

Evaluation of Adherence to RIC Standards for Plastic Packing of Liquid Pharmaceutical Medications

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Abstract

Plastic material packing is commonly used in drug formulations. Quality of plastic can have a direct or indirect harmful effect on quality of medicines. In the current study the Plastic bottles of medicinal formulations were studied for Resin Identification Code (RIC) system. Out of studied 100 plastic bottles studied PET/PETE was found in 84 bottles, HDPE with code 2 in 4 bottles. In 12 medicinal bottles the RIC code was not followed. Multinational companies were found to follow the RIC. In majority of dispensing bottles the RIC was present and it lacked in 12 bottles. PET/PETE a safe plastic ingredient was found in most of bottles (84%). The results of current study underscore the need to completely adhere to the standards for safety of individual as well of community.

Key Words

Plastic Pharmaceutical Packing, RIC, Resin

Introduction

Plastic material packing is commonly used in liquid drug formulations as it offers safety along with reduction of breakage losses, ease in manufacturing and designing.

Though plastic containers forms a bulk of packaging material for medicines but it is not absolutely safe. Quality of plastic can have a direct or indirect harmful effect on quality of medicines. Therefore, resin used should be such that it is not extracted by the medicinal product to interact to ensure physical and chemical stability.(1)

Disposing off plastic bottles is also a matter of concern as the deleterious resins may enter waterbodies, soil to effect ecosystem. (2)

To safeguard this different global standards have been set in to ensure individual and community safety at large (3). So manufacturers are confronted with complexity of packaging material to avoid interaction because of ingredients, excipients and solvents. The appropriate system that indicate the nature of plastic resin used in packing bottle is RIC coding entailing the interactive potential of the resin with the contents.

As RIC code symbol indicate the type of resin used ,

so its presence is essential to ensure product safety. Review of the literature did not reveal any study evaluating the RIC standards in pharmaceutical plastic packing bottles. Therefore, present study was done to see adherence to standards of RIC coding on plastic medicinal bottles.

Materials and Methods








The study was conducted for over a period of one month. The Plastic bottles of medicinal formulations were studied for Resin Identification Code (RIC) system. The study was approved by Institutional Ethics Committee. The RIC coding system identifies the plastic resin content of bottles. Plastic packaging are made of six resins: polyethylene terephthalate (PETE); high density polyethylene (HDPE); polyvinyl chloride (PVC or vinyl); low density polyethylene (LDPE); polypropylene (PP); or polystyrene (PS). The accordingly RIC assigned number of these resins are 1 to 6. While seventh code refers to a resin other than the above six (3) (figure 1).

RIC system refer to the presence, proper sizing and positioning of the RIC on containers.

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Figure 1: Showing Various RIC Codes

Resin Identification Number	Resin	Resin Identification Code –Option A	Resin Identification Code –Option B
1	Poly(ethylene terephthalate)	 PETE	 PET
2	High density polyethylene	 HDPE	 PE-HD
3	Poly(vinyl chloride)	 V	 PVC
4	Low density polyethylene	 LDPE	 PE-LD
5	Polypeopylene	 PP	 PP
6	Polystyrene	 PS	 PS
7	Other resins	 OTHER	 O

In all 100 plastic bottles containing medicine formulations were studied for drug formulations and presence of triangular symbol with resin code in it and its location and size.

Results

Table 1 Showing Dosage Form

Dosage form of medicine	Number	Percentage
Syrups	42	42
Dry powders	30	30
suspensions	24	24
Liquids	4	4

Table 2 Showing Dosage Form

Nature of medicine	Number	Percentage
Cough mixtures	25	25
antibiotics	22	22
Haematinics	10	10
Antiemetics	5	5
Analgesics	5	5
Others	33	33
	100	100

Table 3. Showing RIC

RIC	Number of bottles	Percentage
PET/PETE	84	84
HDPE	4	4
NO CODE	7	7
Only digit	4	4
Only code	1	1

Out of studied 100 plastic bottles there were 42 syrups, 30 dry powders, suspensions 24, liquids drops 4 (Table 1). Antibiotic constituted 22, cough mixtures 25, haematinics 10, analgesics 5 anti emetics 5, others 33. (Table 2).

