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Review article

Colourants used in food and pharmaceuticals – A comparison of natural and synthetic colours

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ABSTRACT

Colourants are mainly used to impart a distinctive appearance to the food and various pharmaceutical dosage forms. Colourants can be considered as the cosmetics for food and dosage forms as the aesthetic appearance are enhanced by various colours. The colourants are strictly studied, regulated and monitored before it is used at the intended level. The colourants used may be either naturally occurring colours or synthetically prepared. A colourant is a substance which when applied to a food, drug or cosmetics is capable of imparting colour. FDA is responsible for regulating all colourants are safe to eat, contain only approved colours and are accurately labelled and certified. Colours are those which are synthetically prepared and are capable of imparting an intense uniform colour, less expensive and blend more easily to create a huge variety of hues. Good health makes a lot of sense, but it doesn't make a lot of dollars. Manufactured food is pumped full of toxic chemicals meant to dress it up and entice consumers to buy. The synthetic colours are responsible for specific teratogenic and carcinogenic effects.

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INTRODUCTION

Colouring agents or colourants are used in the processing of food, drug and cosmetics; are regulated by the US FDA to ensure safety. These are widely used to confer a desirable appearance. Colouring agents are dyes or pigments used to produce attractive colour to the products. The purpose of the colouring agent is to attract customers through visual perception (König, 2015; Šuleková et al., 2017).

According to FDA, colouring agents can be defined as any dye, pigment or other substances that can impart colour to food, drug and cosmetics. There are many reasons behind the addition of colours in food which include maintaining safety, freshness and nutritional value as well as improving taste, texture and appearance to influence the consumer to buy a product through visual perception.

Moreover, the colours are also used to offset colour loss due to exposure to light, air, extreme temperature, moisture and storage conditions, to correct natural variations in colour, to enhance colours that occur naturally, to provide colour to colourless and fun foods, to make food more attractive and appetizing, and to allow consumers to identify products on sight.

HISTORY OF FOOD COLOURS

Cleopatra added saffron in butter as the first colourant to put a rich yellow colour in 1200 BC whereas, in 1500 BC, Candy makers in Egyptian cities added natural extracts and wine to improve the product appearance.

William Henry Perkin discovered the first artificial organic dyes called Mauve by oxidizing aniline while trying to form an antimalarial drug (quinine) in 1856. Thereafter, in 1900, foods and drugs in the US were artificially coloured with many poisonous materials such as lead, arsenic, mercury to hide inferior or defective foods. Hence, in 1906, Congress passed the FDA, which prohibited the use of poisonous or deleterious colours in food industry any more. The first EU directive, focusing on the use of colourants in food was published in 1962. In the year 2009, Barry Callebaut's IBC brand specialized in colour and print technology in food applications has launched power flowers by tempering cocoa butter and 40% colouring agent.

CLASSIFICATION OF COLOURANTS

The colourants are mainly classified on the basis of FDA and drug and cosmetic act. According

to FDA, the colourants are of two types, Certified and Non-certified whereas drug and cosmetic act (1938) divided the colours into two-three categories, FD&C colours, D&C colours and external D&C colours.

FD&C colours are colourants that are certifiable for use food drugs and cosmetics, e.g. FD&C Blue No. 1. On the other hand, D&C colours are dyes and pigments considered safe for use in drug and cosmetics when in contact with mucous membranes or when ingested, e.g. D&C Red No. 21. External D&C colours are those which have oral toxicity and are not certifiable for use in products intended for ingestion but are considered safe for use in products applied externally, e.g. D&C Orange No. 5. The colourants are also classified based on consistency (i.e. dyes and lakes) and availability (i.e. natural colour, natural identical and artificial colour). Natural food colour is any dye, pigment or any other substance obtained from plants, algae or insects whereas synthetic colours are prepared in the industries with the help of various chemicals. In addition, there are many basic differences between natural and synthetic colours are given in Table 1. These are available in the form of liquids, liquid gel dye, powders, gels, pastes, etc.

| Natural colourants | Synthetic Colourants |
|---------------------|------------------------|
| Obtained from | Obtained by chemical |
| natural sources | reactions |
| Processed by | Processed by chemical |
| physical means | means |
| Maybe less stable | Highly stable to light |
| | oxygen and pH |
| Less bright | Highly coloured |
| Not uniform | Colour uniformity |
| May not harmful for | May cause health |
| health | problems |
| Good consumer | Consumer acceptability |
| acceptability | is questionable |
| Expensive | Less expensive |
| High microbial | Low microbial |
| contamination | contamination |

Table 1. Difference of natural and synthetic colours

PERMITTED NATURAL COLOURS

In India, rule 26 of prevention of food and adulteration act 1954 and the prevention of food adulteration rules 1955 and 1999 permitted the following colours which are isolated from natural sources.

