IMPACT OF AZO DYES ON THE BODY AND THEIR USE IN THE FOOD INDUSTRY AND PHARMACEUTICS

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Abstract

Azo dyes are the most widely used class of synthetic dyes in all industries, but particularly in the food and pharmaceutical industries. The present work focuses on more detailed presentation of all aspects of the use of azo dyes class because their use, has skyrocketed, in our country, without having to consider the health of the consumer. These compounds belong to the category of food additives, and by law, have been approved by the experts of the European Union, World Health Organization, the Organization for Agriculture and Food to be used in products food and drugs only in certain doses which do not endanger the life of the consumer.

In this study, we followed the results of a randomized study of: highlighting the most used azo dyes used as auxiliary substances, in the preparation of various pharmaceutical forms (tablets, capsules,and powders) and side effects that they have.

Key words: azo dyes, additives, food, drugs

INTRODUCTION

By azo dyes, it is understood that group of substances that absorb light in the VIS spectrum (400-700 nm) and contain at least one link structure azo, as chromophore group, responsible for the appearance of the colour (Nenițescu, 2015, Sandu, 2014 , Allam, et al., 2011, Waring, et al., 1990).

In food, synthetic dyes are used to replace natural colour, lost during processing. Colors may alter biochemical analyses of laboratory, histopathological structure of the liver and kidneys, if you consume certain foods, as demonstrated in various studies (Sahar S. A. et. al., 2012).

In drugs, dyes are used as excipients in different pharmaceutical forms to be colored, such as tablets, capsules (gelatin capsules, soft gelatin), solutions for internal use, ointments, etc. to: increase the aesthetic appearance, the extension of stability of the preparation etc. (Biswal et al., 2015). Colorants are added to foods, supplements and medicines for commercial, psychological and practical reasons (Sulekova et al., 2016).

In the pharmaceutical industry, can be used those dyes that are included in the list of food colors (Food, Drug and Cosmetic Act, FD & C and according to Directive 94/36 / EC) (Lupuleasa et al., 2009, Allam et al., 2011).

Azo dyes presents some advantages over natural dyes, namely: they have low cost, presents a wide range of colors, are obtained by a very simple and cheap synthesis (diazotizing and coupling), have good heat stability to light and oxygen (Allam et al., 2011, Farah et al, 2011).

In the pharmaceutical industry azo dyes presents some disadvantages: produce difficulties when carrying out analytical control of active substances; over time can interact with active substances, resulting from changing the appearance or therapeutic action; can mask changes arising from the degradation of active principles; may cause allergy or intolerance phenomena in sensitive individuals. These reactions occur mostly as a result of the consumption of drugs containing tartrazine. Therefore, PDMH (Pharmaceutical Department of the Ministry of Health) in France obliges tartrazine indication on the packaging of medicines containing it due to the possibility of allergic reactions in susceptible sensitive individuals (Lupuleasa et al., 2011, 2008, 2009, Niță et al., 2015).

The data FDA (Food, Drug and Cosmetic Act) show a dramatic increase, five times the consumption of azo dyes from 1955 until the present (Potera, 2010).

The reactions induced by foods containing azo dyes range from flushing or runny nose, to anaphylactic shock, or enterocolitis. Azo dyes which have been demonstrated that they can cause allergies are: E124, E102, E129, E110 (Gültekin F. et al., 2012). E102, E 123, E124 known, in particular for the production of side effects in children, such as contact dermatitis, gastrointestinal intolerance, bronchospasm, eosinophilia, angioedema, rash and even hyperactivity (Parnali et al., 2014, Gültekin et al., 2013, Sulekova et al., 2016, Orănescu, 2008).

Another aspect that we recommend is that they can cumulate in the body and may produce delayed effects, such as cancer (Sandu, 2014, Necula et al. 2010, European Commission, 2005).

In our country the OMS 975/1998 (Mo.268/1999) decided: mandatory registration of additives on the label of each package; banning the addition of additives in order to mask the alteration or degradation of the food; establishing the requirements for purity to be met by additives (Mihele, 2008).

It has been found that through sulfonation dyes decrease toxicity due to increase of urinary excretion of the molecule and its metabolites in the body (European Commission, 2005).

The Romanian Pharmacopoeia, allows the use of azo dyes accepted by the Ministry of Health at the coloring of capsules, tablets, dragees, and granules. Azo dyes the most used in the formulation of medicaments are: E

102 – tartrazine, E 110 - orange S, E 122 - azorubine, E 123 – amaranth, E 124 - ponceau 4R and E 151 - brilliant black BN (Lupuleasa, et al., 2008).

