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Evaluation of *Parkia biglobosa* (Jacq.) trunk's bark extracts syrup formulation

Traoré Sidiki, Ouédraogo Salfo, Yoda Jules, Traoré Tata Kadiatou, Traoré Aristide, Lompo Marius, Kini Felix, Ouédraogo Sylvin and Semdé Rasmané

Abstract
Two kinds of syrups based of *Parkia biglobosa* trunk's barks of were prepared and evaluated. One was a dry syrup, prepared by using Tween 80 as a wetting agent, and the other was a suspending syrup. The Physicochemical Analysis, microbiological and Storage Stability from syrups were studied, and both syrups showed the. The syrups had good appearance without deposit, sweet taste with a bitter aftertaste, a dark red color and a faint odor. The chemical composition of the suspending syrups after 3 months years of storage under the conditions studied was always similar and therefore homogeneous composition. These analyses showed insignificant physicochemical alteration of syrups in the storage conditions used. Assessments of bacterial contamination of syrups showed absence of Salmonella and coliforms. These results are in line with the recommendations of the European Pharmacopoeia 6.0 for oral preparations containing naturally occurring raw materials. There is no incompatibility between the selected excipients, extracts and the packaging materials. The trunk's barks extracts of *Parkia biglobosa* has the potential for making stable pharmaceutical syrup.

Keywords: *Parkia biglobosa*, trunk bark, extracts, syrups, pharmaceutical, stable

Introduction
The use of medicinal plants for therapeutic purposes is a very important issue for the African continent, which fortunately is full of natural resources. In fact, of the 300,000 plant species recorded worldwide, more than 200,000 live in the tropical countries of Africa and elsewhere, most of which have medicinal properties [1]. Among the most valued species, we can mention the *Parkia biglobosa* (Jacq.) Benth. (Mimosaceae) all parts of which are used for therapeutic or nutritional purposes. Indeed, bark, leaves and roots are used in the preparation of many traditional recipes used for the treatment of infectious diseases: dental caries, diseases of the respiratory tract, urinary tract and digestive tract, skin diseases. These parts are also used for the treatment of high blood pressure and hemorrhoids to name just a few [1-5]. The tree is known to provide ingredient that is used in treating leprosy and hypertension [6]. In Gambia, the leaves and roots are used in preparing lotion for sore eyes and decoction of the bark is used for fever, hot mouth wash and toothache relief [7]. The stem bark is employed in wound healing while the wood is used for anoes and planking. The pulp has been identified as untapped forest resource that deserves attention. The pulp is used in the local environments as substitute for sugar because of its high sugar content**(7)**. Through an ethnobotanical study of *Parkia biglobosa* (Jacq.) Benth. in West Africa, Ouédraogo (1995) [8] has concluded that *Parkia biglobosa* is a social tree which is considered as the tree of the fields par excellence, because of the multiple functions it fulfills for the benefit of local populations. In several African countries, *Parkia biglobosa* is considered as an improving plant and indicator of soil fertility and therefore protected during crop clearing; in fact, in the presence of *Parkia biglobosa*, the chemical richness of the soil is practically double for most mineral elements, and herbaceous plants have a better development under its cover [9, 10]. Much research has been conducted on the nutrional values of the fruit (pulp and seed) of *Parkia biglobosa* (Jacq.) Benth, on fermenting seeds bacteria for the production of soumbala [11-15]. Previous studies have shown that the hydroalcoholic extract and the decoction of trunk bark were effective on Escherichia coli, Staphylococcus aureus, Salmonella typhi, Salmonella paratyphi B and Salmonella paratyphi, Shigella flexneri, Shigella boydii, Klebsiella pneumoniae. The decoction and the hydroethanolic extract of bark also proved to be very active on Shigella dysenteriae **(16, 17)**. This constitutes an interesting potential from the point of view of the treatment.

These preliminary studies have opened perspectives for the development of prototypes of galenic forms of phytomedicines for a clinical assessment of therapeutic activity. However, scaling up prototype phytomedicines requires a stable dosage formulation to ensure quality monitoring parameters during manufacturing. This study aimed Evaluation of *Parkia biglobosa* trunk's bark syrup galenic formulation.

Materials and methods

The trunks's barks of *Parkia biglobosa* (Jack.) Benth. (Mimosaceae) were harvested in November 2015 in Ouagadougou (Burkina Faso). Its were dried dust-free and then crushed by a blade mill. The powders was macerated with éthanol for 24 hours and then lyophilized. The extracts were kept in the Pharmaceutical Production and Marketing Unit (U-PHARMA) of the Health Sciences Research Institute (IRSS) in Burkina Faso. All chemicals, excipients and reagents used in the study were purchased from a store in a local market in Ouagadougou, Burkina Faso, of brand (FARGON, Belgium; PROLAB, France; MERK, Germany) and were of good pharmaceutical quality.

