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ASSESSMENT OF PHYSICOCHEMICAL PARAMETERS IN NASAL FEEDING TUBES

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ABSTRACT

The main objectives of study were to evaluate the physicochemical test of the leachates of finished plastic biomedical devices; Ryle's tube, four brands were used in the present study. At 60±2°C for 2h the maximum global migration residue was found from S4 sample in 0.9% sodium chloride (3.5 mg/100 ml) while the minimum was in S3 sample in 3% acetic acid (0.3 mg/100 ml) Figure 1. At 25±2°C for 24h the maximum global migration residue was found from S1 sample in 0.9% sodium chloride (2.3 mg/100 ml) while the minimum was in S3 sample in 3% acetic acid (0.1 mg/100 ml) Figure 2. At 60±2°C for 2h the maximum oxidizable materials was found from S1 sample in double distilled water while the minimum was in S4 sample in 0.9% sodium chloride (Figure 3). At 25±2°C for 24h the maximum oxidizable materials was found from S1 sample in double distilled water while the minimum was in S3 sample in 3% acetic acid (Figure 4). These additives are not chemically bound to the matrix of the polymeric materials and leach out during normal use.

Keywords: Biomedical devices, Ryle's tube, physicochemical test, simulants, global migration residue and oxidizable materials

1. INTRODUCTION

Plastics have many unique properties in terms of their manufacturability and production possibilities, and these are being increasingly utilized in the production of medical devices and medical packaging.[1] The finished plastics are generally considered to be safe provided they are manufactured at standard conditions using permitted chemicals recommended by national and international regulatory agencies and used properly.[2–7]

Many inorganic chemical additives can be added to plastic biomedical devices in order to get desired physical, chemical, or mechanical properties. These include stabilizers, fillers, plasticizers, pigments, antioxidants and flame retardants etc.[8, 9]

An organophosphite may be used as a short-term antioxidant to protect the polymer during the high temperature and shear conditions of processing. A phenolic antioxidant may then be used for long-term protection. Some additives are designed to transform during use. An organophosphite will be oxidized to form the phosphate. In this case, BOTH the phosphite and phosphate are potential leachable and extractable. Polymer stabilization is a dynamic process resulting in everchanging transformation and degradation products –all potential leachable and extractable.

Additives can also provide special effects or properties to the polymer system. Benzophenones or benzotriazoles can provide UV protection to a polymer. Phenylglyoxylates can serve as photoinitiators in a UV curable coating. Colorants – dyes or pigments used to impart a particular color to a polymer system. Each of these compounds poses the potential for leachable and extractable. Good stabilization will reduce formation of aldehydes, ketones and color bodies. Some stabilizers, which can terminate alkyl radicals, are especially effective (vitamin E, lactones, hydroxyl amine). Auto-oxidation can be suppressed by the use of radical scavengers. Most polyolefins contain one or more antioxidants at levels of 0.05 – 0.1%%. Primary antioxidants are generally radical scavengers or H-donors i.e. hindered phenols such as BHT, Irganox 1010, or Irganox 1076. Long-term protection for the polymer, Secondary antioxidants are typically hydroperoxide decomposers i.e. trivalent phosphorus compounds such as Irgafos 168. Process stabilization (protects the primary AO against decomposition during processing). These additives are not chemically bound to the matrix of the polymeric materials and leach out under the influence of physicochemical factors such as sun light, temperature, type of solvents and pH of the stored commodity.[10-18] The present investigation is proposed with following objectives:

a. To quantify the leachates from various grades of Ryle's tube using simulating conditions as per BIS and international guidelines.

b. To study the possible migration and quantification of the additives from various grades of Ryle's tube under specific simulating conditions like, temperature and simulating solvents etc.

2. MATERIALS AND METHODS

2.1 Simulating conditions and simulants

Ryle's tube, four brands were used in the present study were purchased from city of Lucknow, Uttar Pradesh, from approved medical shops. Ryle's tubes were washed thoroughly with sterilized double distilled water prior to leaching. Double distilled water, Ethanol (8%), Acetic Acid (3%), Sodium Chloride (0.9%) and Sodium Carbonate (5%) were used as the simulating solvents. Ryle's tubes were exposed in 100 ml of either of the simulating solvents in sterile beakers in a ratio of $2ml/cm^2$. The samples were kept at 25±2°C for 24h (ambient conditions) and 60±2°C for 2h (elevated conditions). Parallel sets having simulating solvents only were also run under identical conditions and served as control.