A very important thing to note is that azo dyes are not pure and can contain more than 10% impurities resulting from the manufacturing process. The FDA has determined which are the legal limits for impurities that cause cancer through the use of dyes (Gültekin F. et al. 2013). Purity is a very important condition when desired incorporation into drugs, and if impurities are present they should be easily detected .

The concentrations in which the colorants are found in the various pharmaceutical forms are: tablets from 0.01% to 0.1%; emulsion 0.005%; molecular solutions 0.0005% to 0.001%; powders 0.1%; syrups 0.05% to 0.1%; suppositories 0.005% to 0.01% (Banu et al., 2010).

MATERIAL AND METHOD

The study consists of analyzing the content of the azo dyes of various pharmaceutical products: drugs (Rx) medicines (OTC), and food supplements. Regarding the number of products we've subjected study, we analyzed a total of 100 of medicinal and non-medicinal products.

RESULTS AND DISCUSSIONS

In the study we noticed that 66.66% of the analyzed products have in composition a single azo dye, 26.66% contain two and the rest of 6.68% contain three, as can be seen in figure 1.

Fig. 1. Number of azo dyes used in the pharmaceutical products

The pharmaceutical formulations that the azo dyes are most used are: capsules 46.66%, followed by the tablets 33.33% and the powders 10%. (Figure 2).

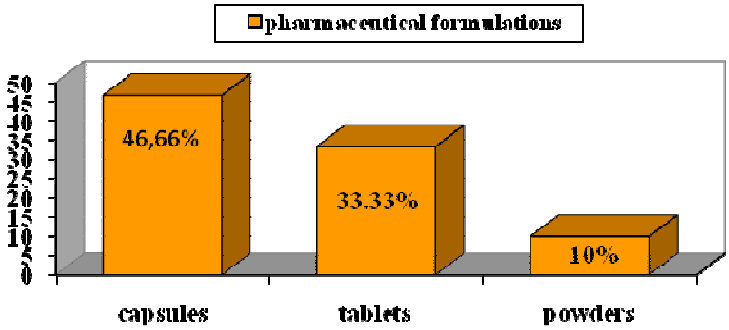

Fig. 2 Pharmaceutical formulations that the azo dyes are most used

The most used azo dyes, in formulating analyzed drugs were: yellow twilight (E 110) 41.02%, ponceau 4R (E 124) 30.76% , tartrazine (E102) 15.38%, allura AC (E 129) 7.69%, amaranth, and black shiny (E 123, E 151) 5.15% (Figure 3).

Fig. 3 The most used azo dyes at the drugs formulations

In the composition of the analysed drugs, besides the azo dyes, have also been used and other dyes, but from other classes: triaryl – methane (blue patent - E 131) 16.66%, xanten (erythrosine - E127) 11.11%, quinoline (quinoline yellow – E104) 22.22% and surface dyes and indigotine – E132 5.55%, the rest of 44.46% being represented by the azo dyes (Figure 4).

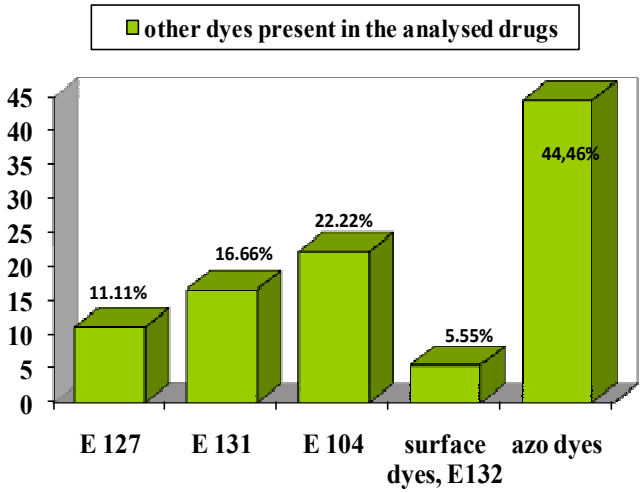

Fig. 4 Other dyes, apart from the azo dyes, present in the analyzed pharmaceutical products

CONCLUSIONS

Because many studies show the toxicity of these dyes, I think that should be specified on the label of food products and medicines the concentration in which are used, in order not to exceed the maximum limit allowed daily.

If these medications are used in combination, or if increase doses to special classes of patients: children, the elderly or pregnant women then the concentration of azo dyes in the body will increase and also the risk of occurrence of adverse effects. reactions that they can give, as a result of the consumption of drugs, may be confused by the patient with the adverse reactions given by the active adverse substance, and in the package leaflet of medicinal products, those effects should be specified.

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