of powder blend.

Bulk Density and Tapped Density Used to evaluate packing ability of powder.

Carr's Index and Hausner Ratio Indicate compressibility and flow characteristics.

Post-Compression Parameters

Hardness Test Measures mechanical strength of tablets.

Friability Test Determines resistance to abrasion.

Weight Variation Test Ensures uniform tablet weight.

Drug Content Uniformity Ensures uniform distribution of active ingredient.

Disintegration Test Measures time required for tablet breakdown.

Dissolution Test Determines drug release profile from tablets.

7. Stability Studies

Stability studies are performed according to ICH guidelines to determine shelf life and storage conditions.

Conditions Accelerated stability: 40°C ± 2°C / 75% RH Long-term stability: 25°C ± 2°C / 60% RH

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Uv Evaluation – Evaluaion of Tablets

PerkinElmer

User Information

Name:

Experiment Information

Title: Pawade
Comment:
Instrument Serial No.: 365K7020210
Software Version: UV Express - Version 4.1.1

Experimental Date: May 19 2026 10:59:38 (GMT +5:30)
System Name: Undefined
Firmware Version: 160529

Method

Experiment Type : Scan Setup

Experiment Setup	Internal Reference	Scan Setup
Data Type: Absorbance Spectra No.: 1 Measurement Range (nm): 800~200 Data Interval (nm): 1.0 0%T / Blocked Beam Baseline : No SBW (nm): 5.0 Beam Type: Double Normal Lamp: UV+VIS Lamp Change (nm): 400 Accessory : Integrating Sphere	Use: No	Monitoring Wavelength (nm): 440, 465, 546.1, 590, 635

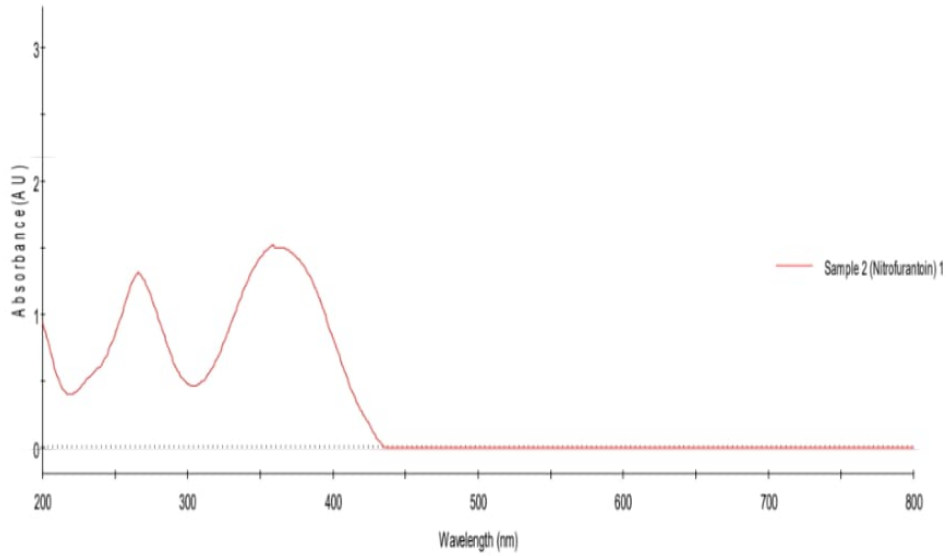
Result Data

Name	AU(440.00nm)	AU(465.00nm)	AU(546.10nm)	AU(590.00nm)	AU(635.00nm)
Sample 2 (Nitrofurantoin) 1	0	0	0	0	0

Spectrum List

Name	Date
Sample 2 (Nitrofurantoin) 1	May 19 2026 11:20:56 (GMT +5:30)

Sample Spectrum



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Evalution of API-

User Information

Name:

Experiment Information

Title: Pawade
Comment:
Instrument Serial No.: 365K7020210
Software Version: UV Express - Version 4.1.1

Experimental Date: May 19 2026 10:59:38 (GMT +5:30)
System Name: Undefined
Firmware Version: 160529

Method

Experiment Type : Scan Setup

Experiment Setup	Internal Reference	Scan Setup
Data Type: Absorbance Spectra No.: 1 Measurement Range (nm): 800~200 Data Interval (nm): 1.0 0%T / Blocked Beam Baseline : No SBW (nm): 5.0 Beam Type: Double Normal Lamp: UV+VIS Lamp Change (nm): 400 Accessory : Integrating Sphere	Use: No	Monitoring Wavelength (nm): 440, 465, 546.1, 590, 635

