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Assessment of Physicochemical Parameters of Tubing's of Intravenous Infusion sets

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Abstract

The main objectives of study were to evaluate the physicochemical test of the leachates of Intravenous infusion sets of seven brands used in the present study were purchased from different medical shops in Lucknow. At 60±2°C for 2 hours condition, the maximum global migration residue was found from IV-6 sample in 5% sodium carbonate (6.2 mg/100 ml) while the minimum was in IV-5 sample in 3% acetic acid (0.2 mg/100 ml) (Fig.1). The results also showed that at 25±2°C for 24 hours condition, the maximum global migration residue was found from IV-6 sample in 0.9% sodium chloride (5.2 mg/100 ml) while the minimum was in IV-5 sample in 3% acetic acid (0.14 mg/100 ml) (Fig.2). The results revealed that at 60±2°C for 2 hours condition, the maximum migration of oxidizable matters was from the leachates of IV-3 sample in double distilled water (3 ml; difference in the volume of sodium thiosulphate consumed) while the minimum migration of oxidizable matters was observed in IV-4 and IV-5 sample in sodium carbonate (0.1 ml) (Fig 3). At 25±2°C for 24 hours condition, the maximum migration of oxidizable matters was from the leachates of IV-3 sample in double distilled water (2.3 ml; difference in the volume of sodium thiosulphate consumed) while the minimum migration of oxidizable matters was observed in IV-2, IV-4, IV-5 and IV-7 sample in sodium carbonate (Fig. 4). At 60±2°C for 2 hours condition, the maximum migration of UV absorbing materials was from IV-1 sample in 0.3% acetic acid (OD – 0.206) whiles the minimum was from IV-5 sample in 0.9% sodium chloride (OD – 0.035). The migration was below the permissible limit (OD – 0.3) (Fig. 5). At 25±2°C for 24 hours condition, the maximum migration of UV absorbing materials was from IV-1 sample in 0.3% acetic acid (OD – 0.161) whiles the minimum was from IV-5 sample in 0.9% sodium chloride (OD – 0.031). The migration was below the permissible limit (OD – 0.3) (Fig. 6). The results showed that the leaching of additives used in plastic biomedical devices is temperature dependent i.e. high at higher temperature. These additives are not chemically bound to the matrix of the polymeric materials and leach out during normal use.

Keywords: Intravenous infusion sets, physicochemical test, simulants, global migration residue, Oxidizable materials, UV absorbing materials.

Introduction

Polymers are viewed as important biomedical materials for a number of reasons, some of which appear contradictory-but only because of different uses require different properties. Some of the important properties are the ability to tailor make structures, surface control, strength, flexibility, rigidity, inertness/reactivity, lightweight, ease of fabrication, ability to achieve a high degree of purity, compatibility, and the ability of some of them to withstand long term exposure to the human body a truly hostile environment. Surface hydrophobicity/ hydrophilicity, presence/absence of ionic groups, chemical and physical surface are all important considerations as one design a material for a specific application. In 1997, Dow introduced syndiotactic polystyrene under the trade name Questra. Targeted areas include medical, automotive, and electronic applications. Index, an ethylene-styrene interpolymer, was introduced in 1998 and is intended to compete with block copolymers such as styrene-butadiene, flexible PVC, polyurethanes and polyolefins. It is being used as a modifier for polystyrene and polyethylene. A number of new materials have been developed because of the health fears associated with the monomer Bisphenol A, which is the comonomer for most polycarbonates. The replacement should possess similar properties to polycarbonates and also be available in large quantity and inexpensive. The applications of plastic are rapidly increasing all over the world. Glance of their usages pattern in daily life indicates that we are approximately surrounded by 70-80% of them ranging from packaging materials, automobiles, kitchenware and children toys to the components of the designed products, aircrafts or the biomedical devices. In hospital, plastic medical devices are being used for storage and transfusion of life saving fluids, syringes, blood bags, biomedical implants, tubing and heart valves for the cardiac patients. Plastic use is dominated by single use or short term use, and at the same time most plastics are extremely persistent in the environment. Plastic products for medical applications are very important and contribute to improved heath (e.g. blood pouches, tubings, disposable syringes, prosthesis). Medical device as defined by the U.S. FDA is anything used for

therapeutic and/or diagnostic purposes in humans or animals, which is not a drug. Medical devices can be classified into two major categories- disposables and non-disposables. Disposable devices include bandages, gloves, blood bags, colostomy bags, catheters, syringes, IV kits, and tubing. All materials used in the manufacture of a medical device should be considered for an evaluation of their suitability for intended use. Consideration should always be given to the possibility of the release of toxic substances from the base materials, as well as any contaminants that might remain after the manufacturing process or sterilization. Plastics used in medical device applications must meet stringent performance requirements through production, packaging, shipping, end use, and disposal. Chain scission leads to degradation and reduces toughness, elongation, and impact strength. The high energy gamma radiation forms radicals along the polymer chain. These radicals subsequently degrade the polymer to lower molecular weight chains leading to reduce physical properties. However many stabilizers like phenols, HALS (hindered amine light stabilizers), phosphates etc have been used to absorb the energy or quench and capture the free radicals formed, thus preventing degradation. Those polymers that require stabilization are given bellow:

Transparent polymers like polyvinyl chloride, acrylics, polycarbonates, and polyurethanes have a tinting agent and some polymers also require free radical scavengers or quenchers to prevent degradation. Plastics used in medical devices can come into contact with various solvents and chemicals either during the manufacturing process or during end use. The medical devices must maintain their integrity, performance, and aesthetics when exposed to such solvents and chemicals. Chemical can react with the additives causing them to leachout of the part or form unwanted byproducts. The finished plastic material is made by the chemical chain called as monomer and several other chemicals added to give its desired shape, color and several other properties which are known as additives. There are about 2000 additives utilized in various types of plastic and can be divided in following common major classes: Antiblocking agents, Antimicrobial agents, Antioxidants, Antistatic agents, Coloring agents, Fillers, Impact modifiers, Mold release agents, Plasticizers, Preservatives, Slip agents, Stabilizers (light and heat) etc.

Antioxidants: Antioxidants are additives that retard or inhibit the oxidative degradation of the plastic material within the intended processing and usage limits of the materials. "Degradation is initiated by the action of highly reactive free radicals caused by heat, radiation, mechanical shear, or metallic impurities. The initiation of free radicals may occur during polymerization, processing, or fabrication. Once the first step of initiation occurs, propagation follows. The function of an antioxidant is to prevent the propagation steps of oxidation. It must be effective at low concentration, non toxic, conveniently and safely handled, and low in cost. Beside this, it must not impart undesirable characteristics to the system in which it is used. Antioxidants are classified as primary or secondary antioxidants depending on the method by which they prevent oxidation"[1]. The most widely used antioxidants in plastics are phenolics. Phenolics are mainly used in polyolefins, styrenics, and engineering resins. Phenolics are generally stain resistant and include simple phenolics (BHT), various polyphenolics, and bisphenolics. A phenolic antioxidant may then be used for long term protection. Primary antioxidants are generally radical scavengers or H- donors i.e. hindered phenols such as BHT, Irganox1010, or Irganox 1076, cyanox 2246 and 425 and bisphenol A. Long term protection for the polymer, secondary antioxidants is typically hydroperoxide decomposers i.e. trivalent phosphorus compounds such as tris-nonylphenyl phosphate (TNPP) is the most commonly used organophosphite followed by tris (2, 4-di-tert-butylphenyl) phosphate (Irgafos 168). Organophosphite are used in polyolefins, styrenics, and engineering resins. Phosphite can improve colour and engineering resins stability, but can be corrosive if hydrolysed. Thioesters act as secondary antioxidants and also provide high heat stability to a variety of polymers (polyolefins and styrenics). Secondary antioxidants are typically used in synergistic combination with primary antioxidants. Lactone stabilizers are a new class of materials that are reputed to stop the autoxidation process before it starts.

Stabilizers: Stabilizers are used to prevent the degradation of a material due to high processing temperatures or to extend their life stability under degrading environmental conditions. The effectiveness of a stabilizer also depends on the presence of oxygen i.e. some are effective in its presence while other are less effective. The effectiveness of a stabilizer is very much dependent upon the grade of resin (degree of polymerization) in which they are compounded. Some stabilizers are highly effective in one grade of PVC but only moderate in another. A judicious choice of stabilizers is therefore very important in the formulation of plastic. The presence of other additives such as plasticizers and fillers also sometimes strongly influence the efficiency of a stabilizer for e.g. Phosphates and chlorinated extenders often reduce the efficiency of a stabilizer. The major classes of stabilizers are mixed metal salt blends, organotin compounds, alkyl/aryl organophosphate, epoxy compounds, polyfunctional alcohols etc.

Light Stabilizers: Light stabilizers are used to protect plastics, especially polyolefin's, polystyrenes, from discoloration, embrittlement, and degradation by UV light. The major classes of light stabilizers are: UV absorbers excited state quenchers, and free radical terminators.

UV absorbing materials: "UV absorbing materials are the substances which give characteristic absorption peak in UV region. The commonly used UV absorbing materials are derivatives of benzophenones, benzotriazoles, phenyl esters, diphenylacrylates, which are added during the synthesis of plastic to protect them from degradation from sunlight and fluorescent light."[1] "Benzophenones UV absorbers have been used for many years in polyolefin's, PVC, and other resins.

