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Review Article

Eye Drops Leakage and Discoloration Market Complaints Investigation and Packaging Solution

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Abstract:

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.

Keywords: leakage; eye care; drug delivery; polymer

Introduction

Leakage and discolouration 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.

Discolouration 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.

Case Study: UV Curable Printing INK

- 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.

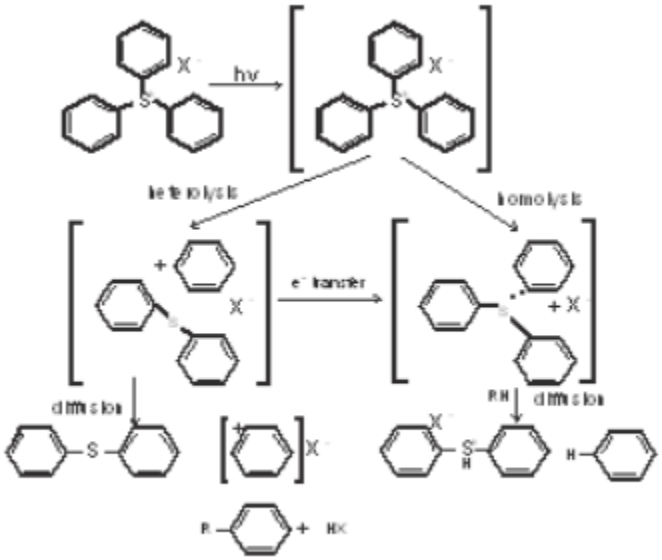
Impact of Leachables in Drugs

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

Bottle Label

Multiple inks, coating and adhesive are using during label printing.

- Printed Label Leachables are Phtoinitiators 1-benzoylcyclohexanol 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



For an extractables from a device component the AET (µg/g) can be determined using Equation 1: Equation 1

$$AET = \frac{SCT.D_t}{D_d\, m}$$

D_d- Doses per day

D_t- Total Labelled doses

m - mass of component

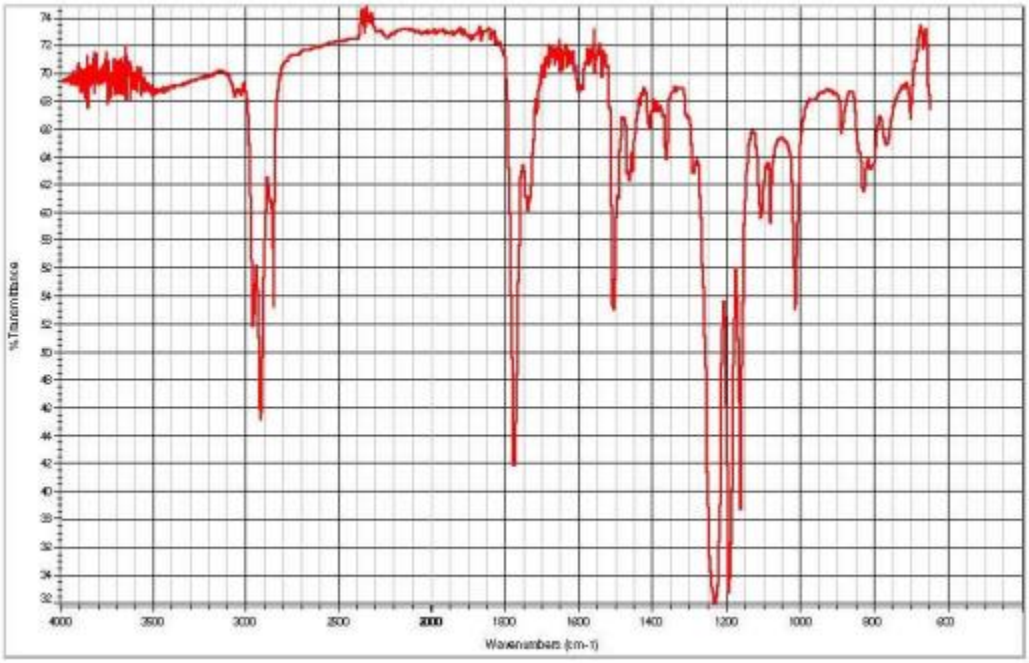
The AET (µg/device) for a drug delivery device (e.g. an MDI) can be determined from Equation 2:

