2. 10 best papers imp discoveries and contributions of Applicant Dr. Gitanjali S. Deokar

1. Gitanjali Deokar, Pooja Shinde, and Sanjay Kshirsagar. "In- vitro biorelevant media and time simulation probiotic proliferation methodology to determine prebiotic potentials of flaxseed powder" Bioactive carbohydrates and dietary fibre 28, (2022): 100335. https://doi.org/10.1016/j.bcdf.2022.100335

   https://drive.google.com/file/d/1tvGYjwMAoiSfW9OOu671__uOchM96raW/view?usp=sharing

   https://docs.google.com/document/d/1vTFH1ShWGnEZm742iGVMthvfR1j8kJ2j/edit?usp=sharing&ouid=106962687213151518134&rtpof=true&sd=true

   - Gastric enzyme pepsin has an inhibitory effect on growth of spores as observed in acidic condition

   - One very important observation is that simulated intestinal pH as well as simulated acidic pH with or without enzymes does not support the growth of spores (Bacillus coagulans SNZ 1969) as well as culture (Bacillus coagulans SNZ 1969 may be indicative of growth media requirement for the incubation and growth of the spores and culture.

   - The real time bio-relevant media digestion study shows that presence of antibiotic (Azithromycin) does not support the growth of probiotic spores(Bacillus coagulans SNZ 1969)and probiotic cultures Bacillus coagulans SNZ 1969) without the presence of growth media components.

   - In case of fermented flaxseed powder in the presence of citric acid even acidic condition with enzyme pepsin supports the growth of probiotic spores.(Bacillus coagulans SNZ 1969).

   - In case of real time bio-relevant media simulation, fermented product shows the supportive nature for the growth of probiotics.(Bacillus coagulans SNZ 1969) as well as antibiotic (Azithromycin) effect has found to be diminished as the scanty growth of the species is being observed.

   - Fermented flaxseed powder could be effective post biotic supplement which could be explored further in post biotic supplement development.

   - It has been observed in present study that factors like gastrointestinal pH, transit time, gastrointestinal fluid composition and presence of prebiotics, fermentation etc play very

important role in proliferation and gastrointestinal colonization of orally supplied probiotics as part of the treatment strategy

- The research findings justify the importance of synbiotic and postbiotic supplements as the part of treatment and prescription strategies in gut flora microbial dysbiosis caused by antibiotics rather than probiotic supplements alone.

- Or probiotics should be prescribed after completion of antibiotic therapy with proper instruction to consume probiotics with prebiotic dietary ingredients.

2. Indian Patent Application No. is 202221076410, date of filing 28 December 2022. Title: An edible prebiotic film and its preparation, (Ragi Whole seed sprouted powder- Proved for prebiotic and probiotic potential-In situ activation process) Inventors: Dr.Gitanjali Deokar, Dr. Sanjay Kshirsagar, Ms. Vaishnavi Pathak. Published:03/03/2023

https://drive.google.com/drive/folders/1GmjZ8-XQZPKNp-c3t2VtZXLL5Q20V2pE?usp=sharing

Findings: It is unique in situ generation of components through typical process used, responsible for functional film formation with prebiotic and probiotic potentials. The present invention provides a film forming composition comprising sprouted ragi whole seed powder; at least one pH adjusting agent; at least one plasticizer; at least one alcohol; and distilled water, wherein said film forming composition characterized in that the weight ratio of the sprouted ragi whole seed powder to the pH adjusting agent is in the range of 1:0.07 to 1:0.13, and the weight ratio of the sprouted ragi whole seed powder to the plasticizer is in the range of 1:0.35 to 1: 0.55. The present invention also provides a film formed from the film forming composition, wherein said film is characterized by Folding endurance in the range of 1000 to 1500 fold. The present invention further provides a process for the preparation of the film forming composition.