- 1. Beta carotene
- 2. Annatto
- 3. Saffron
- 4. Curcumin
- 5. Phycocyanin
- 6. Chlorophyll
- 7. Grape extract
- 8. Luetin

- 9. Cochineal extract
- 10. Beetroot concentrates
- 11. Caramel

PERMITTED SYNTHETIC COLOURS

According to the above rules and regulations, the following synthetic colours are permitted in India.

- 1. Ponceau 4R (Red)
- 2. Carmoisine (Red)
- 3. Erythrosine (Red)
- 4. Tartrazine (Yellow)
- 5. Sunset yellow (Yellow)
- 6. Indigo carmine (Blue)
- 7. Brilliant blue FCF (Blue)
- 8. Fast green FCF (Green)

In the USA, following seven artificial colours are permitted in food.

- 1. FD&C Blue No. 1 Brilliant blue FCF, E133 (Blue)
- FD&C Blue No. 2. Indigotine, E132 (Dark Blue)
- FD&C Green No. 3 Fast green FCF, E143 (Bluish-green)
- FD&C Red No. 40 Alura red AC, E129 (Red)
- 5. FD&C Red No. 3 Erythrosine, E 127 (Pink)
- FD&C Yellow No. 5 Tartrazine, E102 (Yellow)
- FD&C Yellow No. 6 Sunset yellow FCF, E110 (Orange)

E number codes for food additives, usually found on food labels, in EU. There are selected E numbers which cover artificial colours, for example, E 104 (quinoline yellow), E122 (carmoisine), E124 (ponceau 4R), E 131 (patent blue V) and E 142 (green S). The numbering scheme follows that of INS as determined by The Codex Alimentarius Committee is also accepted internationally without the E number (Table 2).

Table 2. Accepted ranges of colours without E numbers

| Range | Colour | |
|---------|-------------------|--|
| 100-109 | Yellows | |
| 110-119 | Oranges | |
| 120-129 | Reds | |
| 130-139 | Blues and Violets | |
| 140-149 | Greens | |
| 150-159 | Browns and Blacks | |
| 160-199 | Others | |

NATURAL FOOD COLOURS

There are many natural food colours available in the market, which are well-accepted by the consumers due to their non-toxic nature.

Beetroot concentrates

Beta vulgaris contains inorganic nitrates which are a precursor to a very important signalling molecule nitric oxide that our body needs to function. Nitric oxide as a vasodilator is to allow more oxygen flow in cardiovascular diseases. Its colour pigments are betalains which is used in the manufacturing of icecreams, ice-bars, candy, jams and jellies. Betalain also has some health benefits including body detoxifier, fat-free and energy source, prevents skin ageing, and excellent food during pregnancy as it contains natural folic acid.

Annatto

Strong pigmentation of *Bixa orellana* seeds makes it a natural food colour and it has plenty of applications in cosmetics, but more importantly, it has more herbal and medicinal benefits. There are many health benefits of annatto which include improves memory, excellent wound healer, improves immunity and prevents constipation. It has two important colour pigments namely bixin and norbixin. The colour of bixin in final food is orange and used in snacks, cakes, butter and popcorn oil whereas norbixin is used in cheese, flavoured milk, drinks, snacks, bakery and confectionery.

β-Carotene

 β -Carotene is an organic, strongly coloured red-orange pigment abundant in plants and fruits. Its major source is *Daucus carota*. This molecule has many health benefits such as it acts as provitamin A, prevents from UV rays and sunburns, having antioxidant and radical scavenging activity, prevents skin ageing and prevents carcinoma of breast and lungs.

