

A REVIEW ON FORMULATION AND EVALUATION OF BUCCAL TABLET FOR ANTI-ULCER AND ANTI- INFLAMMATORY ACTIVITY

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ABSTRACT:

The present study focuses on the formulation and evaluation of a herbal buccal tablet containing Hibiscus sabdariffa and Adenium obesum extracts for potential anti-ulcer activity. The buccal mucosa serves as a promising route for drug delivery, providing advantages such as avoidance of first-pass metabolism and rapid systemic absorption. Hibiscus sabdariffa possesses proven gastroprotective and antioxidant properties, while Adenium obesum is rich in secondary metabolites that exhibit potent biological activity. Both extracts were prepared by ethanol–water extraction and evaluated for physicochemical and biological properties. The buccal tablets were formulated using the direct compression method with excipients such as microcrystalline cellulose, mannitol, and magnesium stearate. The prepared tablets were assessed for weight variation, hardness, friability, surface pH, drug content uniformity, mucoadhesive strength, and in-vitro dissolution studies. Results indicated acceptable pharmaceutical parameters within standard limits, suggesting good mechanical strength, uniformity, and controlled drug release. This study demonstrates the feasibility of developing a stable herbal buccal tablet with potential anti-ulcer efficacy, offering a natural and patient-friendly alternative to conventional synthetic drugs.

KEYWORDS:

Gastric ulcer, Hibiscus sabdariffa calyx, hydroxyproline, nonsteroidal anti-inflammatory drug, Hibiscus subdariffa , Adenium obesum,

INTRODUCTION:

BUCCAL TABLET:-

The mouth's mucosa differs greatly from the rest of the gastrointestinal tract in terms of appearance more like skin. Despite being widely considered to have poor permeability, skin is not typically recognized that the intestinal permeability is superior to that of the oral mucosa. These variations

is mostly due to the arrangement of the epithelia in the gastrointestinal tract, which serve very distinct purposes. The stomach, small intestine, and colon are lined with a straightforward, single-layered epithelium, which ensures that absorbents have a short transport distance [1]. On the other hand, a multilayered or stratified epithelium covers the esophagus and oral cavity and, like skin, is made up of layers in different states of The transition from the basal cell layer to the surface shows differentiation or maturation. Medications have been used for many years in topical applications on the oral mucosa. Nonetheless, there has been interest lately.

in taking advantage of the oral cavity's ability to transport medications into the bloodstream. Despite the This route offers several benefits despite the epithelium's relatively poor permeability characteristics of management [2,3].

