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Case Study
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Eye Drops leakage and Discoloration Market complaints investigation and Packaging Solution

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Abstract

This article investigates the recurring market complaints of leakage and discoloration in ophthalmic (eye drop) products, particularly within the United States. The study systematically examines three primary contributing factors: cap and bottle design flaws, polymer incompatibility with the drug product, and leachables originating from bottle labels. Structural deficiencies in the cap, such as misaligned or improperly sized spikes, are identified as significant contributors to leakage. Discoloration is attributed to excessive pigments and additives in polymer materials, which leach into the formulation over time. Additionally, printed labels containing photoinitiators and adhesives contribute further contamination, posing risks such as toxicity, assay interference, and pH variation. A case study on UV-curable printing inks highlights the migration of extractables into pharmaceutical products, emphasizing the importance of calculating the Analytical Evaluation Threshold (AET). The findings underscore the need for a holistic approach in packaging design—integrating proper material selection, label chemistry evaluation, and component compatibility—to ensure product stability, patient safety, and regulatory compliance.

Keywords: Eye Drop Packaging, Drug Product Leakage, Discoloration in Ophthalmic Formulations, Printed Label Contamination, Cap and Nozzle Design, Printed Label Contamination.

Introduction

Leakage and discoloration of Eye drops are very frequent and market complaint in

USA market. In this Article I will try to explain these issues in three different steps like: Eye drop bottle and Cap design problems, Polymer compatibility problems with product and Leachable issues from Bottle Label.

Structure of the CAP

- Position of the SPIKE should be at the center of the Cap that it exactly places on top of the Nozzle. Else first-time spike will pierce the nozzle but from next time on wards it will place outside the tip of the nozzle and product leakage observe.
- Height of the SPIKE is most important to avoid product Leakage.
- Rigidity of the SPIKE is most important.

Discoloration of Product Observed

- After analyzing of the bottle polymer this has been observed quantity of the pigments are more compare to the standard.
- Excess pigments slowly leach with the product.
- After analyzing the polymer this has also been observed quantity of Additives are more and which was leached and mix with product and discoloration observed.
- Polymer Leachables are Polybutylene terephthalate (PBT)

is a widely used polyester plastic in medical device and MDI valve components.

- PBT oligomers and other residuals or degradants can be similarly leached from the valve components fabricated from this material.

Impact of Leachable in Drugs

- Increased Toxicity
- Interfere Assay
- "Ph 'change.

Bottle Label

Multiple Inks, Coating and Adhesive Are Using During Label Printing

- Printed Label Leachables are Phtoinitiators 1-benzoylcy-clohexanol and 2- hydroxyl-2-methylprophenone from ink used on labels of HDPE and glass bottles were found to migrate into a solid product.
- Adhesive Leachabels are Particulates Protein and Peptide Aggregation

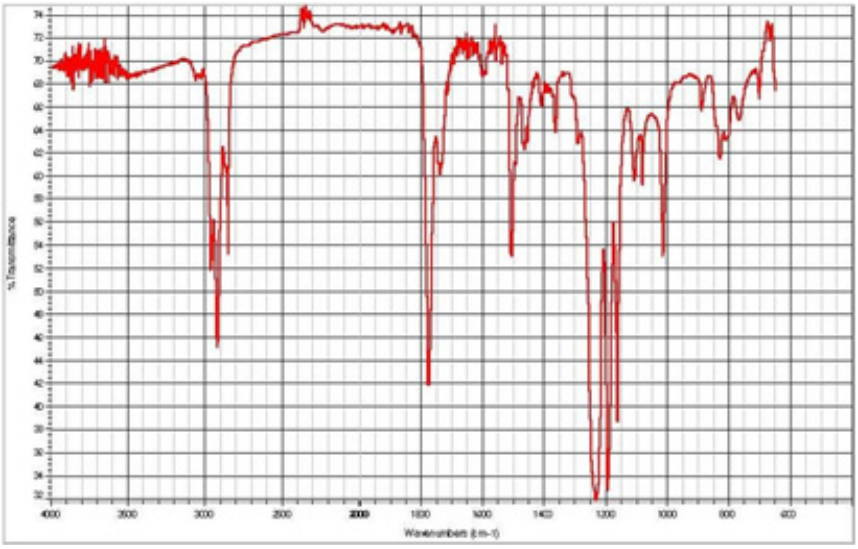
Case Study: UV Curable Printing INK

For An Extractables from a Device Component the Aet (Mg/G) Can Be Determined Using Equation 1: Equation 1

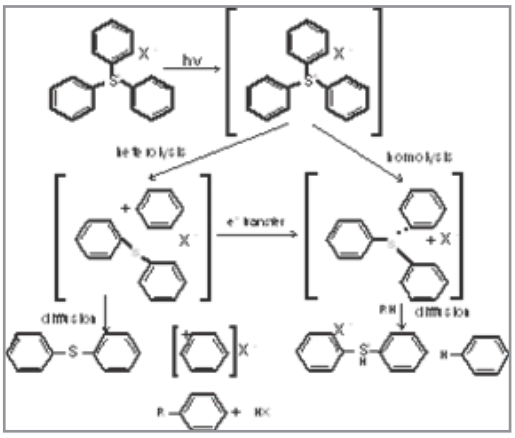
AET = SCT. Dt
Dd m
Dd- Doses per day
Dt- Total Labelled doses
m - mass of component