Some important benzophenones are, 2-hydroxy-4-methoxybenzophenone, 2-hydroxy-4-n-octoxybenzophenone, 2, 4- dihydroxy-4-n-dodecycloxybenzophenone."[1] "Benzotriazoles UV absorbers are highly effective in high temperature resins such as acrylics and polycarbonate. Some important benzotriazole are 2-(2-hydroxy-5-methylphenyl) benzotriazole, 2, 2-(2-hydroxy-5-tert-octylphenyl) benzotriazole, 2-(32-tert-butyl-2-hydroxy-5 methylphenyl) -5 chlorobenzotriazole, 2-(32, 52-di-tert-butyl-22 hydroxyphenyl)-52 chlorobenzotriazole etc." [1] "Benzoates and salicylates such as 3, 5-di-t-butyl-4-hydroxy benzoic acid n- hexadecyl ester function by rearranging to 2-hydroxybenzophenone analogs when to UV light to perform as UV absorbers. Phenyl esters like 3, 5-di-t-butyl-4-hydroxybenzoic acid N-hexadecyl ester. Diphenylacrylates like Ethyl-2-cyano-3, 3-diphenyl acrylate, 2-ethylhexyl-2-cyano-3, 3-diphenyl acrylate. Nickel compounds are used as excited state quenchers and hindered amine light stabilizers (HALS) are used as free radical terminators." [1] Environmental factors such as light, heat, moisture, chemical and biological processes may bring about physical and chemical changes in the polymers causing bond scission and structural deformations[2, 3]. Such polymer degradation causes cracking, erosion, discoloration and delaminating etc[4]. In order to enhance the quality of the commercial polymeric materials many chemicals as additives of various types are consciously added to obtain the desired product. These include stabilizers, fillers, plasticizers, pigments, antioxidants and flame retardants etc[5, 6]. Plastic polymers are not particularly reactive and their large size limit transport across biological membranes[7]. They are, therefore, not considered as toxic. In the polymeric material, however, non-polymeric components such as residual monomers, oligomers, low molecular weight fragments, catalyst remnants, polymerization solvents and a wide range of additives can be present[8]. Several of these are hazardous to human health and the environment, for instance carcinogenic, mutagenic, toxic for reproduction, sensitizing and hazardous to the human health. Since the non-polymeric compounds usually are of low molecular weight and are either weakly bound or not bound at all to the polymeric macromolecules, they, or their degradation products, can be emitted from the plastic product[8, 9] to air, water or other contact media (e.g. food). The residual monomer content depends on polymer type, polymerization technique and techniques for reducing residual monomer content[10]. Release of hazardous substances from plastic products to air, extraction fluids, water, food, food simulants, saliva and sweat have been shown by chemical analysis. Examples of substances studied and released from various plastic products include phthalates[11,12], brominated flame retardants[13], bisphenol A[14-17], bisphenol-A dimethacrylate,[18] lead, tin and cadmium[19], formaldehyde and acetaldehyde[20,21], 4-nonylphenol[22,23], MTBE (methyl tert-butyl ether), benzene[24] and many other volatile organic carbons[25,16]. Due to the ever increasing use of the plastics, manufactures are providing newer formulations and newer ingredients in plastics. During the course of their manufacturing, storage, and administration, pharmaceutical drug products come in contact with materials, components, and systems. Such contact may result in an interaction between the drug product and these entities. One such interaction is the migration of substances from these entities and into the drug product, which is of concern due to the potential toxicity of the migrating substances[27]. Polymeric materials are commonly used in medical devices such as syringes. The plastic materials may interact with drug products contained within the device, potentially affecting the quality of the drug products. These interactions may include leaching, which is the migration of entities out of the material and into the drug product, and binding, which is the migration of substances out of the drug product and into the material[28]. The accumulation of organic compounds associated with plastic materials into pharmaceutical products and their associated solutions has important suitability for use consequences for those pharmaceutical solutions, most notably in terms of safety and efficacy[29]. Tinuvin 770 is a light stabilizer present in numerous polymers utilized in medical or pharmaceutical applications (e.g., manufacturing, packaging, delivery systems and devices). Under conditions of use, Tinuvin 770 and its related substances may leach from the polymers and accumulate in pharmaceutical products that are administered to subjects to produce a therapeutic benefit[30].

Material and Methods

Plastics are being increasingly utilized for the storage and delivery of life saving fluids. Although, virgin polymer generally considered being safe due to its inertness, however, the plastic products could be harmful due to migration of certain chemical additives like plasticizers, stabilizers, pigments and unreacted monomers into the stored commodity. Therefore, plastic products intended for storage and delivery of life saving fluids must be evaluated for their safety. In this regards, different countries have laid down various safety assessment tests and guidelines for the suitability and quality assessment of the finished plastic medical devices. The guidelines provided by the Bureau of Indian Standards, New Delhi has recommended the test for Global migration Residue for safety assessment of plastic. Several International regulatory agencies have also recommended tests for the presence of UV absorbing materials and oxidizable materials in the plastics used in biomedical devices as well as food packaging. In order to assess the risk of human exposure to leachable plastic additives from plastic products, physicochemical and biological studies were conducted using standard procedures laid down by BIS and OECD. It is desirable to study the physicochemical nature of the leachable. The leachates of the samples were prepared in different simulated solvents under varying temperature conditions and then analyzed. The leachates are examined for change in physical state. Chemical tests are the determination of global migration residue, oxidizable materials, UV absorbing materials etc.