3. Deokar GS, Kakulte HD, Kshirsagar SJ, Waghchoure DR. QBD Approach to Predict the in-vivo Performance Based on in-vitro Results using Mucuna pruriens Seed Mucilage as a Novel Tablet Dosage Form Excipient and Diclofenac Sodium as Model drug Candidate. Indian J of Pharmaceutical Education and Research. 2021;55(3):715-27. ISSN:0019-5464 https://www.ijper.org/article/1515

https://www.ijper.org/sites/default/files/IndJPhaEdRes-55-3-715.pdf

Findings: Background: Aim of the present study was to put forth certain modifications in Quality by design approach to predict the in-vivo performance of dosage form based on in-vivo performance parameter simulation using in-vitro experimentations. Materials and Methods: One factor design was used with prime focus on impact of Mucuna pruriens seed mucilage as excipient on dosage form functionality and applicability. During product development stage, apart from manufacturing variables other impacting parameters considered were GI pH, alterations in body temperature and GI motility. Factors considered were simulated pH, Temperature and RPM (Rotations per minutes) variations. Process flow worksheet was developed. QTPP (Quality target product profile) and CQA (Critical Quality Attributes) data was generated. Results: Risk assessment and Ishikawa diagram (Cause and effect analysis) were found to be helpful to generate the results predicting in vivo performance of dosage from. The process capability indices helped for judging product/process performance. The study design could be helpful to analyze the alterations in in-vivo performance based on excipient behavior in simulated conditions tested in-vitro. Conclusion: The present research work has successfully used Quality by design approach to predict the in-vivo performance of Tablet dosage form based on in-vitro data simulation. It can be concluded that study design with more number of simulating variables could be helpful pattern to come up with in-vivo performance predictions.

4. G. S. Deokar *, Sakshi Shewale, S. J. Kshirsagar, manuscript 'Impact of hydrothermal isolation method on the recovery of fenugreek seed hemi-cellulose analyzed through FTIR- DSC-SEM interpretations' International Journal Of Pharmaceutical Sciences And Research, 2019; Vol. 10(10): 4677-84. E-ISSN: 0975-8232; P-ISSN: 2320-5148 Five years projected Impact factor:1.81,web of science-care list

https://ijpsr.com/bft-article/impact-of-hydrothermal-isolation-method-on-the-recovery-of-fenugreek-seed-hemi-cellulose-analyzed-through-ftir-dsc-sem-interpretations/

file:///C:/Users/staff.STAFFPC/Downloads/32-Vol.-10-Issue-10-Oct-2019-IJPSR-RA-11627-1.pdf

Findings: Natural Herbal components like seeds mucilages, exudates, gums, polysaccharides, celluloses, hemicelluloses, starch, etc. are now a day's exploited as excipients. Literature reveals medicinal, nutraceutical and pharmaceutical uses of fenugreek seed hemicelluloses in dosage form design. Hemicelluloses like galactomannans

are water-soluble polysaccharides highly susceptible to hydrolysis either by acidic conditions or by uncontrolled hydrothermal processes. Chances of breakdown of intact polymeric polysaccharides chains into oligosaccharides, disaccharides, monosaccharide, etc. increases. Conversion into basic sugar units may also take place leading to changes in the polymeric behavior of the intact structures. So, in the present research percentage hemicellulose recovery is determined by invasive, indirect method in terms of basic glucose units. FTIR-SEM-DSC analysis was found to be useful characterization tools to interpret and support the recovery details of the hemicellulose isolates. Finally, it is concluded that the method of isolation of any natural component either hemicellulose, cellulose, etc. targeted to be utilized as excipient entity in dosage form design should be strictly optimized because there are numerous factors in processing which may convert these intact high molecular weight polysaccharide polymeric structures into low molecular weight of monomer units which ultimately may lead to alterations in the functional performance of these structures.

5. G. S. Deokar *, S. S. Raut, S. J. Kshirsagar, An attempt to understand and validate the factors controlling in-situ raft formation process, International Journal of Pharmaceutical Sciences and Research, 2019; Vol. 10(10): 4657-4667.. E-ISSN: 0975-8232; P-ISSN: 2320-5148. Five years projected Impact factor:1.81 web of science-care list web of science-care list https://ijpsr.com/bft-article/an-attempt-to-understand-and-validate-the-factors-controlling-in-situ-raft-formation-process/

file:///C:/Users/staff.STAFFPC/Downloads/29-Vol.-10-Issue-10-Oct-2019-IJPSR-RA-11602-3.pdf

