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REVIEW ARTICLE

PHARMACEUTICAL TASTE MASKING TECHNOLOGIES OF BITTER DRUGS: A CONCISE REVIEW

***Patel Chirag J[1], Prof. Satyanand Tyagi[2], Mangukia Dhruv[3], Mangukia Ishita[4], Anil Kumar Gupta[5], Mohammed Rageeb Mohammed Usman[6], Jony Mallik[7], Nikhala Shree[8], Shravan Kumar Paswan[9]**

[1]Editor-in-Chief, Tyagi Pharmacy Association (TPA) & Scientific Writer (Pharmacy), Patan, Gujarat, India-384265.

[2]President & Founder, Tyagi Pharmacy Association (TPA) & Scientific Writer (Pharmacy), Chattarpur, New Delhi, India-110074.

[3]Department of Pharmaceutics, Maharishi Arvind Institute of Pharmacy, Mansarovar, Jaipur, Rajasthan, India-302020.

[4]Department of Pharmaceutics, Parul Institute of Pharmacy, Vadodara, Gujarat, India-391760.

[5]Jyoti Vidyapeeth women's University, Jaipur, discipline of Pharmaceutical Science, Jaipur, Rajasthan, India-303007.

[6]Associate Editor, Tyagi Pharmacy Association (TPA) & Assistant Professor, Department of Pharmcognosy, Smt. S. S. Patil College of Pharmacy, Chopda, Maharashtra, India-425107.

[7]M.Pharmacy Scholar (Department of Pharmacy), Southern University Bangladesh, Department of Pharmacy, 739/A, Mehedibag Road, Chittagong, Bangladesh-4200.

[8]Senior Research Fellow (S.R.F), Tamil Nadu Veterinary and Animal Sciences University, Tamil Nadu Veterinary and Animal Sciences University, Madhavaram Milk Colony, Madhavaram, Chennai, Tamil Nadu, India-6000051.

[9]M. Pharmacy Scholar (Department of Pharmacology), Advance Institute of Biotech and Paramedical Sciences, Advance Institute of Biotech and Paramedical Sciences, G.T.Road, Naramau, Kanpur, Uttar Pradesh, India-209217.

ABSTRACT

Taste refers to a perception arising from the stimulation of taste buds present on the surface of the tongue. Humans can distinguish among five components of taste: sourness, saltiness, sweetness, bitterness, and umami (savory). Taste is an important parameter in case of drugs administering orally and is a critical factor to be considered while formulating orodispersible, melt in mouth, buccal tablet and other formulations which comes in contact with taste buds. Bitter and unpalatable taste is a major problem of certain drugs in formulations. Masking the bitter taste of drugs is a potential tool for the improvement of patient compliance which in turn decides the commercial success of the product. According to the year 2003 survey of pediatricians by the American Association of Pediatrics, unpleasant taste was the biggest barrier for completing treatment in pediatrics. The field of taste masking of active pharmaceutical ingredients (API) has been continuously evolving with varied technologies and new excipients. Two approaches are commonly utilized to overcome the bad taste of the drug. The first includes reduction of drug solubility in the saliva and second approach is to alter the ability of the drug to interact with taste receptor. Various methods are available to mask the undesirable taste of the drugs. Some of them are coating of drug particles, by formation of inclusion complexes, molecular complexes of drugs with other chemicals, solid dispersions, melting method, micro encapsulation, prodrugs, mass extrusion methods and ion exchange resins.

KEY WORDS: Taste, Orally, Bitter, Masking

INTRODUCTION:

Undesirable taste is one of several important formulation problems that are encountered with certain drugs. Oral administration of bitter drugs with an acceptable degree of palatability is a key issue for health care providers, especially for pediatric patients. Several oral pharmaceuticals, numerous food and beverage products, and bulking agents have unpleasant, bitter-tasting components. So, any pharmaceutical formulation with a pleasing taste would definitely be preferred over a competitor's product and would translate into better compliance and therapeutic value for the patient and more business and profits for the company. The desire of improved palatability in these products has prompted the development of numerous formulations with improved performance and acceptability[1, 2].

TASTE BUD:

Four fundamental sensations of taste have been generally described- Sweet, Sour, Bitter, Salty and fifth widely accepted basic taste is Umami. These tastes consistently stimulate taste bud in specific parts of the tongue as sweet and salty mainly at the tip, sour at sides, bitter at back[3] (Fig. 1).