Type of sample	Brand Name	Code
Intravenous Infusion sets	1. RMS infusion set, Ramsons Juniors India	IV-1
	2. JVS Super Delux Quality. S. K. Trading Corporation	IV-2
	3. JVS infusion set, S. K. Trading Corporation	IV-3
	4. Dispocath, infusion set, Trinity Health Care	IV-4
	5. TMS, Extrasuper, Trinity Health Care	IV-5
	6. Infusion set premium, Protec	IV-6
	7. Infusion set, poly Medicure Limited	IV-7

Chemicals used: Acetic acid, ethanol, sodium chloride, sodium carbonate, potassium permanganate, potassium iodide, sodium thiosulphate, starch, sulphuric acid, were procured of AR grade of highest purity available. All the chemicals and reagents used during the course of the study were of reputed brands.

Simulating conditions and solvents: Plastic biomedical devices were washed thoroughly with sterilized double distilled water prior the leaching. Double distilled water, ethanol (8% v/v in double distilled water), acetic acid (3% v/v in double distilled water), sodium chloride (0.9% w/v in double distilled water) and sodium carbonate (5% w/v in double distilled water) were used as the simulating solvents. Plastic biomedical devices were exposed in 100 ml of either of simulating solvents in sterile beakers at a ratio of 2 ml/cm^2. The samples were kept at 4±1°C for 72 h (refrigerated conditions), 25±2°C for 24 h (ambient conditions) and 60±2°C for 2 hours (elevated conditions)[1,2]. Parallel sets having simulating solvents only will also be run under identical conditions and will serve as basal control.

Statistical Analysis: Data were analyzed by one-way analysis of variance (ANOVA) and Dunnett's Multiple Comparision test and No Post Test were employed to assess the significance of variations between the control and samples using a computer based software, GraphPad Prism 5. A *p* value less than 0.05 is considered as significant.

Global Migration Residue: The overall migration of chemical additives which includes the inorganic compounds, heavy metals, phthalates, organo-metallic compounds and other additives which are not volatile up to 95°C. The test has been recommended by various national and international regulatory agencies and is of importance since some of the additives are toxic. Following the simulation, leaching solvents were kept for evaporation till dryness in constant pre-weighed silica crucible in the oven maintained at constant temperature (90°C) for 24 hours (IS 9845: 1998) and the crucible were weighed again. The difference in the weight obtained was taken as the measure of the global migration residue expressed as mg/100 ml of the simulants. The test was performed in triplicates. Migration residues should not be more than 5 mg/100 ml of extract.

Oxidizable matters: Oxidizable materials are also known as antioxidants, which protect the plastics by reacting with the atmospheric oxygen. Commonly used oxidizable matters are organophosphite and derivatives of phenols. The test has been recommended by various national and international regulatory agencies and is essential as some of these chemicals are toxic in nature. Due to migration of these compounds, the durability of plastics may be decreased and the consumers will also be at risk to the other leachable toxic chemicals. Oxidizable matters were measured by titration of plastic extract and corresponding blank against sodium thiosulphate. The extract (20 ml) is taken in an Erlenmeyer flask and 20 ml of 0.01 N $KMnO_4$ and 1.0 ml 2N H_2SO_4 is added and the mixture is boiled for 3 minutes. The solution is cooled and 0.1 gm of KI and 5 drop of starch solution are added and finally titrated with 0.01 N sodium thiosulphate solutions till pink color disappeared. A blank was also titrated in parallel. The difference in the volume of 0.01 N sodium thiosulphate consumed in titration of leachate and blank gave the measure of oxidizable matters.

UV absorbing materials: UV absorbing materials are the substances which give characteristic absorption peak in UV region. The commonly used UV absorbing materials are derivatives of benzophenones, benzotriazoles, salicylates, acrylates, organonickels and amines which are added during the synthesis of plastic to protect them from degradation from sunlight and fluorescent light. The test is essential as some of these compounds are toxic. Following the simulation, leaching solvents were processed for the estimation of migration of UV absorbing materials from the plastic biomedical devices. The samples were scanned between 220-400 nm. The results were expressed as the difference in optical density (OD) obtained from the leachates and blank.

Results and Discussion

Change in Physical State: As per the regulatory agencies, the requirements for physical state, odour and clarity of the leachates are – ''there should be no change in the physical state of the plastic product after leachate preparation. The leachates should be odourless, clear and colourless." The observations revealed that there was no change in the physical state of plastic samples. The leachates of all the samples were odourless, clear and colourless.