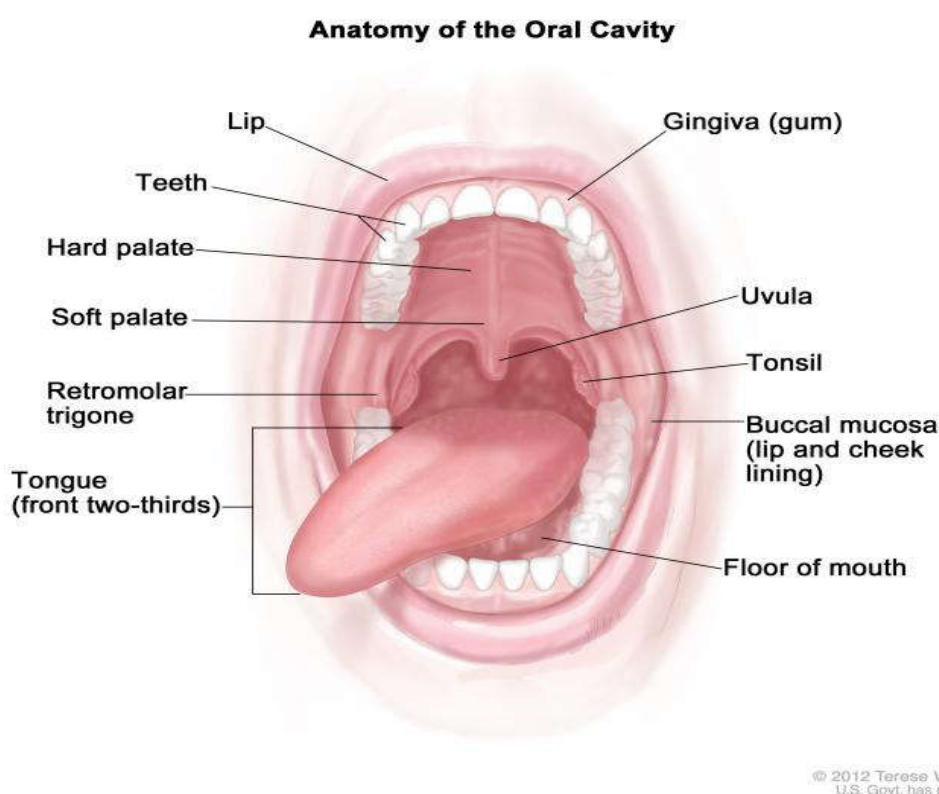


Fig.1- Different Anatomical region of Buccal Cavity

Hibiscus subdariffa:

Peptic ulcer disease (PUD) is the term for lesions caused by acid. of the digestive system, which usually occurs in the stomach, proximal duodenum, or lower esophagus, and is identified by the loss of mucosal tissue with the fibrin-covered defect that penetrates the submucosa or the muscle tissue. [4,5] PUD is one of the most common digestive disorders with a worldwide An annual incidence of 0.1% to 0.3% and a prevalence of 5–10%. [6] In the United States of America, PUD is responsible for the annual health care costs of approximately \$10 million [3], whereas Nigeria's potential national direct costs amount to about 186 billion. 958 million naira. [7] The primary cause of PUD is nonsteroidal anti-inflammatory drugs (NSAIDs), and *Helicobacter pylori* infection. [8,9] NSAIDs are a class of pharmaceuticals. utilized to alleviate the symptoms of fever, pain, and

inflammation. [10,11] They result in gastrointestinal harm due to their systemic and local impacts including inhibition of the cyclooxygenase enzyme in the Arachidonic acid metabolism, which results in reduced production of the prostaglandins I₂ and E₂, which are especially gastrointestinal cytoprotective. mucosa, and a lack of them may cause stomach damage to the mucosa. [10,12] Numerous antiulcer medications have been linked to numerous negative consequences and illness recurrence, increasing the demand for natural product searches possessing possible antiulcer qualities. [13, 14]



Fig.2- Anatomical structure of *Hibiscus Subdariffa*

Adenium Obesum:

Since the beginning of time, plants have been utilized as origin of the medication. Native to the area for thousands of years All across the world, people have utilized traditional herbal remedy for a variety of human infections illnesses [15]. Herbal remedies and natural products are a reliable source of novel medicinal substances and for the creation of alternative and complementary medications as opposed to conventional drug schedules [16]. In theThe past several years have seen an exponential advancement in the herbal medicine field, and

These herbal remedies are steadily gaining appeal in both developed and developing countries nations that are more powerful because of their natural origins in the management of medical issues and fewer adverse effects as like commercially available medications [17,18]. More than half of the The world's population relies on traditional medicine. Regarding medical care, over 80% of the less developed nations [19,20]. Many people use medicinal plants, including every sphere of

human civilization, either directly as medications with traditional significance or indirectly as formulation of pharmaceuticals in contemporary medicine [21].

There are between 10,000 and 53,000 plant species. employed in conventional medicine, and the utilization of plants in Medicine is a significant and pervasive cultural characteristic[22,23]. Utilizing different components of distinct Using medicinal plants to treat specific illnesses has been in style from antiquity. Numerous varied Plants that produce secondary metabolites are produced in reaction to stress as a measure but are not necessary for the plant's immediate survival. of defense against illnesses, microbes, or the surroundings [24]. A sizable portion of secondary Plant metabolites have substantial biological activities with a range of uses [25]. These Typically, medicinal plants are recognized for their significant variety of health advantages via the They contain a variety of phytochemicals [26,27]. Roem. & Schult., *Adenium obesum* (Forssk.), a Desert rose is a succulent plant that is commonly used. belongs to the family of dogbane. The native Apocynaceae from Africa, including Senegal, Ethiopia, and Kenya, Tanzania, Somalia, and Sudan, as well as Oman Yemen and Saudi Arabia as wild plants [28,29]. It is Among the well-liked decorative plants grown in numerous humid, tropical nations for many years, including Thailand, the Philippines, and India are highly relevant in the market for ornaments because of its extensive selection of flower color variation between cultivars, exquisite sculpture Caudex and drought stress tolerance [30,31].

