

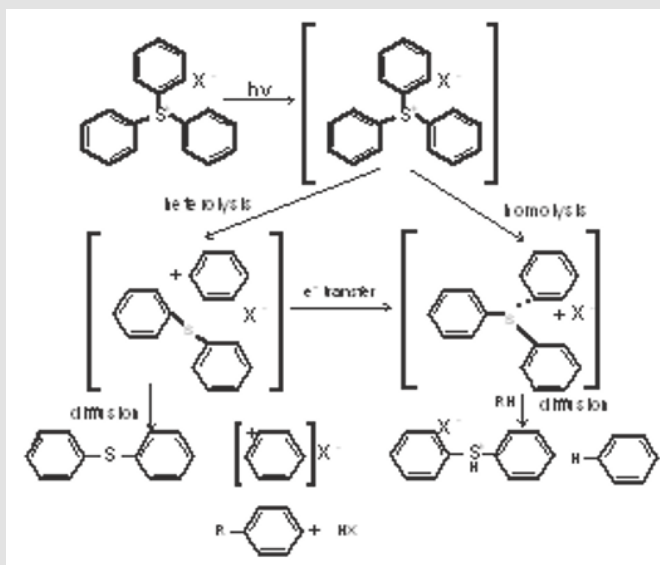
Anupam Chanda*

***Corresponding author:** Anupam Chanda, Packaging and Polymer Science Technologist (PG). Principal Consultant: Bioxytran Inc, MA, Boston, USA

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Introduction

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 (Figures 1-6).



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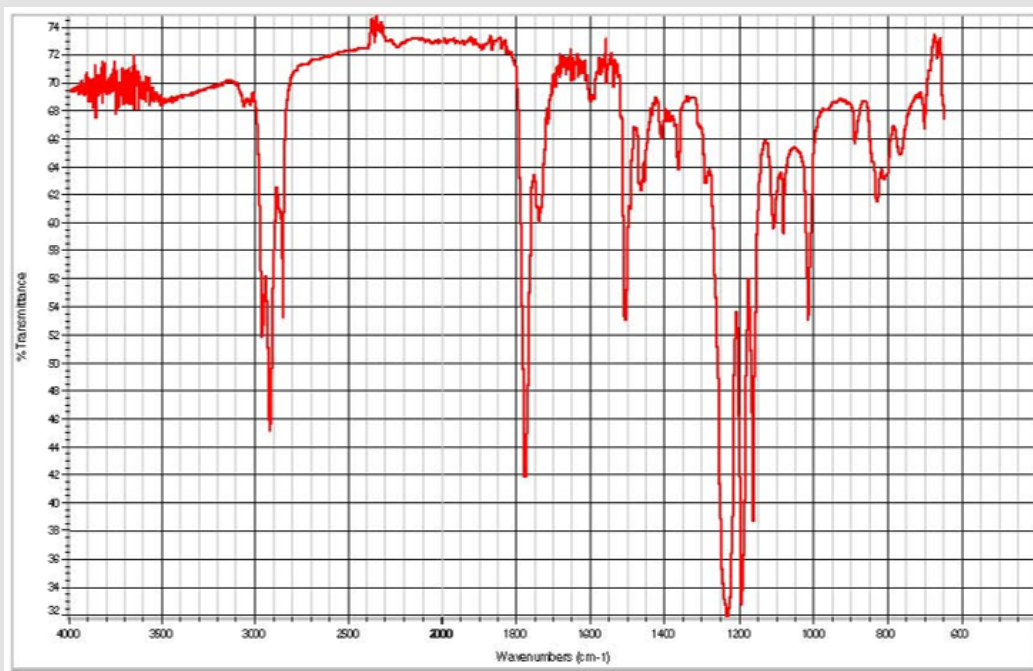


Figure 2: Infrared Spectrum of a Heptane Extract of a Polycarbonate Component.