Estimation of Global Migration Residue (IV sets): The test was performed as per IS 9845: 1998 guidelines. The results showed that at 60±2°C for 2 hours condition, the maximum global migration residue was found from IV-6 sample in 5% sodium carbonate (6.2 mg/100 ml) while the minimum was in IV-5 sample in 3% acetic acid (0.2 mg/100 ml). In the case of

double distilled water, all samples showed the global migration residue bellow the permissible limit i.e. 5 mg/100 ml. The global migration residue ranged between 0.4 mg/100 ml – 2.3 mg/100 ml). In the case of 8% ethanol, all samples showed the global migration residue bellow the permissible limit i.e. 5 mg/100 ml. The global migration residue ranged between 1.1 mg/100 ml – 4.6 mg/100 ml. In the case of 3% acetic acid, all samples showed the global migration residue bellow the permissible limit i.e. 5 mg/100 ml. The global migration residue ranged between 0.2 mg/100 ml – 4.1 mg/100 ml. In the case of 0.9% sodium chloride, all samples showed the global migration residue bellow the permissible limit i.e. 5 mg/100 ml except IV-6 sample (5.6 mg/100 ml). The global migration residue ranged between 2.9 mg/100 ml – 5.6 mg/100 ml. In the case of 5% sodium carbonate, the range of global migration residue to be 1.9 mg/100 ml – 6.2 mg/100 ml. The residue of leachates of IV-1, IV-2, IV-4, IV-5 and IV-6 samples were above than the permissible limit while that of IV-3 and IV-6 samples were well within the limit. The samples showed maximum leachability in sodium carbonate. The global migration residues of all the samples except the IV-6 in sodium chloride and IV-3, IV-5 and IV-6 in sodium carbonate were below than the permissible limit. The global migration residue ranged between 0.2 mg/100 ml – 6.2 mg/100 ml.

The results showed that at 25±2°C for 24 hours condition, the maximum global migration residue was found from IV-6 sample in 0.9% sodium chloride (5.2 mg/100 ml) while the minimum was in IV-5 sample in 3% acetic acid (0.14 mg/100 ml). In the case of double distilled water, all samples showed the global migration residue bellow the permissible limit i.e. 5 mg/100 ml. The global migration residue ranged between 0.3 mg/100 ml – 1.6 mg/100 ml).

In the case of 8% ethanol all samples showed the global migration residue bellow the permissible limit i.e. 5 mg/100 ml. The global migration residue ranged between 0.8 mg/100 ml – 3.5 mg/100 ml. In the case of 3% acetic acid, all samples showed the global migration residue bellow the permissible limit i.e. 5 mg/100 ml. The global migration residue ranged between 0.14 mg/100 ml – 3.31 mg/100 ml. In the case of 0.9% sodium chloride, all samples showed the global migration residue bellow the permissible limit i.e. 5 mg/100 ml except IV-6 sample (5.2 mg/100 ml). The global migration residue ranged between 2.1 mg/100 ml – 5.2 mg/100 ml. In the case of 5% sodium carbonate, all samples showed the global migration residue bellow the permissible limit i.e. 5 mg/100 ml. The global migration residue ranged between 1.2 mg/100 ml – 4.8 mg/100 ml. The samples showed maximum leachability in sodium chloride. The global migration residues of all the samples except the IV-6 in sodium chloride were below than the permissible limit. The global migration residue ranged between 0.14 mg/100 ml – 5.2 mg/100 ml.