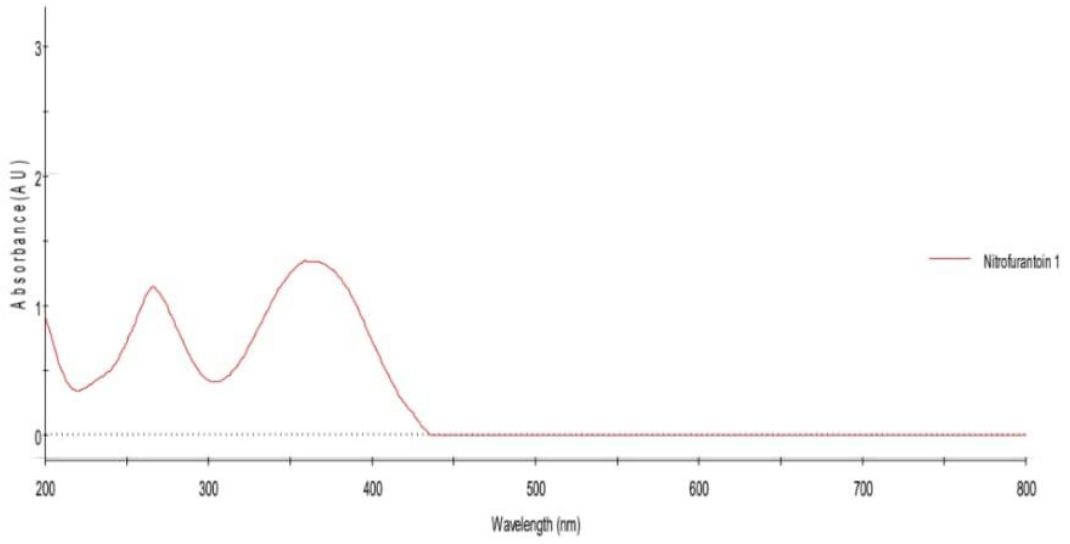
Result Data

Name	AU(440.00nm)	AU(465.00nm)	AU(546.10nm)	AU(590.00nm)	AU(635.00nm)
Nitrofurantoin 1	0	0	0	0	0

Spectrum List

Name	Date
Nitrofurantoin 1	May 19 2026 11:17:28 (GMT +5:30)

Sample Spectrum



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Evalution Of Hplc - Tablets

Pune District Education Association's

Annasaheb Waghire College of Arts, Science & Commerce, Otur

Tal. Junnar, Dist. Pune 412409

DST FIST-funded Central Instrumentation Facility Laboratory

HPLC Sample Analysis Report

Date: 19/05/2026

Candidate: Mr. Omkar Pawade

College: Samarth College of Pharmacy, Belhe

Sample Name / Code: Nitrofurantoin Tablet

Instrument Model: Systronic LC 138

Column: C18

Mobile Phase: Methanol

Detector: UV

Pressure: 10 MPa

Temperature: Room Temperature (30°C)

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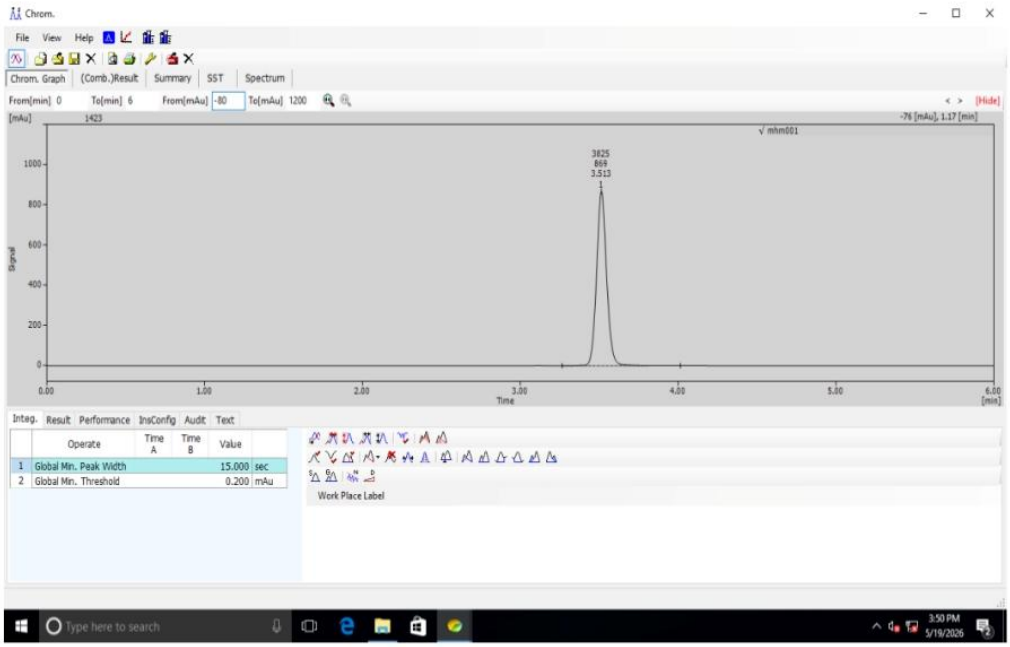