2.2 Global migration residues

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. 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 24h and the crucible were weighed again. The differences in the weight obtained were taken as the measure of the global migration residue expressed as mg/100 ml of the simulants. Migration residues should not be more than 5 mg/100 ml of extract.

2.3 Oxidizable materials

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 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 solution.

3. RESULTS AND DISCUSSIONS

3.1 Physical parameters

As per the regulatory agencies, about the leachates there should be no change in the physical state of the plastic product after leachate preparation; the leachate should be odourless, clear and colourless.

3.2 Global migration residues

The test was performed as per IS 9845: 1998 guidelines. The results showed that at 60±2°C for 2h the maximum global migration residue was found from S4 sample in 0.9% sodium chloride simulants (3.5 mg/100 ml) while the minimum was in S3 sample in 3% acetic acid simulant (0.3 mg/100 ml) Figure 1. At 25±2°C for 24h the maximum global migration residue was found from S1 sample in 0.9% sodium chloride simulants (2.3 mg/100 ml) while the minimum was in S3 sample in 3% acetic acid simulant (0.1 mg/100 ml) Figure 2. The global migration residue is obtained to know about other physicochemical parameters of the samples in the study, like UV absorbing materials and oxidizable materials etc. have estimated with different solvents to determine the extent of toxicity.These residues are due to migration of unreacted monomer and different additives leach out from Ryle's tubes into the simulants at different temperature conditions.

3.3 Oxidizable materials

At 60±2°C for 2h the maximum oxidizable materials was found from S1 sample in double distilled water while the minimum was in S4 sample in 0.9% sodium chloride (Figure 3). At 25±2°C for 24h the maximum oxidizable materials was found from S1 sample in double distilled water while the minimum was in S3 sample in 3% acetic acid (Figure 4). These residues are due to migration of antioxidants as additives leach out from Ryle's tubes into the simulants at different temperature conditions.

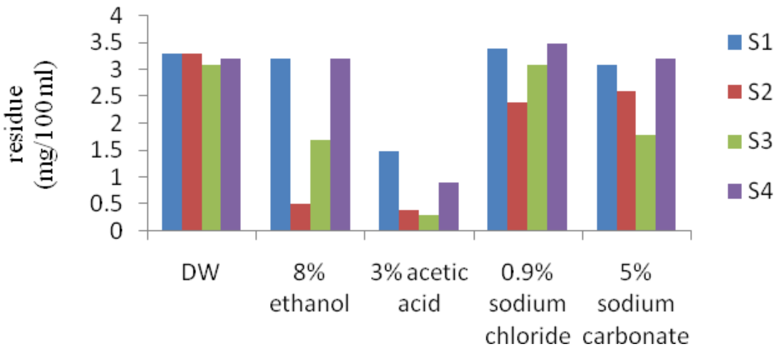

Figure 1. ***Global migration residues (mg/100 ml) of the simulants of Ryle's tube at 60±2°C for 2h.***

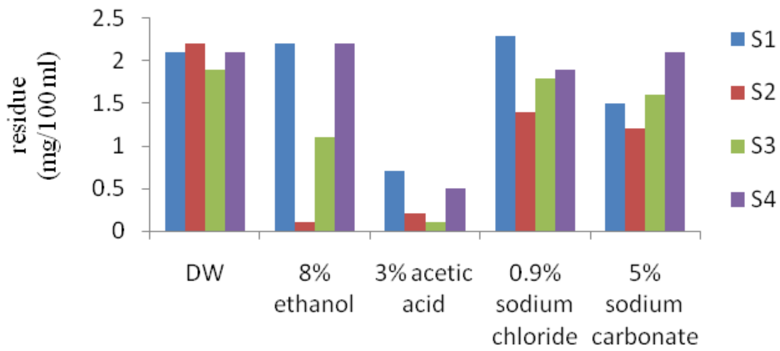

Figure 2. ***Global migration residues (mg/100 ml) of the simulants of Ryle's tube at 25±2°C for 24h.***