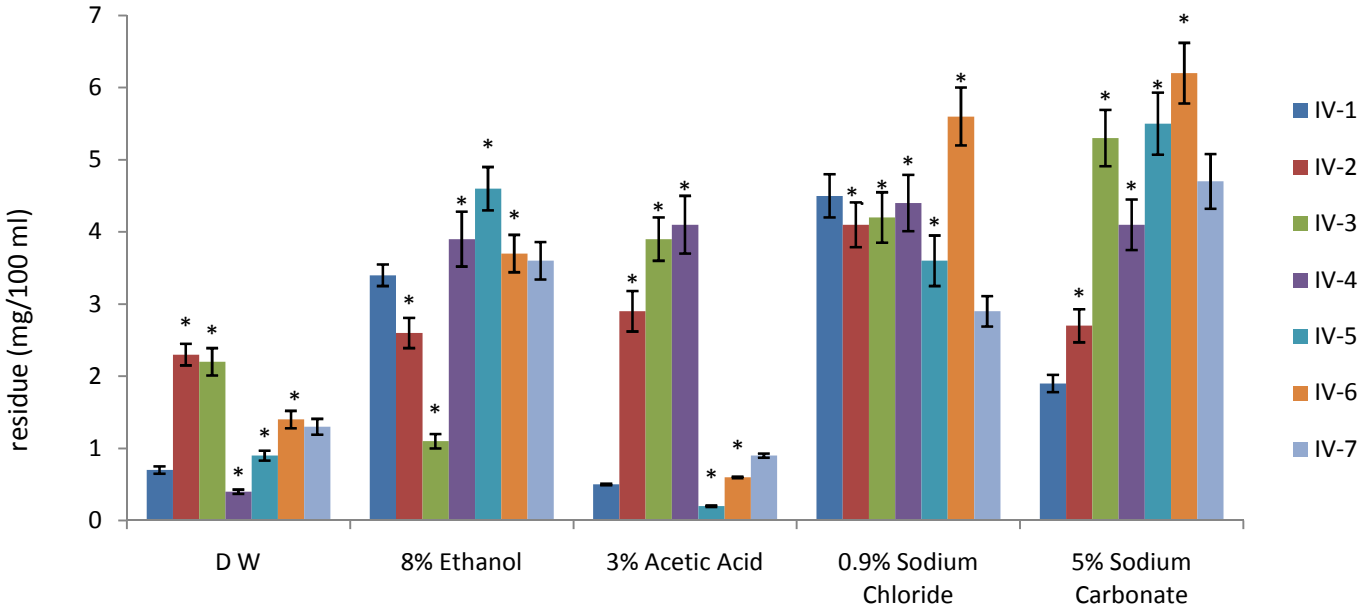

Figure-1
Global migration residues (mg/100 ml) in the leachates at 60±2°C for 2 h (IV sets). The results were reported as a mean ± SD from three set of experiments.* P < 0.05

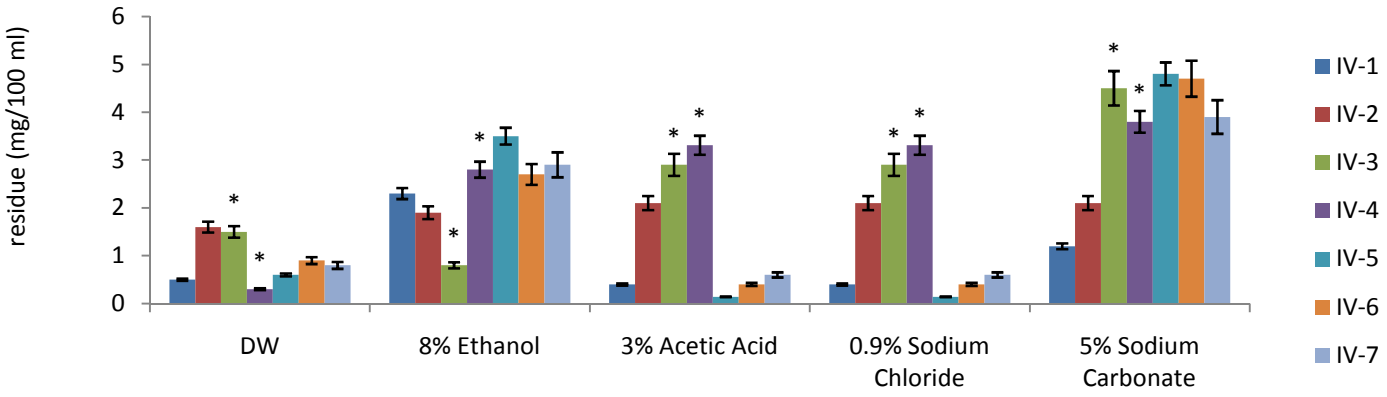

Figure-2
Global migration residues (mg/100 ml) in the leachates at 25±2°C for 24 h (IV sets).
The results were reported as a mean ± SD from three set of experiments.* P < 0.05