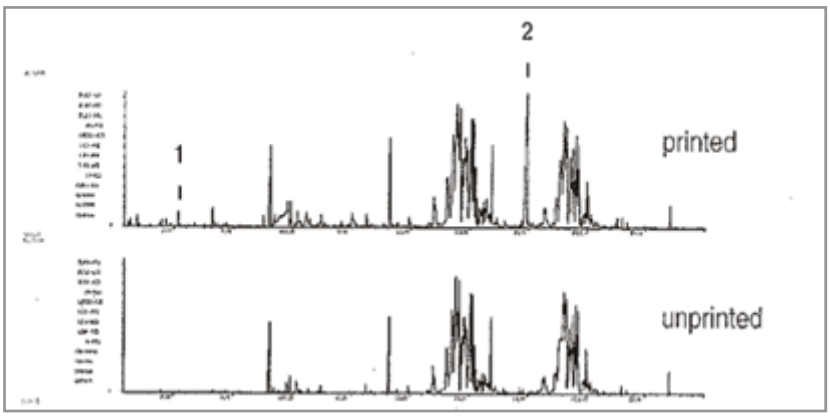
The AET (µg/device) for a drug delivery device (e.g. an MDI) can be determined from Equation 2:

AET = SCT. Dt
Dd
Dd- Doses per day
Dt- Total Labelled doses

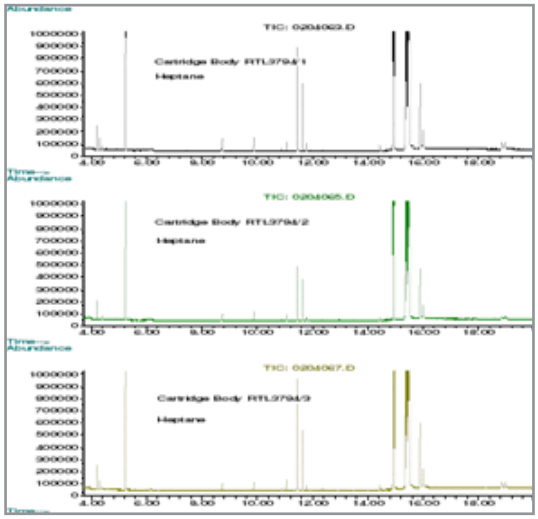


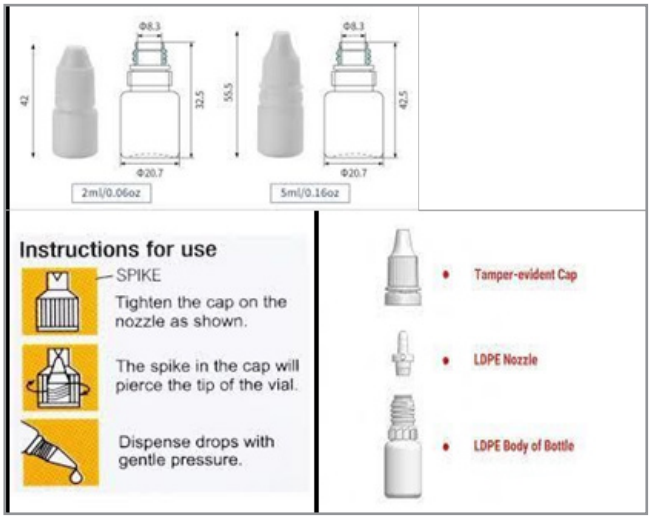
Infrared Spectrum of a Heptane Extract of a Polycarbonate Component





GC-MS Chromatogram of a Heptane Extract of a Polystyrene Component





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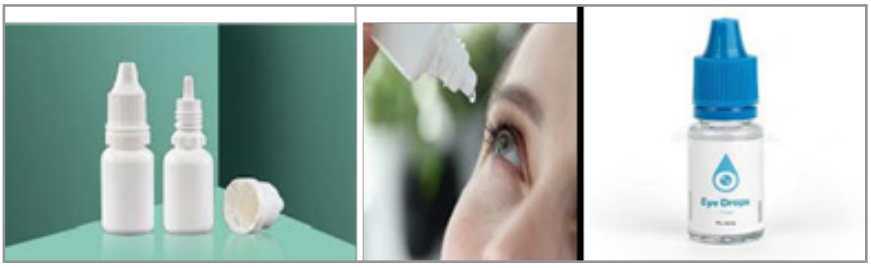

Image

Conclusion

This study highlights the critical role of packaging design, polymer selection, and labeling materials in ensuring the stability and safety of ophthalmic products. The investigation into market complaints revealed that structural flaws in cap and bottle alignment, excessive pigments and additives in polymers, and chemical leachables from printed labels significantly contribute to product leakage and discoloration. These issues not only compromise the efficacy and shelf-life of the eye drops but also pose serious risks to patient safety, including toxicity and pH instability. Therefore, a multidisciplinary approach involving optimized packaging component design, stringent material compatibility testing, and comprehensive extractables and leachables analysis is essential. Implementing such measures will reduce market complaints, enhance product integrity, and ensure compliance with regulatory standards.

References

1. Author/Organization. (n.d.). Importance of extractable and leachable study for primary packaging materials. Retrieved from [URL].
2. Author/Organization. (n.d.). Role of packaging for NDDS (Novel Drug Delivery System) and NCE (New Chemical Entity) products. Retrieved from [URL].

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