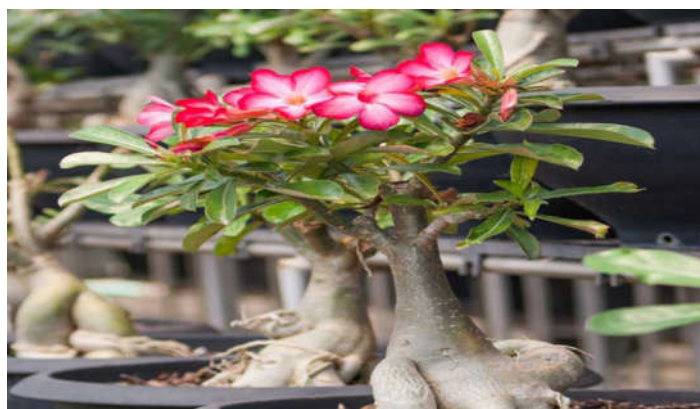


Fig no 3 :*Adenium obesum*

MATERIALS AND METHODS:

Hibiscus Subdariffa:-

Test Animals -Thirty male Wistar strain albino rats in all weighed. We acquired 170–230 g from an animal's home.

university in Nigeria. The rodents were kept on a standard farmer mash, a balanced rat feed, and had free water availability. They had become used to the conditions in the animal room for a minimum of two weeks prior to the start of the research. These creatures were maintained in typical rat cages using commercial wood Sawdust pellets for bedding in an animal with adequate ventilation spaces that are naturally lit. The protocol for the experiment used in this study was authorized by the ethics committee. committee within our organization.[32,33]

Plant Materials - Dried HS calyces were obtained from a local market and were identified as HS Linn at the department of ethnopharmacy and pharmacognosy, faculty of Our university's pharmaceutical sciences, using a sample stored at the botanical garden.

Plant material extraction -Particulate matter and other contaminants were initiallyharvested by hand from the calyces. The calyces were subsequently cleaned using tap water to get rid of dust and then allowed to dry at room temperature. The dehydrated calyceswere subsequently ground using a fine-powder a pestle and mortar. With a 2000 ml flask with a flat bottom 135 g of the powder was combined with a container.500 milliliters of purified water and left for a full day. and the mixture was filtered after being thoroughly stirred.utilizing Whatman filter paper. The resulting filtrate was then dried at 37°C in an oven dryer. This resulted in the AEHSC [34,35]

Adenium Obesum:-

Chemicals -

St. Louis, Missouri-based Sigma-Aldrich supplied the DPPH, methanol, and Standard ascorbic acid was purchased from Sai Scientifics in India.

Table no :

Parameter	Value
Instrumentation	Agilent GC 7890A / MS5975C
Column	Agilent DB5MS
Column length	30 m
Internal diameter	0.25 mm
Film thickness	0.25 μ m
Sample injection mode	Split mode
Carrier gas	Helium
Sample preparation	Extract dissolved in 100% ethanol
Compound identification	Retention time and fragmentation pattern matched with the NIST spectral library

Extraction -

First, the leaves of A. obesum were cleaned under running water and cut and crushed after being shed-dried for roughly six to seven days.

in a grinder separately. The powdered version is acquired and kept in storage.in tubes that are dry. The powdered samples were then placed in a Soxhlet device, extracted using 150 milliliters of 70% ethanol, and 30% water since the highest extraction yield was demonstrated. The resulting mixture was then filtered using a 40° evaporator C). The extract was then dehydrated under Telstar Cryodos and kept for additional examination at -20 °C. The resulting A. obesum (AOE) semi-solid ethanolic extract was kept at 4°C. The following formula was used to determine the extraction yield (%) [36,37] $\text{Extract yield \%} = \frac{\text{Weight of the extract after evaporating solvent and freeze drying}}{\text{Dry weight of the sample}} \times 100$.

PROCEDURE OF BACCAL TABLET:**Method of Preparation:-****Direct Compression Method****1. Preparation of Extracts:**

Dried calyces of *Hibiscus sabdariffa* and leaves of *Adenium obesum* are powdered.

Extract each using ethanol:water (70:30) by maceration for 48 hours. Filter, concentrate under reduced pressure, and dry the extracts.

2. Preformulation Studies:

Determine organoleptic properties, solubility, and compatibility with excipients (using FTIR if required).

3. Powder Blending:

Accurately weigh all ingredients.

Pass through sieve no. 60.

Mix the extract powders with MCC, Mannitol, HPMC, and NaCMC uniformly.