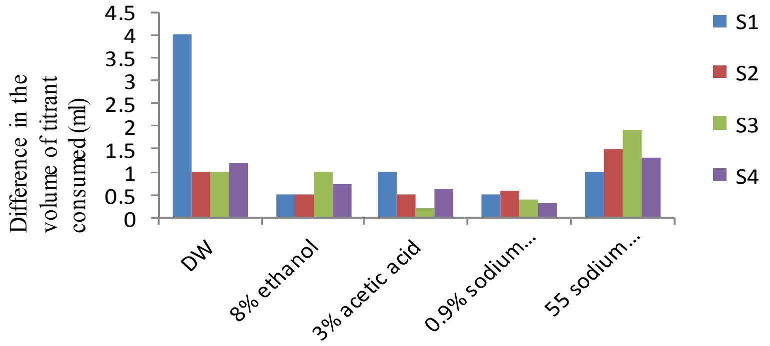

Figure 3. ***Difference in the volume of titrant consumed (ml) at 60±2°C for 2h (Ryle's tube)***

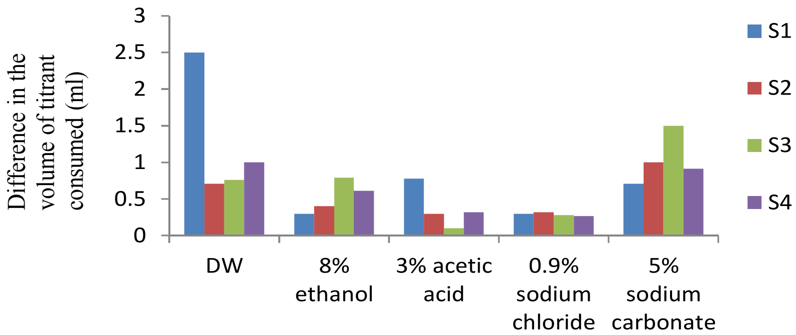

Figure 4. ***Difference in the volume of titrant consumed (ml) at 25±2°C for 24h (Ryle's tube)***

4. CONCLUSION

Ryle's tube, four brands has been tested to determine if it meets the requirements of the national and international regulatory agencies, Physicochemical Tests, Plastics. The tests performed were "Non-Volatile Residue" and "Oxidizable materials". The Ryle's tube met the national and international regulatory agencies requirements for all of the above tests. Results of our study indicate that Leachates of Ryle's tubes contain global migration residues and oxidizable materials in significant amounts.

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6. REFERENCES

1. Lewis, R.; *Occup. Med.* **1999***,* 14(4), 719.
2. Bureau of Indian Standards. List of pigment and colorants for use in plastics in contact with food stuffs, pharmaceuticals and drinking water, **1981** (9833).
3. Bureau of Indian Standards. Method of analysis for the determination of specific and/ or overall migration of constituents of plastic materials and article intended to come in to contact with foodstuffs, **1986** (9845).
4. International Organization for Standardization (ISO), Biological evaluation of medical devices-Part 1: Evaluation and testing, **1997**(10993-1).
5. International Organization for Standardization (ISO), Biological evaluation of medical devices-Part 18: Chemical Characterization of materials, **1997**(10993-18).
6. The United States Pharmacopoeia: The National Formulary. USP-23. Untied State Pharmacopoeial Convention, Inc., 12601. Twinbrook Parkway, Rockville, MD 20852, **1995**.
7. British Pharmacopoeia. Plastic containers for aqueous solutions for intravenous infusion. (Ph. Eur. Test 3.2.7) Appendix XIXC **(1998).**
8. Deanin, R.D.; *Environ. Health. Perspect*. **1975**, 11, 35.
9. Arnold, L.K.; (1968) Introduction to plastics, 4th edn. Iowa State University Press, USA
10. Figge, K.; *Food. Cosmet. Toxicol.* **1977,** 10, 815.
11. Srivastava, S. P.; Saxena, A. K.; Seth, P. K.; *Indian J. Environ. Health*, **1984,** 26 (4), 346.
12. Khaliqui, M. A.; Alam, M.S.; Srivastava, S. P.; *Bull. Environ. Contam. Toxicol.* **1992,** 48, 572.
13. Alam, M. S.; Ojha, C. S.; P.K. Seth, S.P. Srivastava; Indian J. Environ. Protect., **10,** 99. **(1990).**
14. Jenke, D.; *PDA J. Pharm. Sci. Technol.* **2011,** 65(2), 166.
15. Jenke, D.; *PDA J. Pharm. Sci. Technol.* **2010,** 64 (6), 527.
16. Jenke, D. R.; Zietlow, D.; Sadain, M. J. S.; Reiber, D.; Terbush, W.; *PDA J. Pharm. Sci. Technol.* **2007,** 61(4), 286.
17. Jenke, D.; *J. Pharm. Sci. Technol.* **2007,** 96(10), 2566.
18. Müller. U.; *Med. Device Technol.* **2008,** 19(2), 30, 32.