UNIVERSITI PUTRA MALAYSIA

CHARACTERISATION AND DISSOLUTION KINETICS OF TAMARIND AND PINEAPPLE TABLETS

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CHARACTERISATION AND DISSOLUTION KINETICS OF TAMARIND AND PINEAPPLE TABLETS

By

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Thesis Submitted to the School of Graduate Studies, Universiti Putra Malaysia, in Fulfilment of the Requirements for the Degree of Master of Science

July 2015

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Chairman : Yus Aniza Yusof, PhD
Faculty : Engineering

Fruits in fresh form have limited shelf life and often face difficulty during handling and preparation therefore tabletting is one of the best alternative for the fruit juice. This research done due to the lack of research in the area of tamarind and pineapple tablet characterisation and dissolution kinetics. Its dissolution properties are important as it depends on the process of tablets dissolve in distill water, simulated gastric juice of pH1.2 and simulated intestinal juice of pH 6.8 which has been used in this study. Both of the fruits went spray drying process. The powders were then compressed into tablets using a cylindrical uniaxial die. Pressures of up to 22.28 MPa were applied to the die via a universal testing machine. The nutritional value in terms of crude protein (0.33% - 0.60%), moisture content (4.8% - 25.31%), crude fiber (16.92% - 79.92%), and fat (0.40% - 0.63%) for both fruits pulp and powders showed significant differences in values with $p<0.05$. The vitamin C release was analyzed using 2,4-dinitrophenyl hydrazine (DNPH) method. In-vitro dissolution study of the fruit tablet were been analysed by four established release kinetics model equations. The best fit mathematical model for the tamarind and pineapple fruit tablets were determined based on the coefficient of correlation 'R2' values. A microbial stability test was done to calculate the colony forming units (CFU/g) of both tamarind and pineapple fruit powder tablets. The shelf life of pineapple tablet is 14 days and tamarind tablet is 21 days, which were in the acceptable value range of colonies for fruits as it were less than 10000 CFU/ml following the United States Food and Drug Administration (FDA). These findings indicate that it is important to compact fruit powder into tablet because fruit powder in tablet form is easy to dissolve and may provide an excellent alternative for healthy beverage consumption and a creative product development and as an approach to meet consumer's demand.

Abstrak tesis yang dikemukakan kepada Senat Universiti Putra Malaysia sebagai memenuhi keperluan untuk ijazah Master Sains

PEMBUANGAN PENCIRIAN DAN PELARUTAN KINETIK BAGI TABLET ASAM JAWA DAN NANAS

Oleh

TAUFIQ AMINULLAH BIN MOKHTAR

Julai 2015

Pengerusi : Yus Aniza Yusof, PhD
Fakulti : Kejuruteraan

Sisa agro Buah-buahan dalam bentuk segar mempunyai jangka hayat terhad dan sering menghadapi kesukaran semasa pengendalian dan penyediaan Oleh itu penukaran kepada tablet adalah satu alternatif terbaik untuk jus buah. Kajian ini dilakukan kerana kurangnya kajian dalam bidang pencirian asam jawa dan tablet nanas dan pelarutan kinetik.Ciri-ciri keterlarutannya adalah penting kerana ia bergantung kepada proses tablet larut dalam air suling, simulasi jus gastrik daripada pH1.2 dan jus usus simulasi pH 6.8 yang telah digunakan dalam kajian ini. Ciri-ciri fizikokimia dan pembubaran in-vitro daripada asam jawa dan nanas telah dikaji berdasarkan pulpa, serbuk dan tablet. Kedua-dua buah melalui semburan proses pengeringan. Serbuk kemudiannya dimampatkan ke dalam tablet menggunakan die ekapaksi silinder. Tekanan sehingga 22.28 MPa telah digunakan untuk die melalui mesin ujian universal. Nilai pemakanan dari segi protein mentah (0.33% - 0.60%), kandungan kelembapan (4.8% - 25.31%), serat mentah (16.92% - 79.92%) dan lemak (0.40% - 0.63%) bagi kedua-dua pulpa buah-buahan dan serbuk menunjukkan perbezaan yang ketara dalam nilai-nilai dengan $p < 0.05$. Pembebasan vitamin C dianalisis menggunakan kaedah 2,4-dinitrophenyl hidrazin (DNPH). Kajian pelarutan in-vitro tablet buah telah dianalisis oleh empat persamaan model kinetik. Model matematik terbaik bagi tablet asam jawa dan buah nanas ditentukan berdasarkan pekali korelasi nilai 'R2'. Ujian kestabilan mikrob yang telah dilakukan untuk mengira unit koloni yang terbentuk (CFU / g) bagi kedua-dua tablet asam jawa dan nanas. Hasil kajian menunjukkan bahawa jangka hayat untuk tablet nanas ialah 14 hari dan tablet asam jawa ialah 21 hari berada dalam lingkungan nilai yang boleh diterima koloni untuk buah-buahan kerana ia adalah kurang daripada 10000 CFU/ml mengikut peraturan Pentadbiran Dadah dan Makanan (FDA). Oleh itu, penemuan ini menunjukkan bahawa ia adalah penting untuk serbuk buah dipadatkan kepada bentuk tablet kerana serbuk buah-buahan dalam bentuk tablet mudah larut dan memberikan alternatif yang sangat baik untuk kegunaan sebagai minuman yang sihat dan pembangunan produk yang kreatif dan sebagai satu pendekatan untuk memenuhi permintaan pengguna.