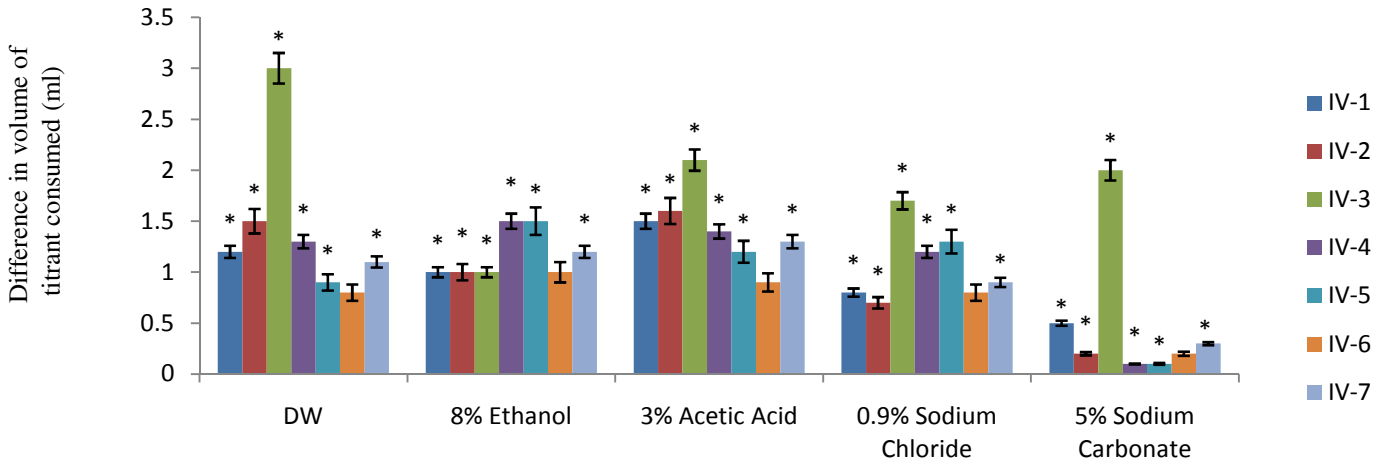

Figure-3
Difference in the volume of titrant consumed (ml) at 60±2°C for 2h (IV sets).
The results were reported as a mean ± SD from three set of experiments.* P < 0.05

Estimation of Oxidizable Matters: The test has been recommended by various national and international regulatory agencies and is essential as some of these chemicals are toxic in nature. Due to migration of these compounds, the durability of plastics may be decreased and the consumers will also be at risk to the other leachable toxic chemicals. The results revealed that at 60±2°C for 2 hours condition, the maximum migration of oxidizable matters was from the leachates of IV-3 sample in double distilled water (3 ml; difference in the volume of sodium thiosulphate consumed) while the minimum migration of oxidizable matters was observed in IV-4 and IV-5 sample in sodium carbonate (0.1 ml). At 25±2°C for 24 hours condition, the maximum migration of oxidizable matters was from the leachates of IV-3 sample in double distilled water (2.3 ml; difference in the volume of sodium thiosulphate consumed) while the minimum migration of oxidizable matters was observed in IV-2, IV-4, IV-5 and IV-7 sample in sodium carbonate.

Estimation of UV absorbing materials: The absorption profiles of various leachates were characterized by spectral scanning from 220-400 nm using a SL160 double beam UV-Visible spectrophotometer, ELICO. The estimation of UV absorbing materials was done following Indian Pharmacopoeia guidelines. At 60±2°C for 2 hours condition, the maximum migration of UV absorbing materials was from IV-1 sample in 0.3% acetic acid (OD – 0.206) whiles the minimum was from IV-5 sample in 0.9% sodium chloride (OD – 0.035). The migration was below the permissible limit (OD – 0.3). At 25±2°C for 24 hours condition, the maximum migration of UV absorbing materials was from IV-1 sample in 0.3% acetic acid (OD – 0.161) whiles the minimum was from IV-5 sample in 0.9% sodium chloride (OD – 0.031). The migration was below the permissible limit (OD – 0.3).

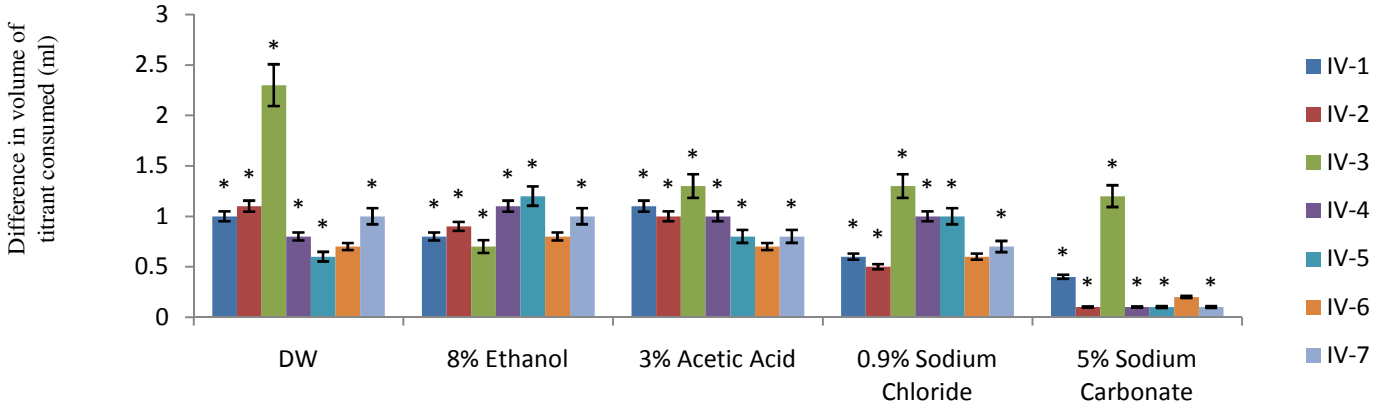

Figure-4
Difference in the volume of titrant consumed (ml) at 25±2°C for 24h (IV sets).
The results were reported as a mean ± SD from three set of experiments.* P < 0.05