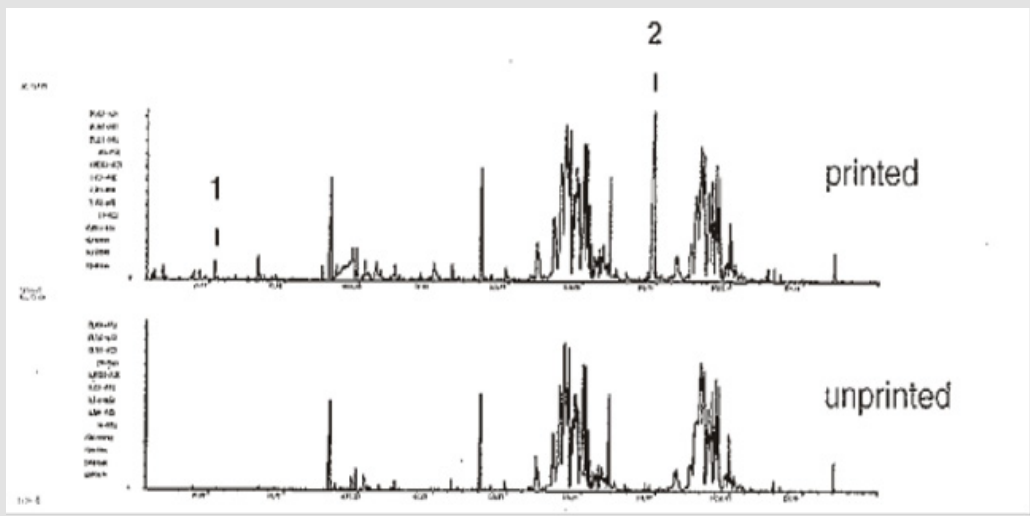


Figure 3: TDS-GC/MS of polymeric material Photolysis of triaryl sulfonium salts.

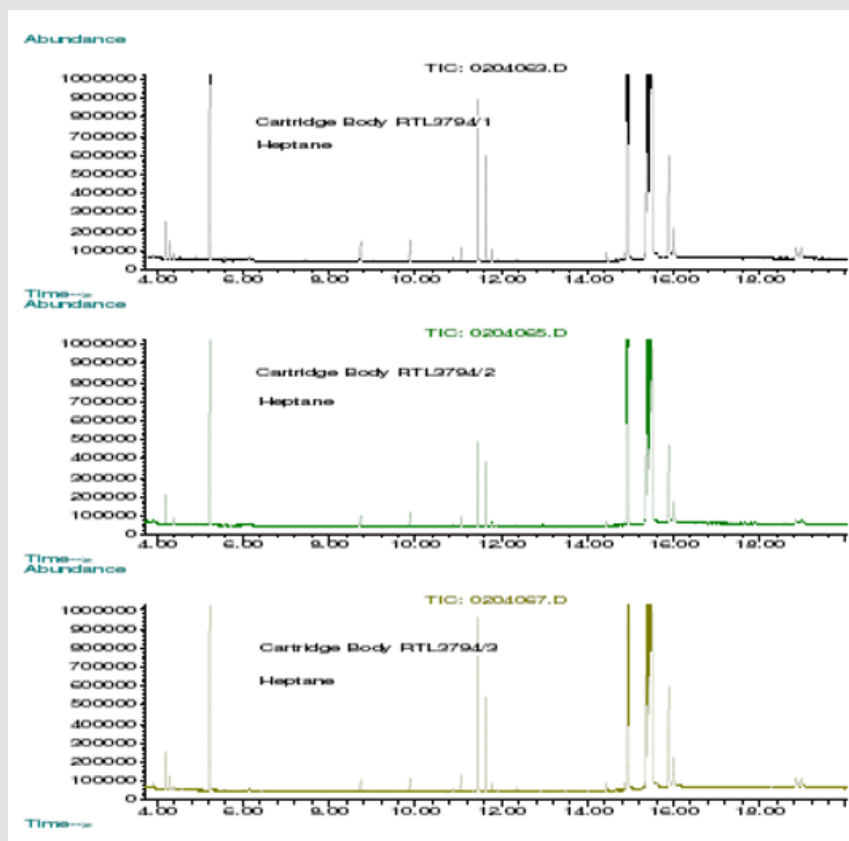


Figure 4: GC-MS Chromatogram of a Heptane Extract of a Polystyrene Component.

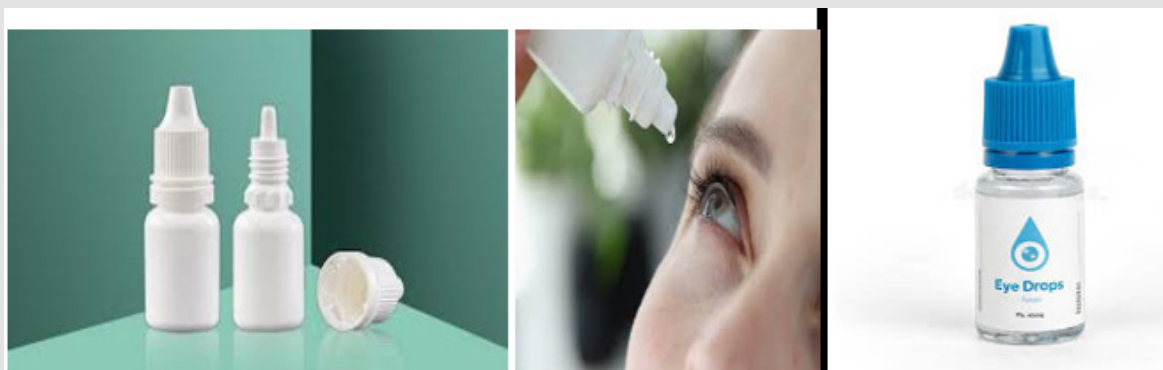


Figure 5.