Characterization of extracts

Macroscopic and organoleptic characteristics: The organoleptic characteristics (taste and smell) were determined by tasting and sniffing the powder. Determination of pH: The pH was determined by putting the pH-meter electrode (Eutech, Singapore) in 1% (w/v) aqueous solutions of each vegetable material (thrice).The test was performed in triplicate and the mean and standard deviation were calculated (m ± standard deviation, n = 3).

Residual moisture content: The residual moisture content of the powders was determined according to the thermogravimetric method of the European Pharmacopoeia 6th edition in an oven (Memmert, Germany). The assay was performed in triplicate on one (01) gram of powder. The mean and standard deviation were calculated (n = 3, mean, standard deviation).

Total ash content: Total ash levels were determined according to the European Pharmacopoeia 6th edition by calcining one (01) gram of each plant powder in a furnace (Bouvier, Belgium) at temperature of about 600°C. Total ash content was expressed as percentage.

Granulometry of powders: The granulometry was determined by the sieving method of the European Pharmacopoeia 6th edition [18].

Formulation development of syrups

The amount of ethanol at 70 ° was determined by adding to the lyophilized extracts, amounts of 2; 3; 4; 5; 6; 7; 8; 9; 10%. That of sodium benzoate was 0.1 to 0.3%, and for simple syrup the sufficient amount per 100 ml of preparation. Sucrose was used at 45%. Tween 80 (0.1, 0.2, 0.3%) as a wetting agent was added to that of the dry syrup. These formulation tests have made it possible to retain an optiamal formulation of the suspended syrups. Thus three (03) batches of 100mL of this syrup formulation were prepared and packaged in amber glass bottles type III, stored at a temperature of 25 ° C (+/- 2) in the laboratory for 6 months. These three lots were subject to quality control.

Evaluation and Physicochemical stability testing of formulated syrups

The syrups were checked from the dates of preparation. The controlled parameters were physical and organoleptic characteristics (color, odor, and flavor), pH, density and other parameters such as fermentation, the microbial quality control and fingerprint by thin layer chromatography (TLC). Fingerprint analyzes carried out by TLC of the syrups were carried out on a lot on the day of manufacture and 3 months later.

Density of a syrup is expressed by the ratio of its mass and volume. Ten (10) mL of syrup from each syrup vial was used to fill a previously weighed 10 mL volumetric flask and average mass was calculated. The difference between this weight and the empty weight of the volumetric flask allowed the average mass of syrup to be given. The mass of the syrup was related to the volume of the syrup, which made it possible to calculate the density.

The fermentation of the syrup is recognized by the formation and the proliferation of molds on the surface of the syrup. The observation was made with naked eyes. Stability studies: Stability was checked from the dates of preparation and were carried out with optimized formulation (F2) according to the International Conference on Harmonization (ICH) guidelines [19]. The samples were stored in closed molded Amber Glass Bottle Type III and kept for 3 month (Fig. 3). Its were removed and evaluated at intervals of 1, 10, 30, 50, 60, 60, 70 and 90 days.

Microbiological Analysis of formulated syrups

Microbiological quality: The microbial load assayed were total microbial flora, Salmonella and thermo-tolerant coliforms. Total microbial flora and Salmonella were determined by the method of the European Pharmacopoeia 6th edition. Thermo-tolerant coliforms were determined according to ISO 7218. Colony counts were performed for calculations of the number of colony forming units per gram (CFU / g).

Chemical Identification by Thin Layer Chromatography (TLC): TLC was performed to establish a fingerprint for the syrups prepared instantly and stored after 3 months. A test portion of 2 g of syrups was dissolved in 15 mL of water and then partitioned with (10 mL x 3) of n-hexane and n-butanol and then concentrated in an oven at a temperature of 40°C. for 24 hours. 50 µL of each fraction is deposited on a TLC plate for the development of the chromatogram. The chromatography was developed over an 8 cm course in the solvent system n-hexane – ethyl acetate - methanol 7: 2 : 1. The revelation was made under ultraviolet light at λ = 365 nm.

Results and discussion

Characterization of extracts

The macroscopic and organoleptic characteristics of trunks's barks extracts of *Parkia biglobosa* (Jack.) Benth. (Mimosaceae) were are dark red color (Fig. 1), with mild odor and a sour taste. The organoleptic and macroscopic characteristics found in the extract can be useful for the quality control and the identification of the raw material [20].