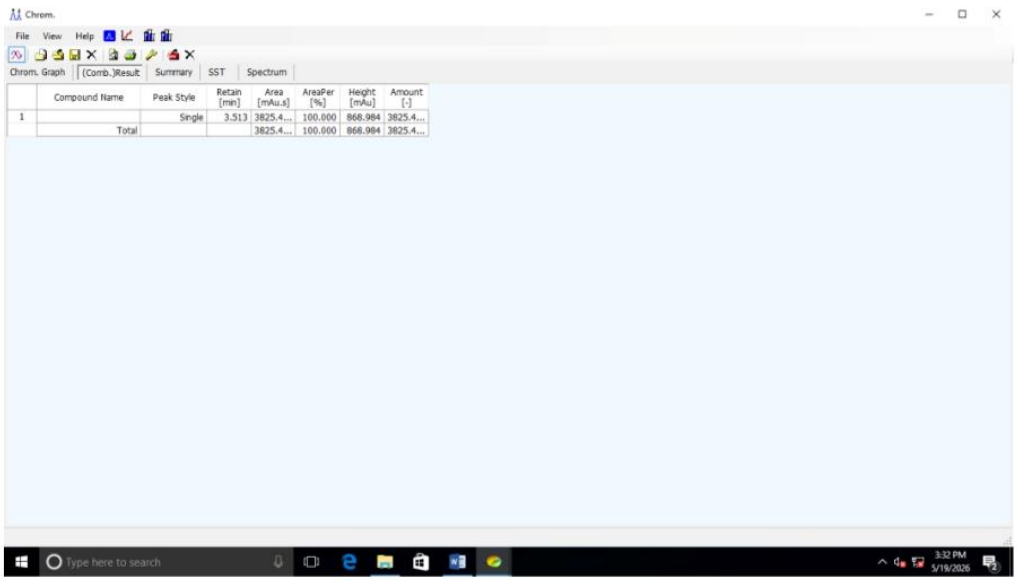

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Evalution Of Hplc – API

Pune District Education Association's

Annasaheb Waghire College of Arts, Science & Commerce, Otur

Tal. Junnar, Dist. Pune 412409

DST FIST-funded Central Instrumentation Facility Laboratory

HPLC Sample Analysis Report

Date: 19/05/2026

Candidate: Mr. Omkar Pawade

College: Samarth College of Pharmacy, Belhe

Sample Name / Code: Sample 2 (Nitrofurantoin)

Instrument Model: Systronic LC 138

Column: C18

Mobile Phase: Methanol

Detector: UV

Pressure: 10 MPa

Temperature: Room Temperature (30°C)

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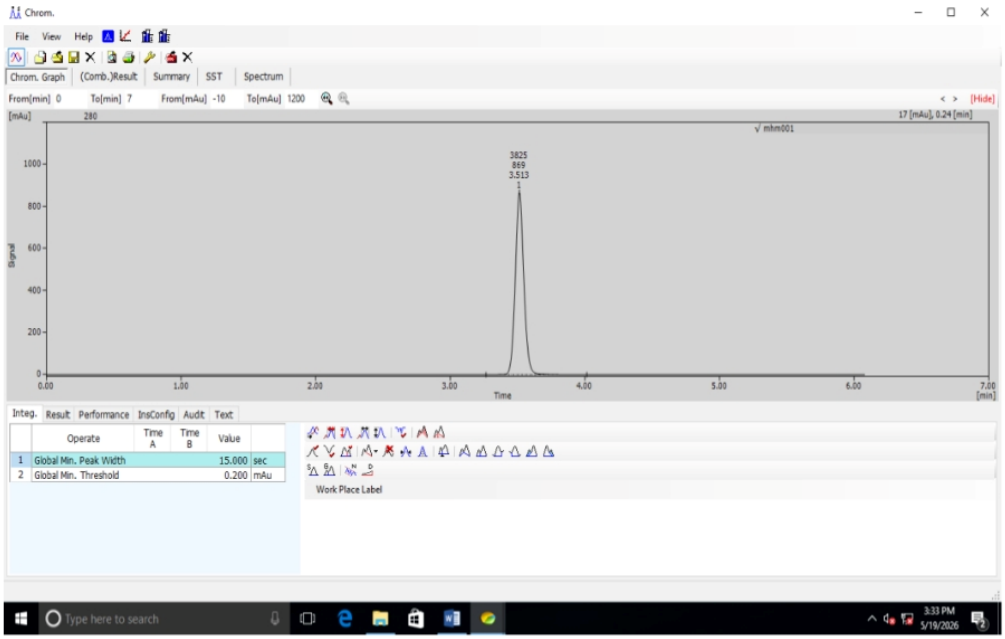