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I certify that a Thesis Examination Committee has met on 9th July 2015 to conduct the final examination of Taufiq Aminullah Bin Mokhtar on his thesis entitled "Characterisation and Dissolution Kinetics of Tamarind and Pineapple Tablets" in accordance with the Universities and University Colleges Act 1971 and the Constitution of the Universiti Putra Malaysia [P.U.(A) 106] 15 March 1998. The Committee recommends that the student be awarded the Master of Science.

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This thesis was submitted to the Senate of Universiti Putra Malaysia and has been accepted as fulfillment of the requirement for the degree of Master of Science. The members of the Supervisory Committee were as follows:

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LIST OF ABBREVIATIONS

AA	Ascorbic Acid
AOAC	Association of Analytical Chemists
CI	Carr Index
DHI	Dehydroascorbic Acid
DI	Deionized Water
DE	Dextrose Equivalent
FAO	Food and Agricultural Organization
HI	Hausner's Ratio
ISO	International Organization for Standardization
MARDI	Malaysian Agricultural Research Development Institute
MAEPS	Malaysian Agro Exposition Park Serdang
PCA	Plate Count Agar
SEM	Scanning Electron Microscope
TKP	Tamarind Kernel Powder
USP	United States Pharmacopeia

NOMENCLATURES

ρb	bulk density
g	gram
kg	kilogram
%	percentage
h	hours
min	minutes
ml	milliliter
N	normality
%	percentage
MPa	Mega Pascal
rpm	rotations per minute
m	mass
v	volume
p	probability
°C	celcius
MJ	Megajoules
mmol	milimol

CHAPTER 1

INTRODUCTION

1.1 Research Background

This chapter gives a detailed introduction of an overall view of this thesis. An overview of tamarind and pineapple fruits, an in-vitro dissolution kinetics study and microbial stability were included in this chapter. The problem statement, scope of study, objectives and organisation of the thesis were also presented.

Tamarind (Tamarindus indica. L) is a multi-use tropical tree grown mostly for its fruits. According to Lewis (2005), tamarind is the third largest family of flowering plants with a total of 727 recognised genera and the number of species is estimated at 19,327. The species has been cultivated in numerous regions and also has a wide geographical distribution in the subtropics and semi arid tropics. Tamarind belongs to the dicotyledonous family Leguminosae. Tamarind fruits are usually used as a seasoning and spice and also can be eaten fresh or processed. The fruits and seeds can also be used as a non-food uses.

In Malaysia, tamarind is commonly grown in the Northern Peninsula where the sufficient sunlight and ecological conditions of the hot climate are suitable for tamarind planting. Tamarind powder is an interesting product because of its features such as flavour, texture and colour. The powder can be used as an ingredient for cooking or as a flavouring agent in some products.

While pineapple (Ananas comosus. L) is an important representative of the Bromeliaceae family and is cultivated in tropical and subtropical countries, including Malaysia, Hawaii, South Africa, Philippines and Thailand for local consumption as well as for export (Elss et al., 2005). Besides that, in The Third National Agriculture Policy, the pineapple has been distinguished as one of the main concerns to be produced for the local and global markets due to potential economic and commercial value of pineapple (Samah, 2004). There are several types of Malaysian pineapple varieties such as Gandol (N19), Moris, Sarawak, MD2, Maspine and Josapine.

Even though pineapple varieties are plentiful only some of the main sorts are sold economically as they are juicier and sweeter. The pineapple can be processed as juices and as a fixing in fascinating foods. It was also generally devoured as both fresh and canned foods, because of its alluring sweet flavour.