*Corresponding author: Patel Chirag J | Email: chirag.bangalore@gmail.com

Figure 1: Taste Points in Tongue[3]

Taste buds are small sense organ in most vertebrates, helps in the detection of taste. Hence a group of cells, found especially on the tongue Taste buds have been identified on the soft palate, pharynx, epiglottis, which allows different types of taste to be recognized[1].

A. Salty taste (edge, upper portion)

The salty taste is one among the four taste receptors of tongue. They are located on the edge and upper front portion of the tongue.

B. Sweet taste (tip)

The sweet taste is one among the four taste receptors in the tongue. They are found on the tip of the tongue.

C. Sour taste (along sides in back)

The sour taste is also one of the four taste receptors of the tongue. They occur at sides of the tongue and are stimulated mainly by acids.

D. Bitter taste (back)

The bitter taste is the last and one of the four taste receptors in the tongue. That is located toward the back of the tongue. It is stimulated by a variety of chemical substances, most of which are organic compounds, although some inorganic compounds such as magnesium and calcium also produce bitter sensations[1, 4-6].

AN IDEAL TASTE MASKING PROCESS AND FORMULATION SHOULD HAVE THE FOLLOWING PROPERTIES:

1. Require minimum number of excipients for an optimum formulation.
2. No adverse effect on drug bioavailability.
3. Involve least number of equipments and processing steps.
4. Can be carried out at room temperature.
5. Require excipients that are economical and easily available.
6. Least manufacturing cost.
7. Rapid and easy to prepare.
8. Require excipients that have high margin of safety[7].

FACTORS AFFECTING SELECTION OF TASTE MASKING TECHNOLOGY:

1. Dose of Active Pharmaceuticals

Dose of a drug may dictate whether a particular formulation strategy would be suitable to achieve taste masking. In pediatric formulations, the dose is small enough so as to allow the usage of flavoring agents to mask the taste of the medicine. For example, low dose palatable pediatric aspirin oral formulation was developed by adding sweeteners, but the same approach failed to address the problem of drugs like acetaminophen because of its high dose. In such cases, coating is preferred to achieve taste masking along with sweeteners to attain an acceptable final dosage form size[3].

2. Extent of Bitter Taste

With aggressively bad tasting medicaments even a little exposure is sufficient to perceive the bad taste. For example, sweeteners could not achieve taste masking of oral formulation of ibuprofen due to its dominating taste. Coating is more efficient technology for aggressively bitter

drugs even though coating imperfections, if present, reduce the efficiency of the technique. Similarly, microencapsulation of potent bitter active agents such as azithromycin is insufficient to provide taste masking of liquid oral suspensions. Viscosity enhancers can complement the taste masking efficiency. Oral suspension containing viscosity enhancers can masquerade the objectionable taste, which arises from the leakage of drug from the coated medicaments or microcapsules. This approach was also used for the microencapsulated oxazolidinone particles to limit the transport of drug from the polymer coated drug particles to the vehicle. Conventional taste masking techniques such as the use of sweeteners, amino acids and flavoring agents alone are often inadequate in masking the taste of highly bitter drugs such as quinine, celecoxib, etoricoxib, antibiotics like levofloxacin, ofloxacin, sparfloxacin, ciprofloxacin, cefuroxime axetil, erythromycin and clarithromycin[3, 8].

3. Drug Particle Shape and Size Distribution

Particle characteristics of the drug would affect the taste masking process efficiency. Core materials with irregular shapes and small particle size lead to poor taste masking efficiency and varying dissolution of coated particles [108]. Fines, abrasion and variable coating thickness can lead to situations wherein the taste mask coating is compromised. Multilayer coating using inner spacing layer to sequester the drug from taste masking layer helps to reduce or eliminate such coating imperfections. Taste masked granules of gatifloxacin and dextromethorphan were formulated by multilayer coating consisting of inner spacing layer followed by outer taste masking layer[3, 5].