Add magnesium stearate and talc, mix gently.

4. Tablet Compression:

Compress the blended mixture using a single-punch tablet machine.

Weight of each tablet: ~250–500 mg.

Flat-faced 8 mm punch is generally used.

5. Drying and Storage:

Store the tablets in an airtight container to avoid moisture absorption.[38,39]

Evaluation Parameters:-**Test Method Specification:**

Weight variation 20 tablets weighed individually $\pm 5\%$

Thickness and diameter Vernier caliper, Uniform Hardness Monsanto hardness tester 3–5 kg/cm²

Friability Roche friabilator $\leq 1\%$ Surface pH Dissolve in buffer pH 6.8 6.5–7.2

Drug content uniformity UV spectrophotometry 95–105%

Mucoadhesive strength Using porcine buccal mucosa Satisfactory.

In-vitro dissolution USP Type II apparatus, pH 6.8 phosphate buffer $\geq 70\%$ in 6 hrs.[40,41]

FORMULATION TABLE:

Sr. No	Ingredients	Source (<i>Hibiscus sabdariffa</i> / <i>Adenium obesum</i>)
1	<i>Hibiscus sabdariffa</i> Extract	<i>Hibiscus sabdariffa</i>
2	<i>Adenium obesum</i> Extract	<i>Adenium obesum</i>
3	Microcrystalline Cellulose	Excipients
4	Mannitol	Excipients
5	Magnesium Stearate	Excipients

6	Talc	Excipients
7	Sodium Starch Glycolate	Excipients
8	Povidone (PVP K-30)	Excipients
9	Lactose Monohydrate	Excipients
10	Distilled Water	Excipients

CONCLUSION:

The formulated herbal buccal tablet of *Hibiscus sabdariffa* and *Adenium obesum* extracts showed satisfactory physicochemical and pharmaceutical evaluation results. The extracts' combination provided synergistic anti-ulcer and antioxidant potential, making the formulation a promising candidate for effective management of peptic ulcer disease. The buccal route of administration proved advantageous for enhanced bioavailability and prolonged therapeutic effect. All evaluation parameters, including weight variation, hardness, friability, and dissolution profile, were within acceptable pharmacopoeial limits. Hence, this study concludes that the developed herbal buccal tablet can serve as a safe, effective, and economical natural alternative for anti-ulcer therapy, warranting further in-vivo and clinical evaluations to confirm its therapeutic efficacy.

REFERENCE:

1. Shaikh, S., Pawar, J. and Raykar, M., 2022. A REVIEW ON BUCCOADHESIVE DRUG DELIVERY SYSTEM.
2. Lesch, C.A., Squier, C.A., Cruchley, A., Williams, D.M. and Speight, P., 1989. The permeability of human oral mucosa and skin to water. *Journal of dental research*, 68(9), pp.1345-1349.
3. Schroeder, H.E., 1981. Differentiation of human oral stratified epithelia. Karger Medical and Scientific Publishers.
4. Kuna, L., Jakab, J., Smolic, R., Raguz-Lucic, N., Vcev, A. and Smolic, M., 2019. Peptic ulcer disease: a brief review of conventional therapy and herbal treatment options. *Journal of clinical medicine*, 8(2), p.179.
5. Rothermel, C.E. and Edwards, A.L., 2020. Challenges in the management of peptic ulcer disease. *JCOM*, 27(6), pp.281-288.
6. Ramakrishnan, K. and Salinas, R.C., 2007. Peptic ulcer disease. *American family physician*, 76(7), pp.1005-1012.
7. Suleiman, I.A. and Okafor, E., 2016. Peptic Ulcer Disease Drugs Usage patterns and its economic burden in a tertiary health institution in Niger Delta, Nigeria. *Nigerian Journal of Pharmaceutical Research*, 12(2), pp.177-187.
8. Sani, N.K., Onwuchekwa, C., Mohammed, U. and Abubakar, M.B., 2022. Gastroprotective Effects of Aqueous Extract of *Hibiscus sabdariffa* Calyx on Nonsteroidal Anti-Inflammatory Drug-Induced Gastric Ulcer in Wistar Rats. *Nigerian Journal of Experimental and Clinical Biosciences*, 10(2), pp.40-46.
9. Chang, Y.K., Liu, J.S., Hsu, Y.H., Tarn, D.C. and Hsu, C.C., 2015. Increased risk of end-stage renal disease (ESRD) requiring chronic dialysis is associated with use of nonsteroidal