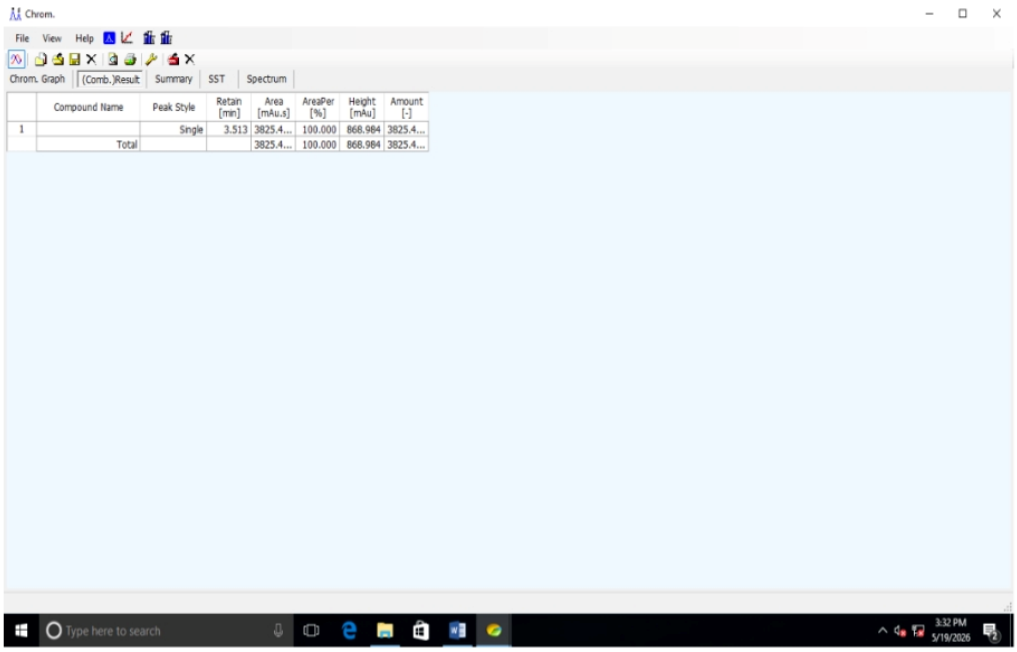

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IV. Result

The developed analytical methods for the evaluation of Nitrofurantoin tablets were found to be simple, accurate, precise, and reliable for routine pharmaceutical analysis. UV spectrophotometric and HPLC methods showed good linearity, specificity, and reproducibility within the selected concentration range. Validation parameters such as accuracy, precision, robustness, limit of detection (LOD), and limit of quantification (LOQ) were found to be within acceptable limits according to International Council for Harmonisation.The formulation evaluation studies indicated that the prepared nitrofurantoin tablets possessed satisfactory pre-compression properties including good flowability, compressibility, and uniform blending characteristics. Post-compression evaluation parameters such as hardness, friability, weight variation, thickness, drug content uniformity, disintegration time, and dissolution profile complied with official pharmacopeial standards.Dissolution studies demonstrated effective and consistent drug release from the tablet formulation, indicating good bioavailability characteristics. Stability studies performed under accelerated and long-term storage conditions showed no significant changes in physical appearance, drug content, or dissolution behavior, confirming the stability of the formulation.Overall, the developed methods and evaluation parameters were suitable for quality control analysis and ensured the safety, efficacy, and stability of nitrofurantoin tablet formulations.

V. Conclusion

Nitrofurantoin tablets are widely used in the treatment of urinary tract infections and require proper formulation and analytical evaluation to ensure therapeutic efficacy and quality. Various analytical techniques such as UV spectroscopy and HPLC are effective for method development and validation. Evaluation parameters including hardness, friability, dissolution, and stability studies are essential for maintaining pharmaceutical quality standards. Continuous research in formulation development and analytical methods can improve the effectiveness and stability of nitrofurantoin tablet formulations.

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