4. Drug Solubility

Physicochemical properties of the drug play an important role in the selection of taste masking technology. For example, ondansetron has a relatively lower water solubility at higher pH, based on which a rapidly disintegrating taste masked composition of ondansetron was formulated by adding an alkalizing agent(sodium bicarbonate) to reduce the water solubility and the consequent taste perception. Douglas and Evans (1994) described different approaches to achieve the taste masking of ranitidine base and its salts having different solubility profiles. The bitter taste associated with a poorly soluble form of ranitidine may be satisfactorily masked by lipid coating of the drug substance. However, for water soluble forms of ranitidine (e.g. ranitidine hydrochloride), the degree of taste masking achieved by simple lipid coating of the drug substance may not be entirely satisfactory, particularly if the product is to be formulated in an aqueous medium. Thus ranitidine hydrochloride was first incorporated into the inner core of a polymeric binder, or a lipid or wax having a melting point higher than that of the outer lipid coating to achieve an efficient taste masking[3, 8].

5. Ionic Characteristics of the Drug

Ionic characteristics of drugs govern the selection of ion exchange resin polymers and the suitability of the drug candidate for this technology. For example, anionic polymers (e.g. alginic acid) are good candidates for cationic drugs like donepezil hydrochloride, and the cationic polymers are choice of excipients for anionic drugs like sildenafil[3, 9].

6. Dosage Forms

It is estimated that 50% of the population have problem of swallowing tablets, especially the pediatric and geriatric population. Chewable tablets and liquid oral dosage forms have been used to address these problems. However, it is difficult to formulate some drugs in these dosage forms due to their poor palatability. For formulations which are swallowed unchewed: capsules, coated tablets and slowly disintegrating hard tablets have been used as preferred taste masking technologies. Chewable tablets and liquid oral formulations are preferable in case of large dose drugs for an ease of intake. Taste masking technologies such as sweeteners, particulate coating, microencapsulation and granulation can be employed for chewable tablets and supported with technologies such as viscosity enhancers and pH modifiers to achieve taste masking in liquid oral formulations. Microencapsulation of the unpleasant tasting active agent with ethyl cellulose or a mixture of ethyl cellulose and hydroxypropyl cellulose or other cellulose derivatives has been used to provide chewable taste-masked dosage forms. However, this approach suffers from the disadvantage that the polymer coating releases the active agent in an inconsistent fashion and may not provide an immediate release. Moreover, coating is more suitable when the formulation is stored in a dry form. Viscosity enhancers or pH modifiers can be used in the suspending medium to achieve taste masking of suspended coated particles, especially for extremely bitter drugs like erythromycin and its derivatives during the shelf life of a reconstituted suspension[3].

TASTE MASKING TECHNOLOGIES:

1. Taste masking by granulation

Granulation is a less expensive, rapid operation and an easily scalable taste masking technology. This step can be exploited as a mean for taste masking of slightly bitter tasting drug. Granulation lowers the effective surface area of the bitter substance that come in contact with the tongue upon oral intake. Liquid and low melting point waxes such as glycerol palmitostearate, glyceryl behenate and hydrogenated castor oil are commonly used

ingredients during the granulation to achieve taste masking[1, 3].

2. Ion Exchange Resins

Ion exchange resins (IER) have received considerable attention from pharmaceutical scientists because of their versatile properties as drug delivery vehicles. In past few years, IER have been extensively studied in the development of Novel drug delivery system and other biomedical applications. Several ion exchange resin products for oral and peroral administration have been developed for immediate release and sustained release purposes. Bitter tasting drugs can be absorbed onto ion exchange resins, thus effectively removing them from solution during the transit through the mouth, at salivary pH 6.8, remains in intact form making the drug unavailable for the taste sensation. Various studies have revealed that ion exchange resins are equally suitable for drug delivery technology. Some ion exchange resins used widely for taste masking purpose in industries are Amberlite IRP64, Amberlite IRP69, Indion 204, Indion 214, Kyron T-114 and Kyron T-104[1, 10].