Both pineapple and tamarind can be employed as an element in cooking food or as a seasoning agent in some products. Its advantages consist of a long shelf life at ambient temperature due to the low water action, low logistic expenditure due to the low weight and volume, and ease of utilisation compared to squeezing juice from tamarind or pineapple flesh. In summation, this form of product development can help to reduce tamarind and pineapple losses caused by microbial, chemical and enzymatic reactions during the height of the cropping season (Weerachet et al., 2011).

In the pharmaceutical industry, dissolution analyses have emerged as one of the fundamental quality tests (Cohen et al., 1990; Banakar et al., 1994; Bressman et al., 2000). As a reflect to the bioavailability and bioequivalence of the drug, eachpharmaceutical tablet batch is tested for its dissolution properties (Banakar et al., 1994; Bressman et al., 2000; Aulton., 1998). The United States Pharmacopoeia (USP) Convention has developed a compendium concerning dissolution standards and policies regarding the bioavailability and bioequivalence of the tablets produced (USA, Pharmacopeia, 2000).

There are conceivable dangers identified with the particular gastrointestinal environment, dose dumping, food consequences for bioavailability, associated with different drugs and evaluation of the best tablet formulation(Sungthongjeen et al., 1999). Besides that,current dissolution studies are the most habitually utilized process as a part of the advancement, characterisation and techniques of controlled release formulations (Longer et al., 1990). Dissolution testing is a new component in food tableting development and manufacturing, especially for natural fruit tablets. The design of new formulations of fruit tablets is seldom guided and assessed based on in-vitro dissolution rates by means of the United States Pharmaceutical (USP) apparatus method (Jennifer et al., 2005). In freeing a drug from the tablet network and checking whether it is accessible for consequent gastrointestinal retention, the in-vitro dissolution procedure was required.

The contamination of a food powder with unwanted bio-life patterns and chemical components is one of the major concerns that could have a substantial impact on animal and human health. A high profile case due to the effect of a contaminated products can creates a significant damage to an individual organization or even entire industry sector. As a result, a lot of work has been undertaken to prevent contamination. Constant monitoring and rigorous implementation of current good manufacturing practices (cGMP) in many of the methods and processes available is key in successful elimination of risks of contamination. A documentation regarding the hygienic design of food equipment, including those dealing with dry particulate solids has been produced by the European Union Hygienic Engineering Design Group (EHEDG) (Hausner et al., 2002). A suitable environment for microbial growth was provided when tablets have high moisture content is still a problem due to the dust development prompting powder settling on the instrument. This situation need to be handle and solved by food engineers seriously.

1.1 Problem Statement

Nowadays, the fast economic development has changed the trend of food consumption from calories assurance to diet nutrient enrichment. The importance of vitamins intake from fresh fruits was one of the consumer awareness today. The global market demand towards the fresh fruits has increased due to this scenario. The fresh fruits are preserved using different techniques, in order to cater the market demand throughout the year. However, fruits in fresh form have limited shelf life and often face difficulty during handling and preparation. The fresh fruit cannot be kept for longer time as it will produce bad smell or possesses a rancid cheese flavour and odour due to its carboxylic acid content (Fugh-Berman, 2003; Duke et al., 2002). The quality loss in fresh foods is increased because of the enzyme activity and microbial growth. This is due to high moisture content in the fruit leads to high water activity (Phisut, 2012). As a new alternative form, the fruit is preserved in powder form and undergoing a tableting process to counter the problems associated with post-processing, handling, packaging and storage. The essential of fruit powder compaction into a tablet form will serves as an excellent alternative to the problematic fruit juice. Furthermore, in the pharmaceutical industry tablets are currently the most famous dosage forms, representing practically 70 % of all moral pharmaceutical arrangements that has been created (Rubeinstict, 2000).

To date, there have been a number of studies about the drying of fruit juices. Some researchers claimed that drying of fruit juice could produce a fruit powder that rapidly reconstituted to a fine product resembling the original juice (Gabas et al., 2007). Nevertheless, there are some difficulties in drying the fruit juice with high sugar content due to their thermoplasticity and hygroscopicity at high temperatures and humidity levels causing their packaging and utilization in trouble (Bhandari et al., 1997; Adhikariet al., 2004; Cano-Chaucaet al., 2005). These characteristics are attributed to low molecular weight sugars such as fructose, glucose and sucrose and organic acids such as citric, malic and tartaric that are the major components in fruit juices (Bhandari et al., 1997; Cheuyglintase and Morison, 2009). The high hydroscopy, low melting point, and high water solubility of these solids lead to a highly sticky or rubbery product when dried (Adhikariet al., 2003; Cheuyglintase and Morison 2009). Additionally, Roos and Karel (1991) stated that these materials are very hygroscopic in amorphous state and loose free flowing character at high moisture content.