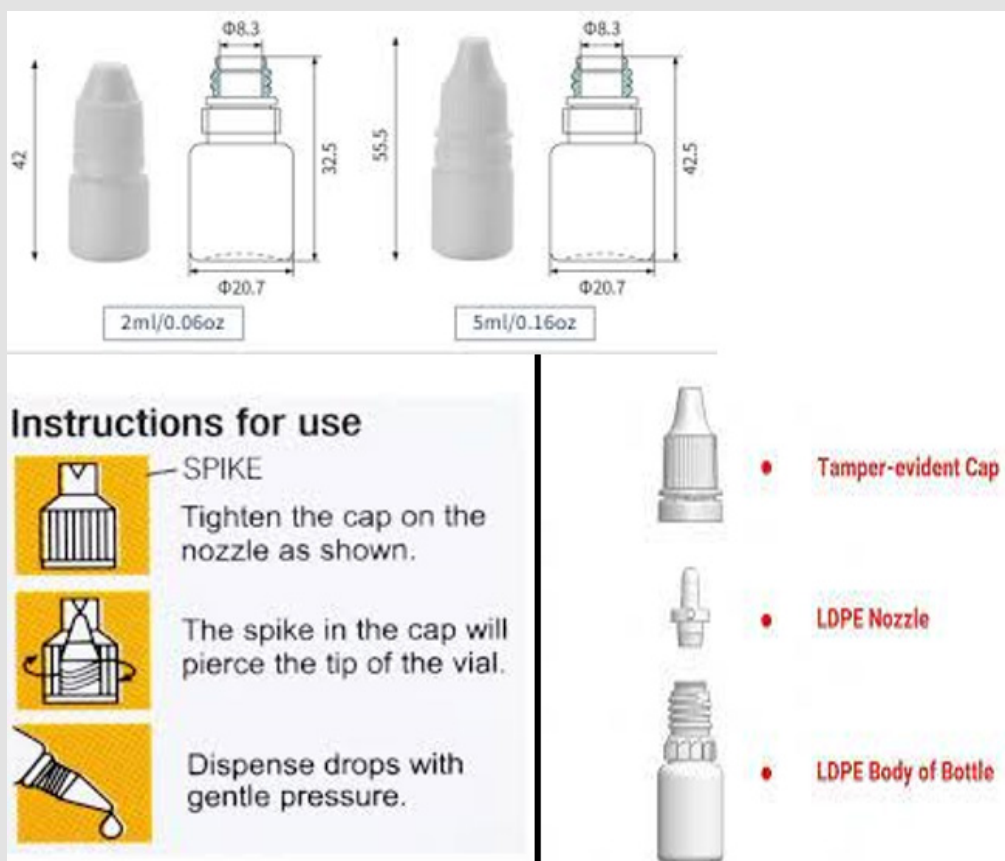


Figure 6.

Structure of the CAP

1. 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 [1,2].
2. Height of the SPIKE is most important to avoid product Leakage.
3. Rigidity of the SPIKE is most important.

Discolouration of Product Observed

1. After analyzing of the bottle polymer this has been observed quantity of the pigments are more compare to the standard.
2. Excess pigments slowly leach with the product.
3. 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.
4. Polymer Leachables are Polybutylene terephthalate (PBT) is a

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

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

Impact of Leachables in Drugs

1. Increased Toxicity
2. Interfere Assay
3. "Ph"change.

Bottle Label

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

1. 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.

2. Adhesive Leachables are Particulates Protein and Peptide Aggregation

For an extractables from a device component the AET ($\mu\text{g/g}$) can be determined using Equation 1: Equation 1

$$AET = SCT.D_t$$

$D_d m$

D_d – Doses per day

D_t – Total Labelled doses

m - mass of component

The AET ($\mu\text{g/device}$) for a drug delivery device (e.g. an MDI) can be determined from Equation 2:

$$AET = SCT.D_t$$

D_d

D_d – Doses per day

D_t – Total Labelled doses

References

1. Importance of Extractable and Leachable study for Primary Packaging Materials.
2. Role of packaging for NDDS (Neval drug delivery system) and NCE (New-chemical entity) products.

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Anupam Chanda. Biomed J Sci & Tech Res



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