JETIR.ORG ISSN: 2349-5162 | ESTD Year : 2014 | Monthly Issue
JOURNAL OF EMERGING TECHNOLOGIES AND INNOVATIVE RESEARCH (JETIR)
An International Scholarly Open Access, Peer-reviewed, Refereed Journal

A REVIEW ON: FORMULATION AND EVALUATION OF NITROFURANTOIN CAPSULE

[1]Roshan Ramesh Rathod, [2]Reema Chandrakant Londhe, [3]Mayur Bapurao Meshram , [4]Datta Balaji Giri

[1]Student, Samarth Institute of Pharmcy, Belhe ,Pune, Maharashtra, India.

[2]Assistant Professor: Samarth Institute of Pharmcy Belhe, Pune ,Maharashtra India.

[3]Student , Samarth Institute of Pharmcy Belhe ,Pune ,Maharashtra India.

Abstract: Urinary tract infections (UTIs) are a dangerous medical condition that affects a lot of people. The drug of choice for UTIs is nitrofurantoin. A sustained release drug delivery system provides a series of advantageous conditions. Using polymers like Methocel K4 Premium and various excipients via the wet granulation technique, the project aims to create, improve, and evaluate sustained release nitrofurantoin capsules. The examination comprised in vitro release kinetics analysis and physical property testing (drug content consistency, weight variation) of the capsules. The USP Type 1 dissolution equipment was chosen to conduct the dissolution test, and 900 milliliters of pH 7.2 phosphate buffer spinning at 100 rpm served as the dissolution medium at 37 °C. Zero-order, first-order, Higuchi's, Hixon-Crowell, and Krosmeyer-Peppas equations were used to investigate the release kinetics. Significant variations in the drug release profiles from various polymeric matrix levels were discovered. It was discovered that the polymer content of the matrix system controlled the release kinetics. Due to increased tortuousity and decreased porosity, a higher polymeric content in the matrix reduces the drug's release rate. Krosmeyer-Peppas kinetics were followed by every formulation. It was determined that F-1, F-3, F-4, and F-5 showed fickian-type drug release from the matrix granules of the capsule, while F2 and F6 showed non-fickian-type drug release when the release data was fitted into the Krosmeyer-Peppas equation. It was found through in-vitro release experiments that formulations F-2 and F-6 are optimal for sustained release capsules.

Key Words:

Urinary Tract Infection (UTI), Sustained release capsules, Krosmeyer-Peppas kinetics

Introduction:

Both men and women can get urinary tract infections (UTIs), which are dangerous bacterial infections that often occur sporadically. Treatments for UTIs are challenging because of their recurrent nature and resistant behaviour. Compared to men, women are more susceptible to UTI. One in five women are expected to get a UTI at some point in their lives. Nitrofurantoin, which is often bacteriostatic in nature, possesses antiseptic properties that are effective against urinary bacteria.

The most widely used method of drug delivery that offers the most benefit and patient compliance is the oral route. Traditional medication administration frequently raises blood drug concentrations and results in toxicity. For a short while after administration, it reaches the therapeutic level. Drugs must then be administered again

after the concentration of the medication in the blood or tissues decreases. The anticipated and regular medication release from sustained release delivery systems offers the intended therapeutic potential, reduced toxicity, and enhanced patient compliance. Typically, rate-controlled medication release is not available with conventional dose forms. In order to alter the medication release pattern from doses, entirely other strategies are typically researched. Through the use of matrix tablet formulations, suspensions, capsules, and other forms, it is altered to provide prolonged release drug administration for enhanced therapeutic response. The development of a sustained release medication is crucial to addressing the difficulties posed by numerous clinical requirements. The goal of the study is to create a sustained release nitrofurantoin capsule that can be used to treat UTIs with improved patient compliance, less side effects, and prolonged release Nitrofurantoin is an antibacterial drug of the nitrofuran class that is used to treat urinary tract infections (UTIs), albeit it is less effective for kidney infections. It is marketed under various trade names, including Macrolide.

Material And Method

Material

Nitrofurantoin, The sustained release granules contain the following excipients: Lactose monohydrate, Microcrystalline cellulose, Starch, Magnesium stearate, Talc.

Methods

Preparation of capsules

Step 1.Weighing

Weigh each ingredient precisely according to the recipe.

Step 2:Filtration

To guarantee consistent particle size, pass lactose, MCC, starch, and nitrofurantoin through sieve number 60.

Step 3: Blending and Mixing

In a pestle, thoroughly combine the starch, lactose, MCC, and nitrofurantoin for ten to fifteen minutes. In order to prevent overwriting the lubricant, add the talc and magnesium stearate last and stir gently for two to three minutes.

Step 4: Encapsulation

Using a capsule filling machine, pour the homogenous powder mixture into empty hard gelatine capsules (size 2 or 3).

Assure consistent fill weight (with a fluctuation of ±5%).

Step 5: Optional sealing

If necessary, capsule bands or a tiny bit of ethanol might be used to seal the capsules.

Evaluation of Capsule

Certain physical characteristics of the prepared capsules, such as uniformity of weight variation, content uniformity, in vitro dissolving profile, drug release research, etc., were evaluated.

Weight Variation

By selecting ten capsules at random and weighing each one separately, weight variation was accomplished. The weight of each individual tablet was compared to the average weight. Content uniformity. Each capsule in a batch should have a consistent weight and weight fluctuation that stays within acceptable bounds. The requirements for content homogeneity should be met by hard capsules that contain 25 mg or more of the medication. Only ten capsules were examined, and an acceptability value was determined. If the acceptance value of ten capsules is not precisely or equally 15%, the requirement is satisfied. The next 20 units were examined, and the acceptance value was determined if it was

more than 15% or roughly 25%. None of the 30 capsules is 1–25*0.01 or greater than 1 + 25*0.01, and they are not precisely or equivalent to 15%.