$$AET = \frac{SCT.\ D_t}{D_d}$$

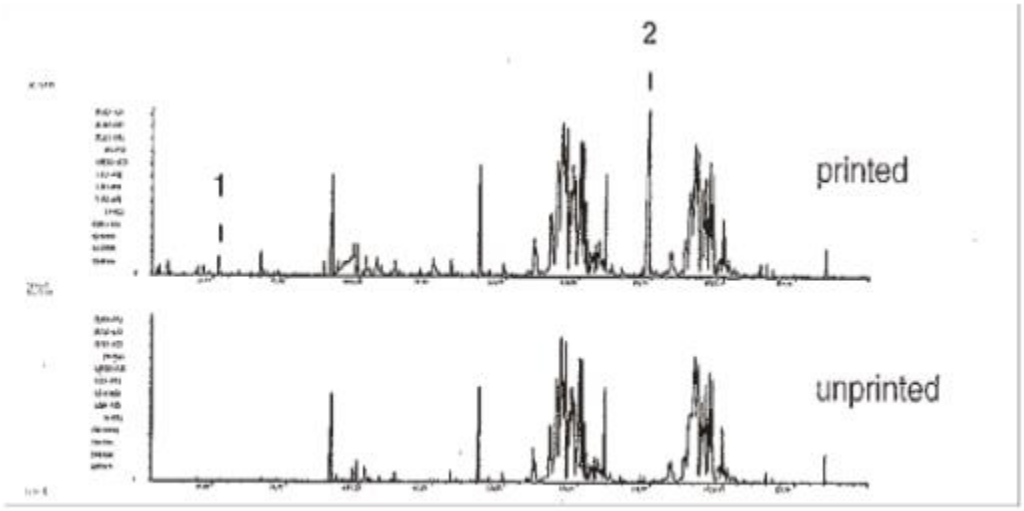
D_d- Doses per day

D_t- Total Labelled doses

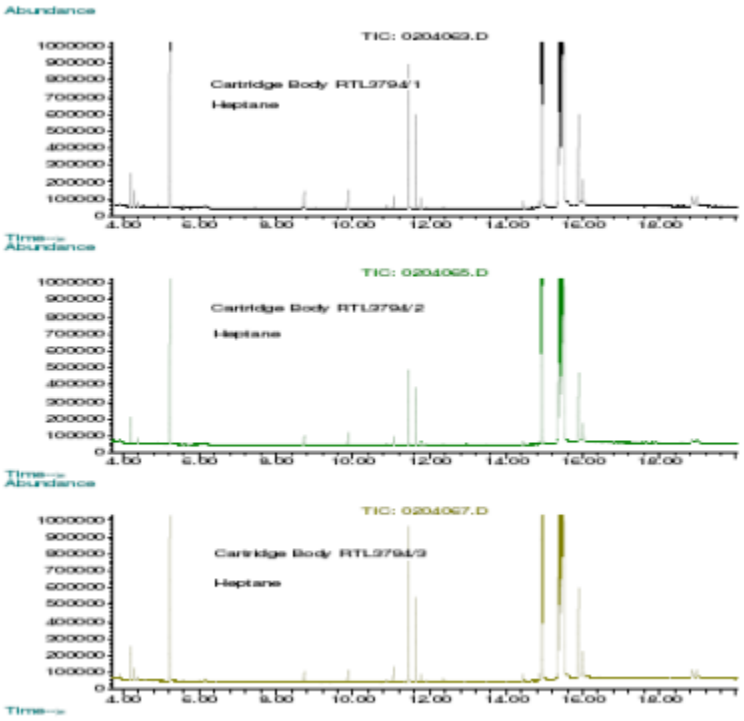
Infrared Spectrum of a Heptane Extract of a Polycarbonate Component

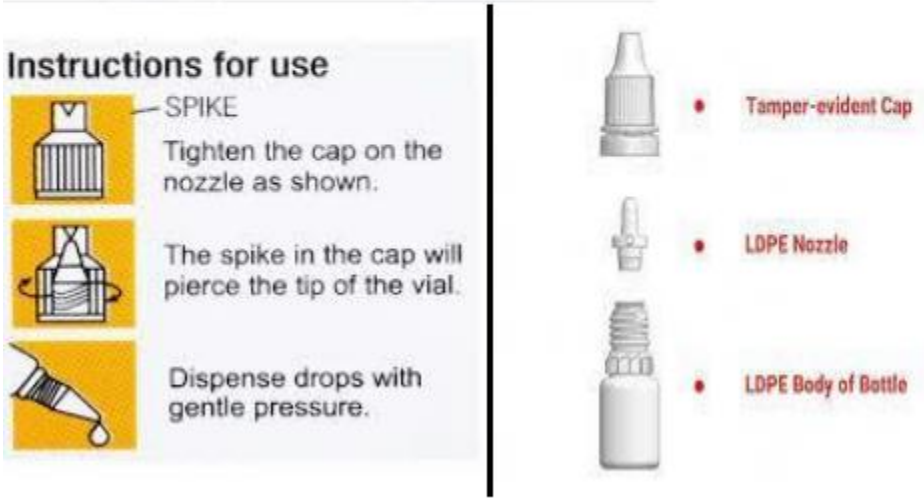


TDS-GC/MS of polymeric material Photolysis of triaryl sulfonium salts



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





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