

Eye drop bottle and Cap design problems, Polymer compatibility problems with product and Leachable issues from Bottle Label

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Received date: 03 September 2025; **Accepted date:** 16 September 2025; **Published date:** 30 September 2025

Citation: Anupam Chanda, (2025), Eye drop bottle and Cap design problems, Polymer compatibility problems with product and Leachable issues from Bottle Label, *J, Biotechnology and Bioprocessing*, 6(5); DOI:10.31579/2766-2314/165

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Abstract

Addiction affects all socioeconomic groups. Little consensus exists regarding the relationship between socioeconomic status (income, wealth, and parental education) and substance use alcohol use, smoking, and marijuana use). Youth from low-income families face unique stressors that can increase the risk of substance abuse which can have substantial adverse outcomes.

Key Words: adolescents; alcohol; smoking; socioeconomic status, substance abuse

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.

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

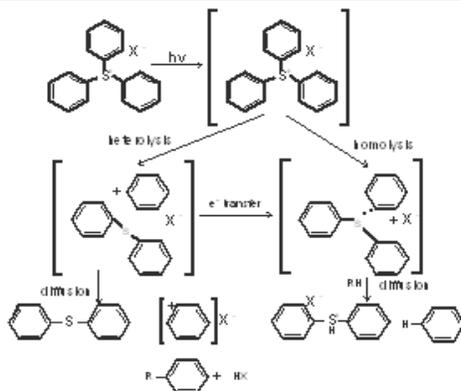
“Ph ‘change.

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 Leachables are Particulates Protein and Peptide Aggregation



Case Study: UV Curable Printing INK

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

$$AET = \frac{SCT \cdot Dt}{m}$$

Dd m

Dd- Doses per day

Dt- Total Labelled doses

m - mass of component

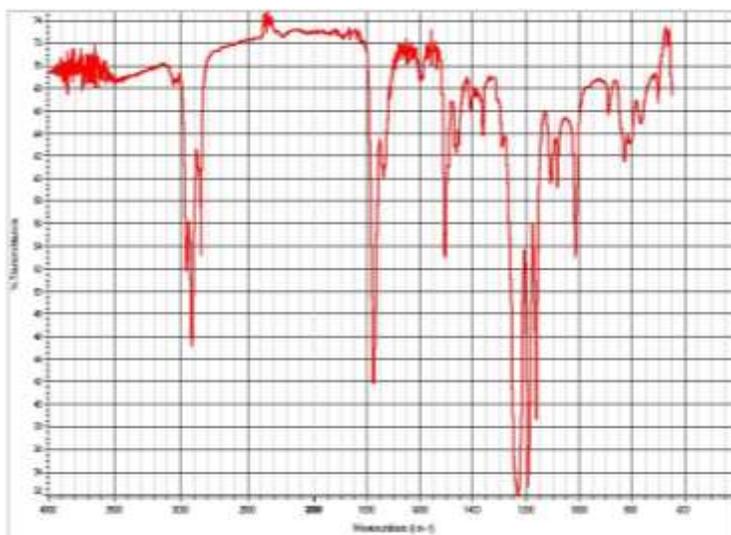
The AET (µg/device) for a drug delivery device (e.g. an MDI) can be determined from Equation 2:

$$AET = \frac{SCT \cdot Dt}{Dd}$$

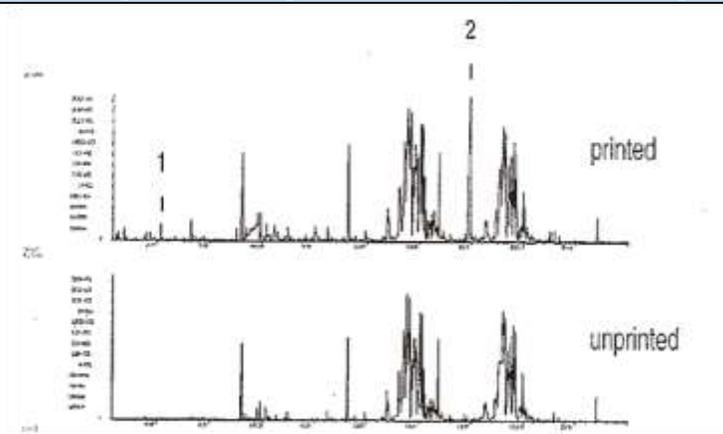
Dd

Dd- Doses per day

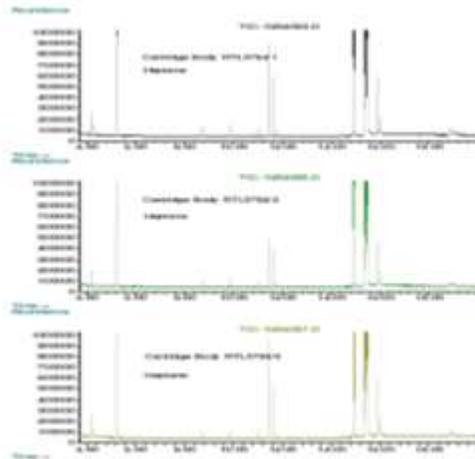
Dt- Total Labelled doses



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



Instructions for use



SPIKE
Tighten the cap on the nozzle as shown.



The spike in the cap will pierce the tip of the vial.



Dispense drops with gentle pressure.



• Tamper-evident Cap



• LDPE Nozzle



• LDPE Body of Bottle

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DOI:[10.31579/2766-2314/165](https://doi.org/10.31579/2766-2314/165)

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