- anti-inflammatory drugs (NSAIDs): nationwide case-crossover study. *Medicine*, 94(38), p.e1362.
10. Walker BR, Colledge NR, Raltson SH, Penman ID. Davidson's Principles and Practice of Medicine. 22nd ed. United Kingdom:Churchill Livingstone, Elsevier Limited; 2014.
 11. Sani, N.K., Onwuchekwa, C., Mohammed, U. and Abubakar, M.B., 2022. Gastroprotective Effects of Aqueous Extract of Hibiscus sabdariffa Calyx on Nonsteroidal Anti-Inflammatory Drug-Induced Gastric Ulcer in Wistar Rats. *Nigerian Journal of Experimental and Clinical Biosciences*, 10(2), pp.40-46.
 12. Almasaudi, S.B., Abbas, A.T., Al-Hindi, R.R., El-Shitany, N.A., Abdel-Dayem, U.A., Ali, S.S., Saleh, R.M., Al Jaouni, S.K., Kamal, M.A. and Harakeh, S.M., 2017. Manuka honey exerts antioxidant and anti-inflammatory activities that promote healing of acetic acid-induced gastric ulcer in rats. *Evidence-Based Complementary and Alternative Medicine*, 2017(1), p.5413917.
 13. Fabricant, D.S. and Farnsworth, N.R., 2001. The value of plants used in traditional medicine for drug discovery. *Environmental health perspectives*, 109(suppl 1), pp.69-75.
 14. Cordell, G.A. and Colvard, M.D., 2012. Natural products and traditional medicine: turning on a paradigm. *Journal of natural products*, 75(3), pp.514-525.
 15. Smith, C.M. and Pristach, C.A., 1998. Management of psychiatric disorders in patients with poor insight. *Disease Management and Health Outcomes*, 4(3), pp.157-175.
 16. Chaudhary, M.I., Qing, H., Xiao, P.G. and Cheng, Y., 2007. Clematis huchouensis T AMURA: A traditional Chinese herbal medicine and its quality control using a high performance liquid chromatography technique. *Biological and Pharmaceutical Bulletin*, 30(1), pp.165-168.
 17. Agarwal, P., Fatima, A. and Singh, P.P., 2012. Herbal medicine scenario in India and European countries. *Journal of Pharmacognosy and Phytochemistry*, 1(4), pp.88-93.
 18. Farnsworth, N.R., Akerele, O., Bingel, A.S., Soejarto, D.D. and Guo, Z., 1985. Medicinal plants in therapy. *Bulletin of the world health organization*, 63(6), p.965.
 19. Silalahi, M., Purba, E.C., Sawitri, I.G.A.R., Wakhidah, A.Z. and Yuniati, E., 2023. International trade of medicinal and aromatic plants (MAPs). In *Medicinal Plants: Biodiversity, Biotechnology and Conservation* (pp. 289-306). Singapore: Springer Nature Singapore.
 20. Nabi, N.G. and Shrivastava, M., 2015. In vitro propagation of Psoralea corylifolia L.-An important Endangered medicinal plant. *Indian Journal of Applied and Pure Biology*, 30(2), pp.201-205.
 21. Uniyal, B., 2003. Utilization of medicinal plants by the rural women of Kulu, Himachal Pradesh. *Indian journal of Traditional knowledge*, 2(4), pp.366-370.
 22. McChesney, J.D., Venkataraman, S.K. and Henri, J.T., 2007. Plant natural products: back to the future or into extinction?. *Phytochemistry*, 68(14), pp.2015-2022.
 23. Saslis-Lagoudakis, C.H., Hawkins, J.A., Greenhill, S.J., Pendry, C.A., Watson, M.F., Tuladhar-Douglas, W., Baral, S.R. and Savolainen, V., 2014. The evolution of traditional knowledge: environment shapes medicinal plant use in Nepal. *Proceedings of the Royal Society B: Biological Sciences*, 281(1780), p.20132768.
 24. Goossens, A., Häkkinen, S.T., Laakso, I., Seppänen-Laakso, T., Biondi, S., De Sutter, V., Lammertyn, F., Nuutila, A.M., Söderlund, H., Zabeau, M. and Inzé, D., 2003. A functional