Findings: In this study, in-situ raft forming Levofloxacin Suspension formulation was developed. In-vitro conditions like temperature, pH, and RPM simulating the in-vivo conditions like gastric pH, body temperature, and gastric motility respectively were identified as critical process parameters in system scale-up studies. Challenging and characterization were performed in-vitro. The working limits were identified and verified by calculation of process capability indices. Process Potential (Cp) and Process performance (Cpk) values greater than 2, and 1.33 respectively helped to select the conditions for the formation of raft system controlling the release up to 8 h with zero order release kinetics found to be significant (R2=0.9930). The release mechanism was found to

be Korsemeyer-peppas showing the mechanism of drug release by diffusion and relaxation of polymeric raft structure. The Suspension formulation subjected to stability studies (40 ºC ± 2 ºC / 75% ± 5% RH) were found to be stable for pH, viscosity, floating lag time, content uniformity and percentage drug release from the raft structure. Moreover, radiographic x- rays evaluation for optimized formulation for the validation of set in-vitro protocol revealed that the raft structure formed in-vivo elicits excellent gastric retention as proposed in observations and removed from the body within safe period of 24 h.

6. Deokar Gitanjali. S*, Nagare Sujata, Pratiksha Deore, kshirsagar Sanjay.J, Ahirrao Sapana P, Kulkarni Prasad K., Coccinia Grandis Fruit Extract Gel For The Treatment Of Mouth Ulcer Along With Associated Wound And Inflammation, J. Res. Educ. Indian Med. 2017;23(1-2) 43-58 doi:10.5455/JREIM.82-1457672904 ISSN 0970-7700

https://www.ejmanager.com/mnstemps/82/82-1457672904_TYP.pdf

Findings: Culinary utility of the Coccinia grandis (Cucurbitaceae) indicates the use of fruits in the form of different recepies. Coccinia grandis (Cucurbitaceae) is a perennial plant popularly known as kundru, Tondlee, Ivy gourd, Bimbi and Scarlet gourd etc. This herb is used in folk medicine in the form of intact fruits for healing oral ulcers. So the present work was done with an objective to develop a gel formulation from hydroalcoholic extract of coccinia grandis fruit for the treatment of ulcer and for healing of associated wound and inflammation. Molecular docking study was carried out for lupeol and taraxerone, the chemical constituents contained in the fruits. The dock score values were found to be -51.83 and -35.87 respectively for antiulcer activity. For wound healing activity the values found were -27.25 and -27.17 respectively for the two components, whereas the dock score values obtained for the anti-inflammatory activities were -58.6632 and -58. respectively for lupeol and taraxerone. The negative dock score value shows better affinity to bind receptor site. Application of hydroalcoholic extract gel of (20%w/w) for antiulcer and wound healing activities caused a significant reduction in ulcer and wound area when compared with the untreated controls and marketed formulation. Topical application of gel at 20%w/w concentration showed significant reduction in carrageenan induced rat paw edema. Studies carried out for Antiulcer, Wound Healing and Anti-Inflammatory activities showed promising results proving the standardized utilization of traditional herb having culinary applicability. Moreover, the data was also supported by the results of

computational studies of major constituents responsible for the said activities. The approach in the present study was fruitful to prove the prospectives of hydroalcoholic extract gel of Coccinia grandis fruit as the effective treatment for ulcer and healing associated with wound and inflammation.

7. Deokar Gitanjali S., Sadgir Priyanka1, Kshirsagar Sanjay J. Kakulte Harshada D.1, Patil Sushil M, 2016, Tulsi Oil Loaded Biocompatible, Stable Organogel With Improved Physical Stability And Prolonged Activity., International Journal Of Drug Delivery Technology; 6(2); 30-46, ISSN: 0975 4415; Sciverse Scopus; Impact Factor: 1.221, sjr-0.21 http://impactfactor.org/PDF/IJDDT/6/IJDDT,Vol6,Issue2,Article1.pdf