The thermoplasticity and hygroscopicity troubles occurring in drying the fruit juice with high sugar content can be overcome by adding some drying carriers such as maltodextrin (MD) (Gabaset al., 2007). According to Cano-Chaucaet al. (2005) and Langrishet al. (2007), MD is the most popular in spray drying method due to its physical propertiessuch as high water solubility. Gabas et al. (2007) described that MD consists of β-D-glucose units linked mainly by glycosidic bonds and are typically classified by their dextrose equivalent (DE). Bhandari et al. (1993) and Silva et al. (2006) pointed out that MD could improve the stability of fruit powder with high sugar content because it reduced the stickiness and agglomeration problems during storage. Due to the lack of research in the area of tamarind and pineapple tablet production; this study was carried out with several objectives.

In pharmaceutical industry, most tablets can be considered as porous, heterogeneous solids, which, when ingested, release the active ingredients from their excipient matrices as a function of both their structure and the properties of the surrounding environment. It is this process of dissolution which product designers often strive to control, whether this means releasing all drug content as quickly as possible or in a controlled manner. In response to this need, understanding of how solid dosage forms will behave and isolate the governing mechanisms is necessary, therefore these ideas were applied for natural fruit powder tablets. Moreover, multiple modelling methodologies related to dissolution have been developed and researched over the years (Lobo and Costa, 2001).

Consequently, in-vitro dissolution investigation of the pharmaceutical dose structure has developed as an essential parameter that guarantees quality of product and additionally for separating among formulations of the same therapeutic operators (Ayres et al., 1984). The characteristics of the active ingredient release by the natural fruit tablet dosage forms are very new to the pharmacopoeiatest strategies under higher standard conditions. Therefore, these methods need to be established in the food industry as it can be broadly used as implementation for quality control and for the dosage forms optimisation (Grzegorz et al., 2009). While there are many physiological factors specific to the patient ingesting the dosage form, pharmaceutical manufacturers have no control over the unique biological processes of a specific patient. What can and should be controlled by the manufacturer are the formulation and processing conditions of the tablet which influence its in-vitro dissolution performance.

The understanding of relationship of dietary intake and human health is very important to determine the accurate and specific nutrient contents of the fruits. The vitamin C exists in a broad variety of food. Fruits, organ meats and vegetables are normally the best sources of the ascorbic acid (Combs, 1992). A reasonable understanding of their nourishing esteem and in addition the vitamin C estimation is vital for better use of vegetables and fruits as a human sustenance.

For the microbial stability, the dry tablets could possibly undergo microbial spoilage or degradation. This is a serious problem when there are no obvious signs of the spoilage as a result of the microbial contamination. Therefore, it is advisable to develop a knowledge of the microbial content of the tablets whether they require to be sterile or non-sterile (Parker, 2000).

1.3 Objectives

The objectives of this study are:

i. To characterise the physical and chemical properties and microbial stability of tamarind and pineapple pulps, powders and tablets.

ii. To investigate the in-vitro dissolution of tamarind and pineapple powder and tablets.

iii. To determine the dissolution kinetics of tamarind and pineapple powder and tablets.

1.4 Organisation of Thesis

There are five chapters in this thesis. The first chapter provides an outline of the overall research project, including the research background, such as the introduction to tamarind and pineapple fruits, in-vitro kinetic release studies and some empirical modelling. The problem statement is given after reviewing the current scenario of the natural fruit tablet process in the food industry compared with the established pharmaceutical standard procedure. The problem statement reveals that there is some drawback of having fruits in the fresh natural form as well as lack of guidance in assessing the qualities of natural fruit tablets. The main objectives of this research project are then carefully formulated in the case of fruit tablet development.

Chapter two consists of an in depth review of the current researches in this field. It includes the drying process of the fruits, the uniaxial compaction method for the fruit tabletting, the nutritional content determination using proximate analysis and dissolution kinetic studies through an in-vitro process. Specific empirical modelling and the microbial stability of fruit powder storage are described in this chapter.

Chapter three shows the methodology of the experimental works. This chapter gives detailed information about the overall flow and works in conducting this research. All the chemical, laboratory instruments and apparatus used are also reported.

Chapter four illustrates all the data and results of the experiments in tables and graphs. The explanation of every result is discussed in a detailed manner. The data has been arranged to include the standard deviation calculated from the mean data from triplicate measurements. The SPSS software and Microsoft Excel 2007 are used as analytical tools.

The last chapter of this thesis, which is chapter 5 gives an outline of the results got in this examination. This chapter additionally finishes up the general exploration extend and gives suggestions for future studies which identify with this research work.

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