Fig 1: Freeze-dried extract of trunks's barks of *Parkia biglobosa*

The residual moisture content was 8.11 ± 0.06 meaning the extracts were adequately dry and could be kept for a long time without the development of mold or yeast [21].

The microbial quality control showed absence of and thermotolerant coliforms in sample extract. The absence of specific pathogenic germs such as Salmonella and the low presence microbial flora confirmed a good microbial quality of extracts [22]. This quality is in accordance with the recommendations of the European Pharmacopoeia 9th edition of natural raw materials administered by oral route.

Granulometry of extracts

The granulometry determined by method of the 6th edition of the European Pharmacopoeia showed results ad presented in the Fig. 2. The extracts obtained with the 1 mm to 0.1 mm sieves were used for the preparation of the syrups.

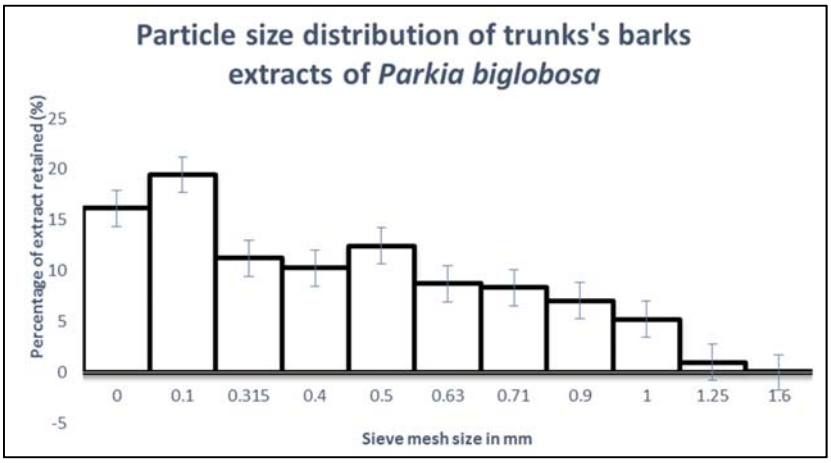

Fig 2: Particle size distribution of the extracts

Physicochemical Analysis and Storage Stability Studies

Characterization of syrups

Dry syrup powders were amorphous, brown color (Fig. 3), with a faint odor and a sweet taste. The batchs of suspending syrup packaged in an amber glass bottle was retained for the rest of the study because no bottle experienced any change in the characteristics of the powder under the preservation conditions tested. The syrups had good appearance without deposit, sweet taste with a bitter aftertaste, a dark red color and a faint odor. The density at the preparation was1.27± 0.012 and the pH was 5.3± 0.028.

Fig 3: Syrups stored in closed molded Amber Glass Bottle Type III and in Falcon® conical bottom tubes

Physicochemical stability testing of formulated syrups

Chemical Fringerprinting by Thin Layer Chromatography (TLC)

The Fingerprint analyzes by TLC of the syrups were carried out on a lot on the day of manufacture and then 3 months later.

The chromatographic fingerprints (Fig. 4) will serve as an identity for the quality control. According to data from the literature, results obtained by TLC can be used for routine analyzes of pharmaceutical [23]. The chromatographic profiles of syrups showed similar spots between the day of manufacture and 3 months later. This indicates that there is no incompatibility between the selected excipients and the active ingredient so as to destroy certain chemical groups. Indeed excipients must be inert in respect of the active ingredient, packaging materials and the human body [24].

Fig 4: Fingerprints of *n*-hexanic extracts of the syrups at the date of manufacture and 3 months later by TLC; Eluent: *n*-Hexane – ethyl acetate - méthanol 7:2:1 *Revelation under ultraviolet lamp at λ = 365 nm*

Stability Study

After three moths of storage, the syrups kept the same colors, the same tastes and were free of mold. The average pH of the syrups measured in distilled water at 25 °C was 4.76 ± 0.06. The density remained constant around 1, Its average value was 1,28±0,003. These analyses showed insignificant physicochemical alteration of syrups in the storage conditions used (Fig. 5 and Fig. 6).