https://ijddt.com/volume6issue2/

Findings: Tulsi oil, though reported to be affective against broad spectrum bacteria and fungi the simple conventional gel formulations could not enter the clinical trials due to instability of Tulsi oil. Microbial growth in the formulation, phase separation and incompatibility with aqueous components are the major concerns associated with formulation and development involving Tulsi oil as the active component. In last few decades several studies have been carried out by Indian scientists and researchers to suggest the role of essential oils and Eugenol in therapeutic potentials of Ocimum sanctum Linn. Eugenol is a phenolic compound and major constituent of essential oils extracted from different parts of Tulsi plant. Various workers have tried extract of Ocimum sanctum against some well known fungal etiological agents as Candida albicans. Candidiasis is a very common disease not only in human but also in animals and therefore always has been a challenge to scientist. Overgrowth of several species including albicans can cause superficial infections such as oropharyngeal candidiasis (thrush) and vulvo vaginal candidiasis (vaginal candidiasis). Oral candidiasis is common in elderly denture wearers. In otherwise healthy individuals, these infections can be cured with topical or systemic antifungal medications (commonly over-the-counter antifungal treatments like miconazole or clotrimazole). Ointments, creams, liquid preparations, powders, aerosols, gels are various topical drug delivery systems. A ternary plot depicting proportions of water, Tulsi oil and surfactant mixture with gelator, was prepared to predict the gelling compositions. To figure out the area of ternary plot fulfilling MIC, antifungal susceptibility testing of Tulsi oil was carried out. In- vitro diffusion study was done and percent release was quantified in terms of Eugenol. Further Stability studies were performed. HET- CAM test

was carried out to assess biocompatibility. The drug release was found to follow Korsmeyer-peppas model with zero order release pattern which was supported by higher release exponent value, indicating super case II transport systems. The optimized organogel showed shelf life of 54, 42, and 22 days at 4^{0C}, 25^{0C}, 50^{0C} respectively and was found to be biocompatible and physically stable for longer period as compared to conventional Tulsi oil gel formulation. The present study highlights the usefulness of approach selected for study to improve the formulation aspects in terms of physical stability of oily active components.

8. Application No.3010/MUM/2011 A, Published: Dr Deokar G. S., Dr Pramod Yeole, Mr.Erande.K.B Title 1: Development Of Antifungal Formulations For Nail Fungal Infections, Filed On 25/10/2011, The Patent Office Journal, Published On: 21/06/2013;. **Pp:13508** PART -1 https://ipindia.gov.in/ipr/patent/journal_archieve/journal_2013/pat_arch_062013/official_journal_21062013_part_i.pdf

Findings: The present investigation is related to the fungal and yeast infections of the nails on the hands and the toes. The present formulations are in the paste as well as ready to mix powder form which is the combination of the three active ingredients Viz- Boerhaavia diffusa root extract, (Rakta punarnava/Ghetuli in marathi), Red lead/lead tetroxide powder (shendur in marathi), Calcium hydroxide powder (chuna in marathi). The paste form is preferred as the formulation can remain in contact of nail for longer period of time, and it will not be washed of easily. About 11 case studies were carried out taking the consent of the patients. It has been concluded by observing the patients that Red lead acts as wound

healer which first helps in attachment of the detached nail plate from the nail bed. Boerhaavia difusa is antibacterial agent as well as antifungal agent playing major role if secondary bacterial infection persists with the onychomychosis, also it act as tissue rejuvenator. The rejuvenative action of punamava is via its opening and cleansing activity allowing effective nourishment and oxygen supply to the tissues. Where in fungi find difficult to survive in oxygen environment. Calcium hydroxide is found to have strong antifungal activity against the species Trichophyton rubrum, Candida albicans and Epidermohyton flocossum representive species most commonly found in the onychomychosis infected nail. It takes about a week or one month to get rid of the infection depending on the seriousness of the infection. The formulation is applied on infected nails and is kept covered overnight with cotton strip. Similarly apart from paste formulation ready to use powder mix of above mentioned ingredients, is also equally effective in treating the infection. Ready to use powder mix (sufficient quantity) is mixed with little amount of water ,mixture is applied on infected nail and tied up with the cotton strip and kept wet with water as possible. No side effects have been reported with the present formulations.

9. Deokar Gitanjali,*, Pethkar Prajaktaa, Bakshe Swatia, Erande Kiran and Bhambar Rajendra, Antimalassezia Activity of Medicated Antidandruff Shampoo Formulated with Microwave Dried Garlic Powder with Improved Allicin Stability, The Natural Products Journal, 2014, 4, 23-32. DOI: 10.2174/2210315504011407151445 11 https://www.eurekaselect.com/article/61414

Findings: Dandruff is a common non-inflammatory scalp condition caused by lipophilic, dimorphic yeast Malassezia furfur. Garlic (Allium Sativum, Liliacae) contains allicin which is its potential principle constituent that possesses antiviral, antifungal, and parasitic activity. