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Review Article

A Review On: Formulation And Evaluation of Atropine Sulfate Capsule

Shridhar Das Kolekar*, Reema Chandrakant Londe, Ganesh Jayram Lamkhade, Roshan Ramesh Rathod, Mayur Bapurao Meshram

Samarth Institute of Pharmacy, Belhe, Pune, Maharashtra, India.

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ABSTRACT

Because of its parasympatholytic properties, atropine sulfate is still a significant anticholinergic medication that is frequently used in medical practice to treat organophosphate poisoning, manage bradycardia, and reduce salivary and bronchial secretions. This review focuses on the quality control criteria, excipient selection, and formulation techniques used in the production of atropine sulfate capsules. The pharmaceutical factors necessary to achieve dose homogeneity, stability, and bioavailability of the finished product are highlighted. The impact of several formulation techniques on capsule performance is examined, including the use of lubricants, disintegrants, and fillers. The review also examines developments in encapsulation methods and the regulations controlling the manufacture of atropine sulphate capsules. All things considered, this study offers a thorough summary of current procedures and new developments in atropine sulfate capsule formulation, making it a useful resource for formulation scientists and pharmaceutical researchers.

INTRODUCTION

Atropa belladonna and similar plants in the Solanaceae family are the source of atropine sulphate, a well-known antimuscarinic chemical. It reduces parasympathetic activation in several organs by competitively blocking acetylcholine's ability to attach to muscarinic receptors. In clinical settings, atropine sulfate is frequently used to treat bradycardia, as an antidote for organophosphate and carbamate poisoning, and as a pre-aesthetic drug to reduce salivary and respiratory secretions. Its therapeutic significance and adaptability are shown by its inclusion in the World Health Organization's list of essential medicines.

Accurate dosing, better patient compliance, and increased medication stability are only a few benefits of atropine sulphate's packaging into capsule dosage forms. For medications that need exact dosage control and little excipient interaction, capsules are recommended. However,

***Corresponding Author:** Shridhar Das Kolekar
Address: *Samarth Institute of Pharmacy, Belhe, Pune, Maharashtra, India.*
Email ✉: shridharkolekar10@gmail.com
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the manufacture of capsules requires extreme precision in weighing, mixing, and encapsulating to guarantee uniform drug distribution and constant therapeutic efficacy because of the strong pharmacological activity of atropine sulphate and its low dose needs.

With an emphasis on formulation methods, excipient selection, quality control criteria, and recent innovations in encapsulation technology, this paper attempts to provide an overview of current knowledge and advancements in the creation of atropine sulphate capsules. The paper aims to provide an integrated understanding of the scientific and practical aspects involved in creating safe, effective, and stable atropine sulfate capsule formulations by combining findings from previous research and pharmacopeial guidelines.

MATERIAL AND METHOD:

MATERIAL

Atropine Sulfate, Lactose monohydrate, Starch, Talc, Hard gelatin capsule shell, Magnesium stearate.

METHOD

1.Calculation of Dose and Quantities

The required quantity of atropine sulphate is calculated based on the prescribed capsule strength (e.g., 0.25 mg or 0.5 mg per capsule).

The amount of excipients such as diluents, disintegrants, and lubricants is determined to achieve the desired fill weight and capsule size.

2.Weighing of Ingredients

All ingredients are accurately weighed using an analytical balance to maintain formulation precision.

Atropine sulphate is handled carefully due to its potent pharmacological activity and low dosage requirement.

3.Blending of Ingredients

The weighed atropine sulphate is mixed with a small portion of the diluent to form a uniform premix.

The remaining excipients (diluents, disintegrants, and lubricants) are gradually added and blended to ensure homogeneous distribution of the drug throughout the powder mixture.

Mixing is typically performed in a mortar and pestle or a mechanical mixer for a specified duration.

4.Filling of Capsules

The uniform powder blend is filled into empty hard gelatin or HPMC capsules using a manual capsule filling machine or automated encapsulator.

Each capsule is filled to the required weight and checked periodically for uniformity.

5. Sealing and Polishing

After filling, the capsules are closed securely and inspected for any damage or leakage.

Capsules may be lightly polished with a soft cloth to remove adhering powder particles.

6.Packaging and Storage

Capsules are packed in airtight containers or blister packs with desiccants to protect from light and moisture.

The final product is labeled appropriately and stored in a cool, dry place.

Evaluation Of Capsule:

1.General Appearance:

The physical appearance of the capsules is examined visually for color, shape, surface texture, and overall uniformity. Capsules should be free from cracks, dents, or any visible defects. A smooth and uniform appearance indicates proper encapsulation and material compatibility.

2. Weight Variation Test:

This test is conducted to ensure that each capsule contains a uniform amount of the formulation. A sample of 20 capsules is individually weighed, and the average weight is calculated. The deviation of each capsule's weight from the average should be within pharmacopeial limits—generally ±7.5% for capsules weighing 300 mg or less and ±5% for capsules weighing more than 300 mg. Consistency in capsule weight reflects accurate filling and uniform powder flow.

3. Content Uniformity:

Content uniformity ensures that the active pharmaceutical ingredient (API) is evenly distributed in all capsules. A specific number of capsules are assayed spectrophotometrically or chromatographically to determine drug content. The amount of atropine sulphate in each capsule should fall within 85–115% of the labeled claim. Uniform drug content confirms the effectiveness of the mixing and filling process.

4. Disintegration Test:

The disintegration test determines how quickly the capsule breaks apart after ingestion. Capsules are placed in a disintegration testing apparatus containing water or simulated gastric fluid maintained at 37 ± 2 °C. The capsules should completely disintegrate within 30 minutes unless otherwise specified in pharmacopeial guidelines. Proper disintegration ensures timely drug release and absorption.

5. Dissolution Test:

This test measures the rate and extent of drug release from the capsule. It is performed using a dissolution apparatus with a suitable dissolution medium, such as phosphate buffer. Samples are withdrawn at specific time intervals and analyzed spectrophotometrically to determine the percentage of drug released. Typically, not less than 80% of the drug should be released within the prescribed time limit. The dissolution profile helps predict the bioavailability of the drug.

CONCLUSION:

Atropine sulfate capsule preparation is an essential pharmaceutical procedure intended to guarantee precise dosage, patient adherence, and reliable therapeutic results. Atropine sulfate is a powerful medication that is delivered in extremely minute amounts, hence formulation and encapsulation must be done precisely. Achieving homogeneity and stability in the finished product requires careful blending, meticulous attention to quality control requirements, and the selection of appropriate excipients. Evaluation tests such as weight variation, content uniformity, disintegration, dissolution, and stability studies confirm that the capsules meet pharmacopeial standards and maintain their efficacy throughout their shelf life. The use of appropriate packaging further safeguards the formulation against environmental factors like moisture and light.

REFERENCES

1. Al Azhar Journal of Pharmaceutical Sciences. (2023). Preparation and characterization of

atropine sulfate orodispersible tablets; Vol. 68, Issue 2, pp. 43 63.
2. Formulation and characterization of atropine sulfate in albumin chitosan microparticles for in vivo ocular drug delivery.
3. Formulation and evaluation of fast disintegrating sublingual tablets of atropine sulfate: the effect of tablet dimensions and drug load on tablet characteristics.
4. Development of atropine sulphate nasal drops and its pharmacokinetic and safety evaluation in healthy human volunteers.
5. Development and clinical study of submicronic atropine sulphate respiratory fluid as a novel organophosphorous poisoning antidote.
6. HPLC method validation for atropine sulfate in injection form. World Journal of Pharmaceutical Research.
7. Clinical pharmacokinetics of atropine oral gel formulation in healthy volunteers.
8. Enhanced ophthalmic bioavailability and stability of atropine sulfate via sustained release particles using polystyrene sulfonate resin.
9. Johnson, P., & Akerman, [Initials]. Safe and Effective Low Dose Atropine Can Be Stable and Comfortable Too – Review of Myopia Management. Review of Myopia Management.
10. The dynamics of the drug release from ointment bases. Part 5: The effects of tensides on the liberation of atropine from eye ointments.
11. Vineetha, K., Shabaraya, A. R., Bhavyashree, T., Celvia, F. M., & Deekshitha, K. Formulation and evaluation of orodispersible films of atropine sulfate for sialorrhea. World Journal of Pharmaceutical Sciences.
12. An exact model for predicting tablet and blend content uniformity based on the theory of fluctuations in mixtures.
13. Isocratic HPLC analysis method for simultaneous estimation of hydrocortisone acetate and atropine sulphate in marketed formulation. (IJSDR) International Journal for Scientific Development and Research.
14. Efficacy of atropine sulfate/obidoxime chloride co formulation against sarin exposure in guinea pigs.
15. Pharmaceutical regulatory/quality control documentation: "Specifications of the drug substance as specified in the monograph of Atropine Sulfate Hydrate in the JP" (Japan's PMDA document) – manufacturing process and quality control strategy.

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