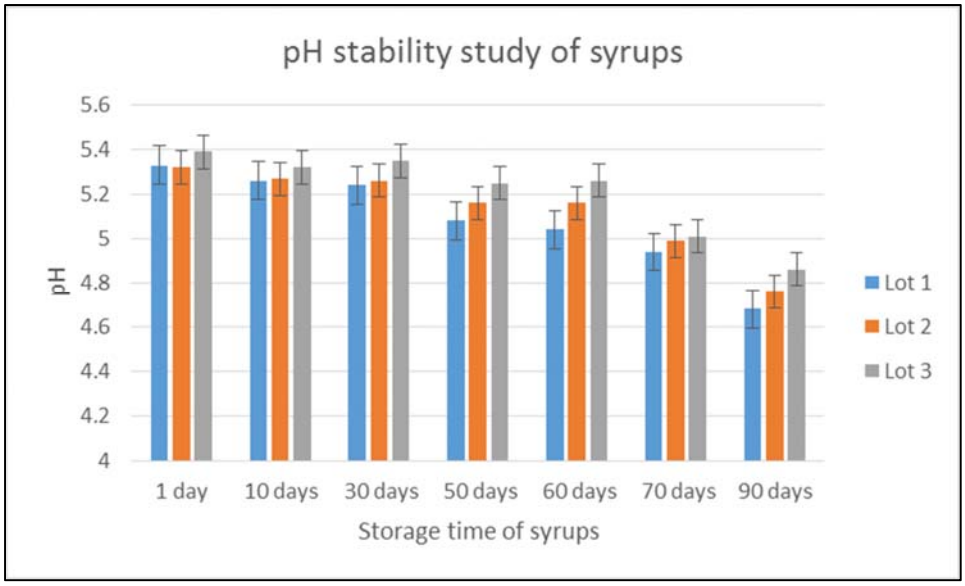

Fig 5: pH variation of syrups as a function of time

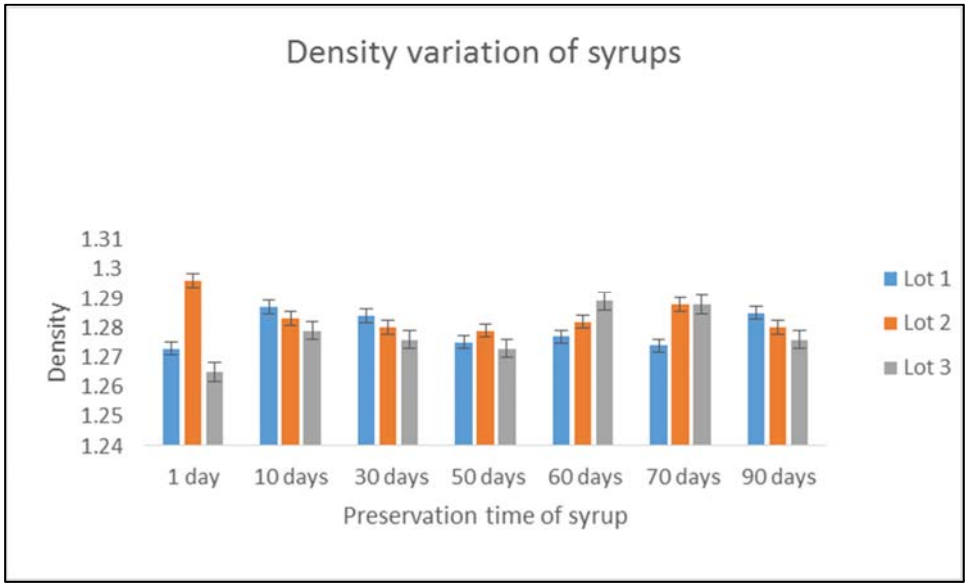

Fig 6: Density variation of syrups as a function of time

Assessments of bacterial contamination of syrups showed absence of Salmonella and coliforms. These results are in line with the recommendations of the European Pharmacopoeia 6.0 for oral preparations containing naturally occurring raw materials [18, 25]. This indicates that the syrups have maintained a good microbiological quality during the shelf life and under the conditions studied.

The chromatographic profiles show similar spots between the syrups at the date of manufacture and 3 months later (Fig. 4). This means that the chemical composition of the syrup after 3 months years of storage under the conditions studied was always similar and therefore homogeneous composition. The syrups could be stored for 3 months under the same conditions.

Conclusion

The formulation development of oral liquid solutions presents many technical problems to the industrial pharmacist. Based on the results of this study, it may be concluded that storage of freeze-dried extract syrups of trunks's barks of Parkia biglobosa in bottles Amber Glass Bottle Type III for 6 months did not adversely affect the microbiological and physicochemical properties of the syrups. Thus, it can be concluded that with the carefully designed experimentals tests, the formulated syrups were subjected to stability studies and they were found quite stable. The syrups were of good pharmaceutical quality and could be stored for 3 months under the conditions used during the clinical confirmation study in humans.

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