3. Sweeteners

Sweeteners are commonly used in combination with other taste masking technologies. They can be mixed with bitter taste medicaments to improve the taste of the core material which is prepared for further coating or may be added to the coating liquid. Taste masked lamivudine (antiretroviral drug) was prepared by using lemon, orange and coffee flavors. Synthetic sweeteners such as sucralose are commonly used in most taste masked products. Newer sweeteners derived from plant parts have been evaluated for taste masking efficiency. For example, stevia was used to prepare the taste masked ibuprofen. Sweeteners have been commonly used for the taste masking of pharmaceuticals. Artificial sweeteners such as sucralose, aspartame and saccharin have been used in combination with sugar alcohols such as lactitol, maltitol and sorbitol to decrease the after-taste perception of artificial sweeteners. Sucralose can be used with physiologically acceptable acids (e.g. citric acid) to increase the taste masking efficiency of the sweetener. Recently, sweeteners of plant sources such as stevia and glycyrrhizin have emerged as a viable alternative to the artificial sweeteners. Glycyrrhizin is extracted from glycyrrhiza root and is 50-60 times sweeter than sucrose. Stevia is obtained from 'honey leaf', which originated in Brazil and Paraguay. Non sucrose component of sugar beet extract was used as an edible flavor improving agent[3].

4. Taste masking by Microencapsulation

Microencapsulation is a process by which very tiny droplets or particles of liquid or solid material are surrounded or coated with a film or polymeric material. Coating is an extremely useful technique for a number of applications in pharmaceutical field. Although it is used primarily for production of sustained release, Gastro-intestinal dosage forms, it also has major applications in masking the unpleasant taste. It is important to understand that only soluble portion of the drug can generate the sensation of taste. Coating the active drug with a properly selected polymer film can reduce its solubility in saliva and thus taste could be masked. Coating the drug particles created a physical barrier between the drug and the taste buds and taste of active could be masked. The goal of Microencapsulation may be accomplished by any of the following techniques.

a. Air suspension coating
b. Coacervation - phase separation
c. Spray drying and spray congealing
d. Solvent evaporation
e. Multiorifice - centrifugal process
f. Pan coating
g. Interfacial polymerization

Polymers used for coating in Microencapsulation:

Coating is an extremely useful technique for number of applications in the pharmaceutical field. It is classified based on the type of coating material, coating solvent system, and the number of coating layers. By coordinating the right type of coating material it is possible to completely mask the taste of a bitter drug, while at the same time, not adversely affecting the intended drug release profile. Polymers have been exclusively used as coating materials, either alone or in combination, as a single or multi-layer coat, in the taste masking of bitter medicaments. Combinations of pH independent water insoluble polymers such as cellulose ethers, cellulose ester, polyvinyl acetate and water soluble polymers such as cellulose acetate butyrate, polyvinylpyrollidone, hydroxyethyl cellulose have been used to attain a balance between the taste masking and in vitro release. Hydrophobic polymers have been popularly used for coating bitter medicaments to achieve taste masking. These coating agents simply provide a physical barrier over the drug particles.However, hydrophilic polymers may also providetaste masking of Ibuprofen, by coating with hydrophilic polymers such as hydroxyethyl cellulose or a mixture of hydroxyethyl cellulose and hydroxypropyl methylcellulose. Sweeteners can be included in the coating solution for a better taste masking performance. One of the most efficient methods of drug particle coating is the fluidized bed processor. In this approach powder as fine as 50ìm, are fluidized in expansion chamber by means of heated, high velocity air and the drug particles are coated with a coating solution introduced usually from the top as

spray through nozzle. The coated granules are dried with warm air[1, 11].

5. Taste masking by formulation of inclusion complexes

Inclusion complexation is a process in which the guest molecule is included in the cavity of a host or complexing agent. The complexing agent is capable of masking bitter taste of drug by either decreasing its oral solubility on ingestion or decreasing the amount of drug particles exposed to taste buds. Cyclodextrin is most widely used complexing agent for inclusion type complexes. It is sweet, non toxic, cyclic oligosaccharide obtained from starch. The following are the examples of drugs that the bitter taste can be suppressed by making inclusion complexes[12].

6. Taste masking by adsorption

Adsorbents are commonly used in taste masking technologies. Adsorbate of bitter tasting drug can be considered as the less saliva soluble versions of these drugs. Adsorption involves preparing a solution of the drug and mixing it with an insoluble powder that will absorb the drug, removing the solvent, drying the resultant powder, and then using these dried adsorbates in the preparation of the final dosage form. Many substrates like veegum, bentonite, silica gel and silicates can be used for the reparation of adsorbate of bitter drugs.The bitter taste of ranitidine is masked by forming an adsorbate with a synthetic cation exchange resin[13, 14].