- genomics approach toward the understanding of secondary metabolism in plant cells. *Proceedings of the National Academy of Sciences*, 100(14), pp.8595-8600.
25. Birari, R.B. and Bhutani, K.K., 2007. Pancreatic lipase inhibitors from natural sources: unexplored potential. *Drug discovery today*, 12(19-20), pp.879-889.
 26. Sarikurcu, C., Eryigit, F., Cengiz, M., Tepe, B., Cakir, A. and Mete, E., 2012. Screening of the antioxidant activity of the essential oil and methanol extract of *Mentha pulegium* L. from Turkey. *Spectroscopy Letters*, 45(5), pp.352-358.
 27. Alzoubi, H.M., Ibrahim, A.I., Alsbou, M.S. and Aqel, A.A., 2014. Inhibitory effect of Mediterranean sage and rosemary on clinical and community isolates of methicillin-resistant *Staphylococcus aureus*. *Jordan Journal of Biological Sciences*, 7(3), pp.161-164.
 28. Sinha, S.N. and Paul, D., 2014. Antioxidant potentials of *Parthenium hysterophorus* L. leaf extracts. *Scientific Research Journal of India*, 3(2), pp.80-86.
 29. Dharajiya, D., Khatrani, T., Patel, P. and Moitra, N., *Journal of Chemical, Biological and Physical Sciences*.
 30. Dhinek, A. and Sowmia, C., 2015. Phytochemical analysis and free radical scavenging potential of *Ricinus communis* based polyherbal formulation. *Malaya Journal of Biosciences*, 2(2), pp.96-103.
 31. Kaewsuwan, S., Yuenyongsawad, S., Plubrukarn, A., Kaewchoothong, A., Raksawong, A., Puttarak, P. and Apirug, C., 2015. Bioactive interruptins A and B from *Cyclosorus terminans*: antibacterial, anticancer, stem cell proliferation and ROS scavenging activities. *Songklanakarin J. Sci. Technol*, 37(3), pp.309-317.
 32. Dimmitt, M.A. and Hanson, C., 1991. The genus *Adenium* in cultivation. Part 1: *A. obesum* and *A. multiflorum*.
 33. Arbonnier, M., 2004. Trees, shrubs and lianas of West African dry zones.
 34. Rose, D., 2008. *Adenium obesum* (Forssk.) Roem. & Schult.
 35. Win, N.K.K., Back, C.G., Kim, Y.H. and Jung, H.Y., 2012. Desert rose witches' broom disease associated with 'Candidatus *Phytoplasma aurantifolia*'. *Journal of general plant pathology*, 78(1), pp.73-76.
 36. Crouch, N., Prentice, C., Smith, G.F. and Symmonds, R., 1999. South Africa's rarest caudiciform cucurbit, *Gerrardanthus tomentosus*. *Bradleya*, 1999(17), pp.95-100.
 37. Varella, T.L., Silva, G.D., Cruz, K.Z.C.M., Mikovski, A.I., Nunes, J.D.S., Carvalho, I.D. and Silva, M.D., 2015. In vitro germination of desert rose varieties. *Ornamental Horticulture*, 21(2), pp.227-234.
 38. Kanchanapoom, K., Sunheem, S. and Kanchanapoom, K., 2010. In vitro propagation of *adenium obesum* (Forssk.) Roem. and Schult. *Notulae Botanicae Horti Agrobotanici Cluj-Napoca*, 38(3), pp.209-213.
 39. McBride, K.M., Henny, R.J., Mellich, T.A. and Chen, J., 2014. Mineral nutrition of *Adenium obesum* 'red'. *Hortscience*, 49(12), pp.1518-1522.
 40. Akuodor, G.C., Essien, A.D., David-Oku, E., Chilaka, K.C., Akpan, J.L., Ezeokpo, B. and Ezeonwumelu, J.O.C., 2013. Gastroprotective effect of the aqueous leaf extract of *Guiera senegalensis* in albino rats. *Asian Pacific Journal of Tropical Medicine*, 6(10), pp.771-775.
 41. Nnamonu, E.I., Ejere, V.C., Ejim, A.O., Echi, P.C., Egbuji, J.V., Eze, T.R. and Eyo, J.E., 2013. Effects of *Hibiscus Sabdariffa* calyces aqueous extract on serum cholesterol, body weight and liver biomarkers of *Rattus Novergicus*. *International Journal of Indigenous Medicinal Plants*, 46(4), pp.1405-1411.