Study of RIC code revealed that PET with code 1 was found in 75 bottles and PETE with 1 code on 9 bottles. HDPE with code 2 was present on 4 bottles. No triangular symbol with digit was found in 7 bottles, while only digit code without triangle symbol was seen in 4 bottles whereas 1 bottle contained only triangle symbol with no digit in it. 88% had RIC code at the bottom and were of proper size (Table 3).

These bottles were also studied for company and manufacturing unit. Total twelve bottles were found with incomplete labeling and all of them were of local manufacturing units and four amongst them were marketed by multinational company.

Discussion

Plastic is a family of related materials with varying properties and resultant products should form right material for right use.

Though RIC code essentially addresses the recyclers' needs and provide manufacturers a consistent, uniform system of packaging containers

But the coding system also identifies resin content of containers. The nature of the resin has immense implications on the health of the individual and community at large.

Plastics have certain disadvantage of Product-Plastic interactions like permeation (transmission of gases, vapors, or liquids through plastic packaging materials), leaching (migration of some plastic ingredients from the container to the drug product), sorption (removal of drug content from the product by the packaging material), chemical reaction(plastic formulations may react

chemically with one or more components of a drug product), and alteration in the physical properties of plastics or products (changes in physical and chemical properties).(4)

There has been reports of mineral water bottles causing estrogenic disturbances (45). This may lead to early puberty in females, reduced sperm counts, altered functions of reproductive organs, obesity, altered sex specific behavior, increased ovarian, breast, testicular and prostate cancers. Polyethylene terephthalate may also lead to endocrine disturbances.(6)

Plastic containers safety issue hit the headlines when concerns were raised about the polycarbonate products containing bisphenol-A (BPA)(7) It has been documented that BPA leach into contents of bottle and cause endocrine disturbance.

It is the most common building block of polycarbonate plastics used for food and beverage storage. BPA is now fully established to be endocrine disruptor with estrogenic activity (8). So much so there are campaigns in Canada, Europe and the United States highlighting that all single-serve plastic bottles are harmful to the environment.

Polyethylene terephthalate (PET) is a common types of plastic used in bottles . PET (also known as PETE) plastic products are designated by the recycling code 1. PET does not contain BPA and is recognized all over world as a safe, most easily recyclable packaging material. In the current evaluation we have found that most of the bottles (84%) had PET/PETE mark suggesting safe dispensing as far health or recycling issues are concerned. HDPE (CODE2) was observed in 4% of the bottles. It can also be recycled but is comparatively not that safe.

However, it was alarming to note that 7% of bottles had no RIC code , while 4% had only digit and 1% had only triangular symbol .

This observation underscores that in substantial number of bottles the RIC standards were not adhered while dispensing the pharmaceutical preparations though the positioning and size of symbol was in accordance in all bottles except in two . The disposing of these plastic containers safely is also important as it may lead to serious health hazards.

Since 12 percent of the bottles not following the standards of RIC. It was interesting to note that all these

bottle were not manufactured by reputed MNC, though four of them were marketed by MNC but were manufactured by local pharmaceutical house .

This observation highlights that RIC is not completely adhered by the substantial number of manufacturing units, more so in those cases where MNC is only marketing the locally manufactured products.

The current study had limitations of being a small sample sized study. No correlation was made with health hazards and nature of plastic. There may be other confounding factors to affect health in relation to dispensing and these were beyond the scope of study .

Conclusions

In majority of dispensing bottles the RIC was present and it lacked in 12 bottles. PET/PETE a safe plastic ingredient was found in most of bottles (84%). The results of current study warrant urgent need to adhere the standards for safety of individual as well of community.

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