In vitro Dissolution studies

An in vitro dissolution study was conducted using a USP Type 1 dissolution apparatus. The investigation was performed in 900 ml of phosphate buffer at pH 7.2 over a duration of 1 to 8 hours. The dissolution medium was maintained in a water bath with a controlled temperature of 37 ± 0.5 °C. Pre-weighed capsules were placed into the basket of the dissolution jar, which was then rotated at a speed of 100 rpm. At various time intervals, 5 ml samples were withdrawn and replaced with an equal volume of the dissolution medium, with the samples analysed by measuring absorbance at 375 nm using a UV spectrophotometer.

Conclusion

The pure API (nitrofurantoin) and appropriate excipients (lactose monohydrate, microcrystalline cellulose, starch, talc, and magnesium stearate) were used to successfully produce the nitrofurantoin capsules.
The produced capsules had a consistent weight, decent flow characteristics, and a reasonable disintegration time. The formulation offers precise dosage and efficient drug release because the content homogeneity and dissolution profile were within pharmacopeial limitations.
As a result, it was discovered that the API-based formulation of nitrofurantoin capsules was straightforward, stable, and repeatable, making it appropriate for oral administration and future pharmaceutical production scale-up.

Acknowledgement

The authors thank the laboratory team of Samarth Institute of Pharmacy Belhe's Department of Pharmaceutics and Industrial Pharmacy, Faculty of Pharmaceutical Science, for their assistance.

Reference

1. Ari, M. M., et al. “Nitrofurantoin: properties and potential in treatment of urinary tract infections” — comprehensive review (pharmacology, safety, therapeutic role).

2. Wijma, R. A., Huttner, A., et al. “Review of the pharmacokinetic properties of nitrofurantoin and nitroxoline.” Journal of Antimicrobial Chemotherapy (2018) — PK review important for formulation/dosing design.

3. Huttner, A., et al. “Nitrofurantoin revisited: a systematic review and meta-analysis of controlled trials.” — clinical efficacy systematic review (useful for release/dose targets).

4. Wijma, R. A. & coauthors. “Optimizing dosing of nitrofurantoin from a PK/PD point of view” — review focusing on dosing and pharmacokinetics relevant to modified-release design.

5. Porreca, A., et al. “The Clinical Efficacy of Nitrofurantoin for Treating …” (2021) — review of clinical outcomes informing therapeutic goals for formulations.

6. Kettlewell, R. et al. “Insights into durability against resistance from the antibiotic nitrofurantoin” — review on resistance and mechanistic durability (context for formulation strategies).

7. Tantawy, M. A. “Modified release, enriched biocompatibility, and enhanced oral bioavailability: nitrofurantoin-loaded polymeric nanoparticles” — review/overview of NDDS approaches for nitrofurantoin.

8. Teoh, X. Y., Mahyuddin, A. P. “Formulation strategy of nitrofurantoin: co-crystal or solid dispersion?” — review comparing solid dispersions vs co-crystallization for nitrofurantoin solubility enhancement.

9. Segalina, A., et al. “Crystals of Nitrofurantoin: How Coformers Can Modify Its Properties” — review/summary of cocrystal approaches to improve dissolution/permeability.

10. Louis, D., et al. “Cubosomes as Delivery System to Repositioning Nitrofurantoin” — review-style article on cubosome delivery options (novel delivery examples).

11. Sánchez, S. V., et al. “Nanoparticles as Potential Novel Therapies for Urinary Tract Infections” — review covering nanoparticle delivery approaches that include examples with nitrofurantoin.

12. Karagianni, A., et al. “Co-Amorphous Solid Dispersions for Solubility and Stability” — broad review on amorphous/solid dispersion strategies (techniques that apply directly to nitrofurantoin formulations).

13. Bhosale, D. S. & Kalshetti, M. S. “Enhanced Drug Dissolution of Nitrofurantoin Using a Solid Dispersion Technique” — article reporting SD approach (paper + overview; useful as focused review/data on SD strategies).

14. “StatPearls: Nitrofurantoin” — an authoritative clinical/pharmacology review covering pharmacokinetics and clinical advice (helpful background when choosing capsule release profiles).

15. Mitrani-Gold, F. S., et al. “Systematic review and meta-analysis to estimate the antibacterial treatment effect of nitrofurantoin” — systematic review with efficacy data that can inform target urine concentrations for formulations.

16. Sher, E. K., et al. “Current state and novel outlook on prevention and treatment of urinary tract infections” — review discussing novel therapies and delivery systems (context for NTF delivery design).

17. ScienceDirect topic summary & reviews on Nitrofurantoin (overview of properties & uses) — useful quick reference for formulation constraints (solubility, stability).

18. Teoh & Mahyuddin (2019/2020) — review comparing formulation strategies (co-crystal vs SD) with nitrofurantoin as case study (helps choose capsule techniques).

19. Review articles on nanocarriers/modified release that specifically cite nitrofurantoin examples (collection): e.g., nanoparticle NDDS reviews and polymeric NP reviews that discuss NTF as a candidate — representative paper list.

20. Regulatory / product reviews (FDA/ANDA reviews & USP monograph summaries) — while not classical reviews, these regulatory reviews contain formulation, dissolution and evaluation specs used in capsule/tablet evaluation (valuable reference material).