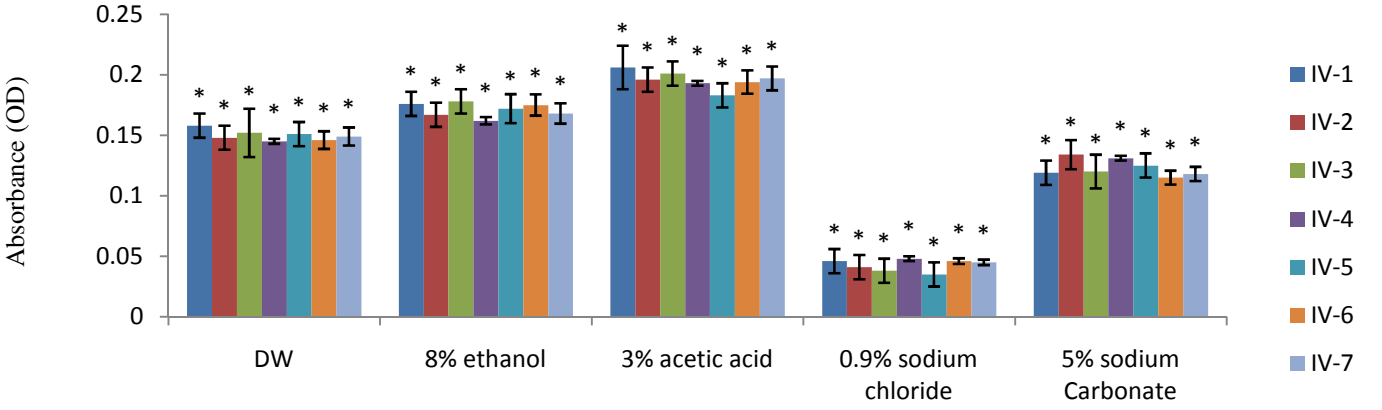

Figure-5
Absorbance of the leachates λ max 220-400 nm at 60±2°C for 2h (IV sets).
The results were reported as a mean ± SD from three set of experiments. * P < 0.05

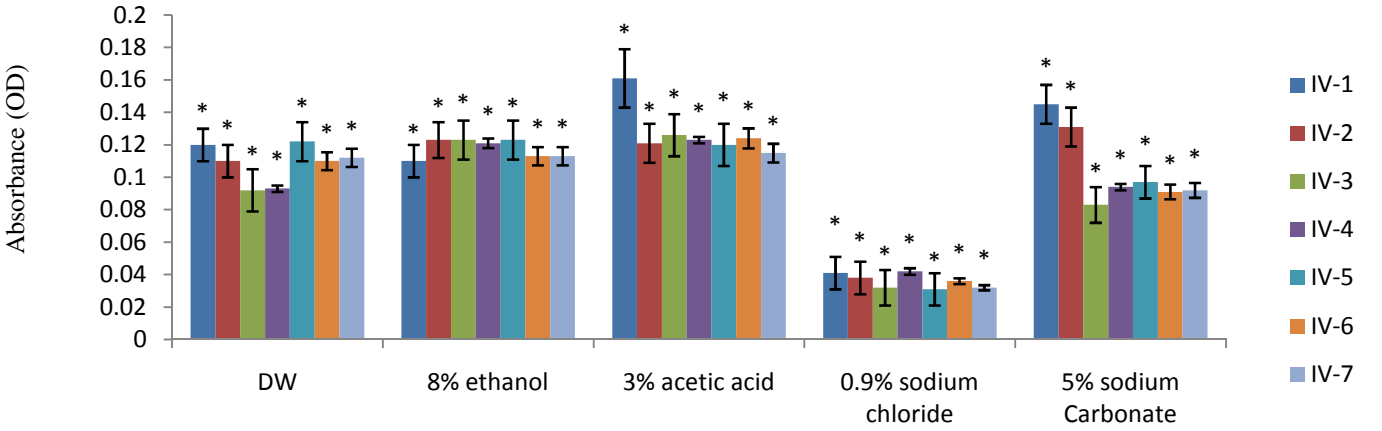

Figure-6
Absorbance of the leachates λ max 220-400 nm at 25±2°C for 24h (IV sets).
The results were reported as a mean ± SD from three set of experiments. * P < 0.05

Conclusion

The low molecular weight substances and additives possess high mobility and therefore there is a likelihood of their migration from the plastic medical devices into the contained solution, thereby contaminating solution with a possible toxic hazard to the health of the patient. Therefore, guidelines for proper use of plastics for medical device applications have been realised and threshold limits have been laid down. This threshold approach has been found to be an excellent model, by which majority of plastics materials are evaluated, and on the basis of which medical device application certificates are issued.

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