Cochineal extract

The cochineal is a scale insect from which the natural colour carmine is derived. It does not contain many nutritional aspects rather it is sometimes responsible for some allergic reactions. It has magenta red colour and has carmine or carminic acid pigment. It is used in the preparation of cakes, sweets, alcoholic drinks, beverages, and icecreams.

Lutein

Lutein in marigold (*Tagetes erecta*) along with zeaxanthin is potentially antioxidant useful for removing a deposited mass in the retina of eyes and preventing macular degeneration. It is a light yellow colour pigment found in the flowers of marigold. It is used in baked foods, breakfast cereals, chewing gum, beverages, and dairy products.

Grape extract

Anthocyanins and flavonols are the most important grape polyphenols that possess many biological activities like antioxidant, cardioprotective, anti-inflammatory, anti-ageing, anti-allergic, anticarcinogenic, vasodilators and antimicrobial properties. It is blue in colour and used in fruit filling gelatin desserts, jam, jellies, ice cream, candy and sweets.

Paprika oleo resin

Its active pigments account for 30%- 60% of total carotenoids in fully ripe fruits which composes of conjugated double bond single keto group and a cyclopentane ring. These structural characteristics give rise to free radical scavenging ability and prevent colon carcinogenesis. Its source is red pepper (capsicum) and its colour is bright orange to red-orange. Its colour pigments are capsanthin and capsorubin used in the seasoning of salads, snacks, popcorns and beverages. Capsanthin has many nutritional benefits such as anti-inflammatory and antioxidant, natural source of omega 3 fatty acid, fights against gastritis and acidity, decreases motion sickness and nausea, a rich source of vitamins and relaxes respiratory muscles.

Turmeric oleoresin

Turmeric (*Curcuma longa*) had been using for 4,000 years to treat a variety of conditions. Its colour is yellow-orange and its pigments are curcumin and curcuminoids. It is useful in treating digestive problems, infections, inflammation and some cancers. It is used to preserve foods like a pickle.

Saffron

The bioactive properties of high antioxidant safranal component have the scavenging ability at a cellular level. Its source is *Crocus sativus*. Its colour forming components are picrocrocin and safranal. Its applications including seasoning in desserts, health drinks, sweets, traditional food items. In addition, it has many nutritional benefits include treating depression, preventing cancer, curing insomnia, relieving toothache and helping in arthritis.

Phycocyanin

Among all microalgae, genus Spirulina is the most inexpensive. It has pharmaceutical action in oxidative stress-induced diseases. Its source is blue-green algae and the colour is light greenish blue to intensively dark blue. Its colour pigments are phycocyanin and spirulina. It is useful in the dairy industry, coated candy, baked foods and cheese.

LIMITATIONS OF NATURAL FOOD COLOURS

Natural colours have their own flavour which may affect the taste of the finished product (Cortez et al., 2017). Actual colours may not retain as such when subjected to high temperatures, e.g. grape juice extract. They may cause an allergic reaction, e.g. cochineal extract and annatto. Some of the natural food colours are very expensive, e.g. saffron while some times, raw ingredient remains scarce, e.g. marigold. Such colourants are required in large quantities when compared to artificial dyes, e.g. cochineal extract.

SYNTHETIC FOOD COLOURS

Ponceau 4R (E124)

Its molecular formula is $C_{20}H_{11}N_2Na_3O_{10}S_3$. This colour is manufactured by coupling diazotized naphthionic acid. It is used in bakery items, edible ices, confectionaries, sauces etc. There are some health risks associated with this synthetic colour like urticaria, glomerulonephrosis, genotoxicity and carcinogenicity. Its accepted daily intake is 0.7 mg/kg (EU) and 4 mg/kg (WHO/ FAO) whereas it is banned in Norway and USA.

Carmoisine (E122)

Its molecular formula is $C_{20}H_{12}N_2Na_2O_7S_2$. It is an azo dye having two hydrocarbon disodium salt and two nitrogen atoms. It is mainly used when food is heat treated. It is used in baked products, candy, drinks, ice creams, jelly crystals. The health issues associated with its use are hyperactivity in children, skin allergies, difficulty in respiration, carcinogenic and tumorigenic. Its permitted dose is 0-2 mg/kg. It is not approved in Canada and the USA.

Indigo carmine (FD&C Blue No. 2)

Its molecular formula is $C_{16}H_8N_2Na_2O_8S_2$. Indigo carmine is an organic salt derived from indigo by sulfonation. It is used in obstetric surgery to detect amniotic fluid leaks. In urologic surgery, i.v. injection is often used to highlight the portions of kidneys. It is harmful when given to pregnant women and also harmful for respiratory tract when inhaled and irritant to the skin and eyes. Its permitted dose per day is 5 mg/kg. It is banned in Norway.

Brilliant Blue FCF (E133) (FD&C Blue No. 1)

Its molecular formula is $C_{37}H_{34}N_2Na_2O_9S_3$. It is produced using aromatic hydrocarbons from petroleum. It has the appearance of reddish-blue powder soluble in water. It is used in ice creams, canned foods, sweets, drinks, blue raspberry, flavoured products, etc. Its permitted dose is 12.5 mg/kg (USA) and 0-6 mg/kg (EU). This dye is banned in Austria, Belgium, Denmark, France, Germany, Greece, Sweden and Switzerland.

Fast green FCF (E143)

Fast green FCF is a synthetic organic dye, which belongs to triphenylmethane group. Colour is more brilliant and less likely to fade. It is used in tinned green peas and other vegetables, jellies, sauces, fishes, desserts, etc. It has a tumorigenic effect, caused irritation to eyes, skin, digestive tract and respiratory tract. The recommended dose for this colour is 0.2 mg/kg. It is banned in the European Union.

Allura red AC (129) (FD&C Red No. 40)

This is a red azo dye made from byproducts of petroleum. It is originally introduced in the United States as a replacement of amaranth as a food colour. It appears as a dark red powder and used in soft drinks cotton candy and children medications. Its permitted dose is 0.5 mg/kg and banned in Denmark, France, Sweden, Belgium and Switzerland.

Erythrosine (E127) (FD&C Red No. 3)

Its molecular formula is $C_6H_{20}I_4Na_2S_5$. It is an organoiodine disodium azo dye compound, specifically a derivative of fluorine. It is reported to caused thyroid cancer. Its permitted dose is 0-0.1 mg/kg/day. This dye is banned in Norway and USA.

Tartrazine (E102) (FD&C Yellow No. 5)

It is a lemon yellow synthetic azo dye derived from coal tar which is used in cheese, canned or bottled fruit or vegetables. The possible health risks associated with this dye are lethal asthma, DNA damage, tumours of the thyroid and ADHD. Its permitted dose is 5 mg/kg. it is banned in Norway and Austria.

Sunset yellow FCF (E110) (FD&C Yellow No. 6)

Its molecular formula is $C_{16}H_{10}N_2Na_2O_7S_2$. This is petroleum derived orange azo dye used in ice creams, foods cosmetics and preserved fruits. It caused a runny nose, nasal congestion, kidney tumours, nausea and vomiting. Its permissible dose is 0-4 mg. this dye is banned in Norway and Finland.

HAZARDS EFFECTS OF SYNTHETIC COLOURS

As shown in Table 3, there are various hazards effects of synthetic food colourants.

| S.No. | Colourant | E-number | Uses | Adverse effects |
|-------|-------------------|----------|--------------------|--|
| 1 | Ponceau 4R | E124 | Food colour | Asthma, rhinitis, urticaria |
| 2 | Sunset-yellow FCF | E110 | Food colour | Growth retardation and weight loss |
| 3 | Allura red | E129 | Snacks soups | Allergic reactions |
| 4 | Tartrazine | E102 | Food colour | Hyperactivity in children, migraine, hypersensitivity |
| 5 | Erythrocine | E127 | Confectionaries | Thyroid allergies |
| 6 | Amaranth | E123 | Wine, fish, cheese | Asthma, rhinitis, urticaria |

Table 3. Hazards effects of synthetic colourants

Hence, on the basis of the above discussion, it can be said that natural colours are best over artificial colours as artificial colours caused ADHD, behavioural problem, depression, allergies, headaches and migraine.

FUTURE PROSPECTS OF NATURAL FOOD COLOURS

Microencapsulation

Increased light stability will be achieved with encapsulation of some sensitive colours, i.e. annatto and paprika.

Addition of antioxidants

To increase the nutritional value of some food colours, external antioxidants like tocopherols, ascorbic acid and rosemary extracts can be added.

Emulsions

By formulating an easy to disperse colour emulsion to remain stable in many different food applications like gums or modified starches. Development of new sources should be discovered for introducing new agents in the market.

Pharmaceutics

Colourants or colouring agents are mainly used to impart a distinctive appearance to the pharmaceutical dosage forms (Allam and Kumar, 2011). The colourants are also considered as the cosmetics for pharmaceutical preparations. These are added to the drugs to increase acceptability, for identification and stability purpose, as an indicator of quality, degradation and loss of potency, and also as a brand's identity.

IDEAL PROPERTIES OF A COLORANT

An ideal colourant should be non-toxic and physiologically active. It must be free from any impurity. Its tinctorial power should be high so that only small quantities are required. It should be unaffected by light temperature, hydrolysis and microorganisms. It should be unaffected by oxidizing or reducing agents and pH changes. In addition, it should be compatible with medicines and free from objectable taste and odour.

CLASSIFICATION OF COLOURS USED IN PHARMACEUTICALS

There are mainly three categories of colours used in the pharmaceutical industries, which are organic dyes and lakes (e.g. tartrazine and sunset yellow), organic/ mineral colours (e.g. titanium dioxide, red and yellow ferric oxide) and natural colours (e.g. turmeric).

A dye is a chemical that shows colour when it is dissolved. They are water soluble and will not mix with oil whereas a lake pigment is an insoluble material that colours by dispersion. Lakes are defined by FDA as aluminium salts of FD&C watersoluble dyes extended on a substratum of alumina. The resulting pigment is called a lake pigment. The lakes are colour stable. The commonly used dyes are iron oxide and titanium oxide whereas aluminium lakes are commonly used in pharma industries. The widely used colourants (Table 4) in pharmaceuticals are as following.

1. FD&C Blue No. 1 (Brillant blue)

- 2. FD&C Blue No. 2 (Indigotine)
- 3. FD&C Blue No. 3 (Erythrosine)
- 4. FD&C Red No. 40 (Allura red)
- 5. FD&C Yellow No. 5 (Tartrazine)
- 6. FD &C Yellow No. 6 (Sunset yellow)

Table 4. Colorants in various dosage forms

| SNo. | Nature of colour | Colouring agent | Pharmaceutical doses form |
|------|---------------------|--------------------|------------------------------|
| 1 | White | Titanium | Sunscreens, |
| | | dioxide | capsules, tablets |
| 2 | Blue | Brilliant | Mouthwashes |
| | | blue, carm- | |
| | | ine indigo | |
| 3 | Red | Carmine | Ointments |
| 4 | Yellow | Tartrazine, | Vitamins and |
| | | sunset | antacids |
| | | yellow, | |
| | | saffron, | |
| | | annatto | |
| 5 | Green | Chloro- | Soaps |
| | | phyll | |
| 6 | Brown | Caramel | Syrups |

PLANTS HAVING COLOURING EFFECTS

There are many plants found in the earth having colouring properties (Semwal et al., 2014). *Rubia cordifolia* and *Ventilago maderaspatana* are known for red and pink colours whereas *Crocus sativus*, *Curcuma longa* and *Punica granatum* produced a yellow colour. Similarly, *Indigofera tinctoria* and *Pterocarpus marsupium* have blue dye, *Acacia catechu* has brown and *Emblica officinalis* has a black colour dye.

CONCLUSION

Natural dyes are not only having dyeing property but also have a wide range of medicinal properties. Nowadays, fortunately, there is increasing awareness among people towards natural dyes and dye-yielding plants. Due to the nontoxic properties, fewer side effects and medicinal values, the natural dyes are used in day today food products and pharmaceutical industry. More detailed studies and scientific investigation are needed to assess the real potential and availability of natural dye yielding resources in great demand on the therapeutic formulations of natural dyes commercially.

There is a need for proper methods, documentation and characterisation of dye yielding plants for further development of the pharmaceutical industry to formulate the natural plant pigments into therapeutically beneficial pharmaceutical dosage forms.

CONFLICT OF INTEREST

Authors declare no conflicts of interest.

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