7. Taste masking by Prodrug approach

Chemical modification, including prodrug design is an effective method for reducing solubility, and thereby improving taste. A prodrug is chemically modified inert drug precursor which upon biotransformation liberates the pharmaceutically active parent compound. Bitterness of a molecule may be due to the efficiency of the taste receptor substrate adsorption reaction, which is related to the molecular geometry of the substrate. If alteration of the parent molecule occurs by derivative formation, the geometry is altered, affecting the adsorption constant. Thus the magnitude of a bitter taste response or taste receptor-substrate adsorption constant may be modified by changing the molecular configuration of the parent molecule. The extremely bitter antibiotics have been the focus of much work in reversible drug modification[15].

8. Taste masking by gelation

Water insoluble gelation on the surface of tablet containing bitter drug can be used for taste masking. Sodium alginate has the ability to cause water insoluble gelation in presence of bivalent metal ions. Tablet of amiprolose hydrochloride have been taste masked by applying an undercoat of sodium alginate and overcoat of calcium gluconate. In presence of saliva, sodium alginate reacts with bivalent calcium and form water insoluble gel and thus taste masking achieved[1].

9. Solid dispersion system

Solid dispersion has been defined as dispersion of one or more active ingredients in an inert carrier or matrix at solid state prepared by melting (fusion) solvent or melting solvent method. Recently solid dispersions were introduced as a taste masking technology. Tsau and Damani (1994) disclosed a drug-polymer matrix composition to achieve the taste masking of dimenhydrinate. Amine or amido group of dimenhydrinate can have a physical and chemical interaction with the carboxylic acid and esters groups of copolymers such as shellac, zein and cellulose acetate phthalate hydrophobic polymers and long chain fatty acids have been used to achieve the taste masking by solid dispersion. This approach usually requires a higher concentration of excipients compared to other taste masking techniques. Natural polymers such as shellac and zein, and enteric polymers like derivatives of acrylic acid polymers and phthalate are good choices to develop the taste masked solid dispersions[1, 15].

10. Development of Liposome

Another way of masking the unpleasant taste of therapeutic agent is to entrap them into liposome. For example, incorporating into a liposomal formulation prepared with egg phosphatidyl choline masked the bitter taste of chloroquine phosphate in HEPES (N-2-hydroxyetylpiperzine-N'- 2- ethane sulfonic acid) buffer at pH 7.2[16].

11. Multiple Emulsions

A novel technique for taste masking of drugs employing multiple emulsions has been prepared by dissolving drug in the inner aqueous phase of w/o/w emulsion under conditions of good shelf stability. The formulation is designed to release the drug through the oil phase in the presence of gastrointestinal fluid[17].

12. pH Modifiers

Many natural and synthetic polymers, resins and waxes alone or in combination have been employed for taste masking. The enteric polymers like eudragit L are used for taste masking but the pH of saliva is near 5.8 and these polymers solubilize at pH beyond 5.5 so there is a possibility of drug being partially leached. Therefore there is a need for the development of taste masking polymer such that the bitter taste is completely masked by the polymer at the pH of saliva in mouth and in the reconstitution medium as in case of the liquid orals and further which is able to protect the drug in a biologically active form, from the moisture in the dosage form and releasing the drug rapidly in the stomach without affecting its absorption and bioavailability[18].

13. Use of amino acids

Amino acids and their salts (alanine, taurine, glutamic acid, glycine) in combination with bitter drugs reduces the bitterness of the drugs for example, taste of ampicillin improved markedly by preparing its granules with glycine and mixing them with additional quantity of glycine, sweeteners, flavors and finally compressing them into tablets[19].

14. Miscellaneous taste masking approaches:

A. Rheological modification

Increasing the viscosity with rheological modifier such as gums or carbohydrates can lower the diffusion of bitter substances from the saliva to the taste buds. Acetaminophen suspension can be formulated with xanthan gum (0.1-0.2%) and microcrystalline cellulose (0.6-1%) to reduce bitter taste. The antidepressant drug mirtazapine is formulated as an aqueous suspension using methonine (stabilizer) and maltitol (thickening agent). Maltitol is stable in the acidic pH range of 2 to 3 and besides masking the unpleasant taste of the drug, it also inhibit its undesirable local anesthetic effect .

B. By effervescent agents

Effervescent agents have been shown to be useful and advantageous for oral administration of drugs and have been employed for use as taste masking agents for dosage forms that are not dissolved in water prior to administration. A chewing gum composition of bitter medicament was formulated to supply the medicament to oral cavity for local application or for buccal absorption. It comprise a chewing base, an orally administrable medicament, a taste masking generator of carbon dioxide, and optionally a taste bud desensitizing composition (e.g., oral anesthetic such as benzocaine) and other non active material such as sweeteners, flavoring components, and fillers. Recently, effervescent tablets of fentanyl and prochlorperazine were developed to supply these drugs to the oral cavity for buccal, sublingual, and gingival absorption. The formulation contains the drug in combination with effervescent agent to promote their absorption in the oral cavity and to mask their bitter taste. An additional pH adjusting substance was also included in fentanyl formulation for further promotion for absorption.

C. Continuous multipurpose melt (CMT) Technology

The CMT method was developed for the continuous granulation and coating of pharmacologically active substances. It was concluded that this method could be successfully applied for taste masking of bitter drugs[19-21].

EVALUATION:

Evaluation of taste masking is tedious work as the taste sensation varies person to person and involves taste masking efficiency as quality control parameter and determining the rate of release of drug from taste-masked complex and asses by *in vivo* and *in vitro*.

***In vivo* Evaluation**

In vivo taste evaluation carried out on a trained taste panel of healthy volunteers with organoleptic sense, with their prior consent. On placing the dosage form in mouth for 60 seconds, bitterness recorded against pure drug using a numerical scale. The numerical scale may bears values as 0 = pleasant, 1 = Tasteless, 2 = No bitter but after taste give bitterness, 3= immediately gives bitterness, 4 = slightly bitter, 5 = extremely bitter.

In vivo assessment usually demands large panels and elaborates analysis, raises safety and scheduling issues and can be time consuming and expensive[22, 23].

***In vitro* Evaluation**

Invention of "E-Tongue" electronic sensor array technology overcomes this problem, which is a device for recognition, quantitative multicomponent analysis and artificial assessment of taste and flavor. It recognizes three levels of biological taste including receptor level (Taste buds in humans, probe membranes in E-Tongue), circuit level (neural transmission in humans, transducer in E-Tongue), and perceptual level (cognition in the thalamus humans, computer and statistical analysis in the ETongue). The probes consist of a silicon transistor with proprietary organic coatings, which govern the probe's sensitivity and selectivity, and measurement done potentiometrically. Each probe is cross selective to allow coverage of full taste profile and statistical software interprets the sensor data into taste patterns. Liquid samples directly analyzed without any preparation, whereas solids require a preliminary dissolution before measurement. Reference electrode and sensors are dipped in a beaker containing a test solution for 120 seconds (fig. 2). A potentiometric difference between each sensor and a reference electrode measured and analyzed by the E-Tongue software. Sensory analysis employs to measure and control taste and flavor quality during manufacturing process development, clinical use, stability studies, validation, commercial manufacturing and batch release[22, 23] (table 1).

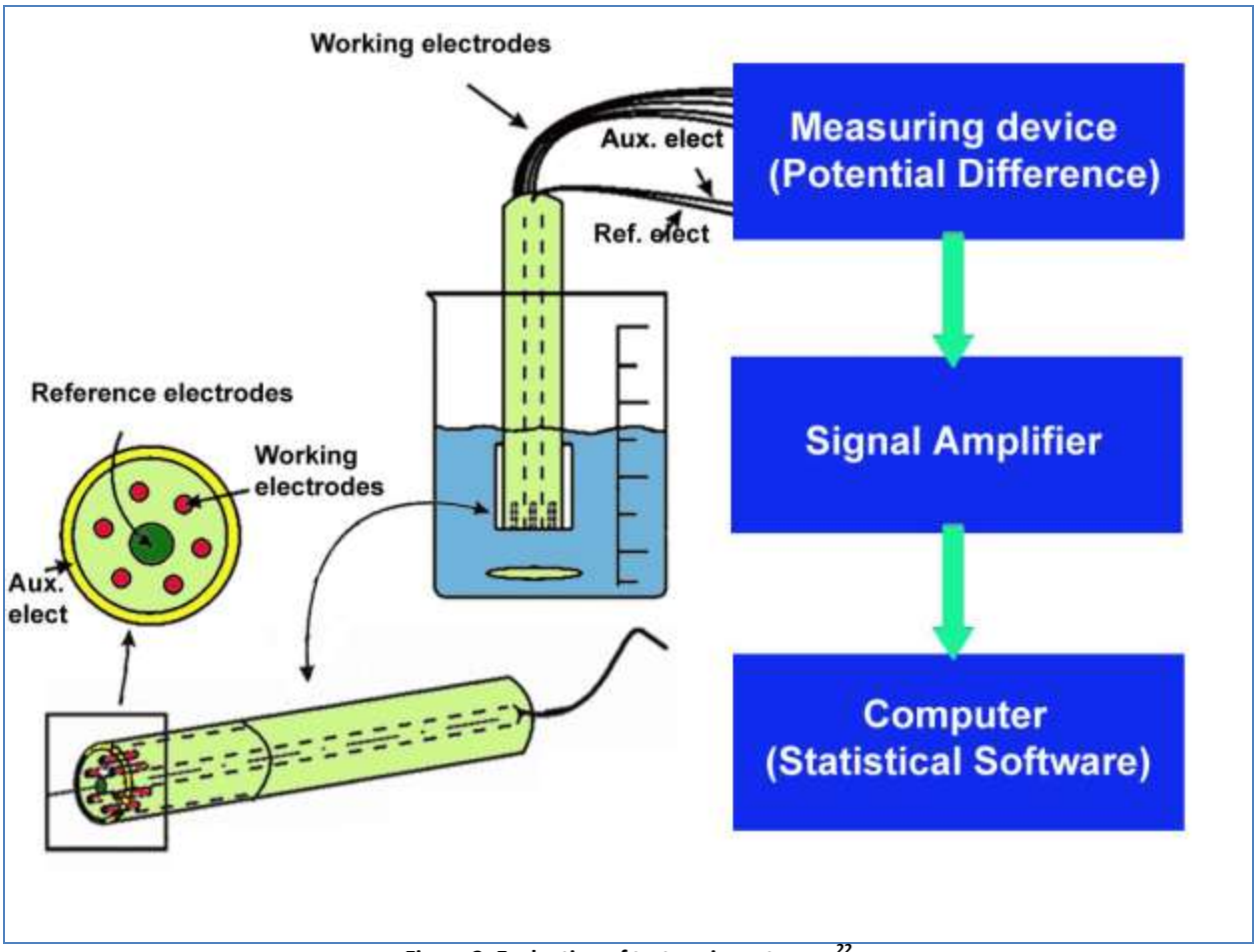

Figure 2: Evaluation of taste using e-tongue[22]

These data represent the input for mathematical treatment that will deliver results. The E-Tongue enables us to test taste accurately without the need for human volunteers at earlier stages of drug development. Furthermore, the E-Tongue cannot be poisoned and it won't fatigue or lose its sense of taste after long periods of testing.

Table 1: Sensory analysis using e-tongue[22]

Methods	Types	Description
Affective tests	Paired preferences	Measures the response of product with paired reference
	Acceptance	Measures the degree ranging from "like extremely" to "dislike extremely"
	Specificity	Determines the appropriateness of a specific attribute
Descriptive methods	Flavour profile	Objective description of product (characteristics and intensities)
Discrimination	Difference	Differentiates between samples for specific characteristic
	Ranking test	Rank for specific characteristic
Scaling tests	Scoring	collect information on specific product attributes

CONCLUSION:

Now a day's most of the potent drugs that may be cardiac, analgesics, anti inflammatory, anti tubercular, anthalmentics, antibacterial, anticoagulants, anti epileptics, antimalarials, anti neoplastics, anti thyroids, antiprotozoal, diuretics, histamine receptor antagonists, nutritional agents, opioids analgesics, oral vaccines and sex hormones, most of them are bitter in taste. So it becomes necessary to develop such a dosage for that must be acceptable in taste to patient especially in case of children or geriatrics. Taste masked drug delivery research is gaining importance and commercial success for the quality of treatment

provided to suffering patients, especially children. As evidenced by the number of patents and technological developments we made an attempt that an ideal taste masking is widely accepted in the development of more palatable and acceptable dosage forms which not only lead to better patient compliance but with an ultimate clinical output.

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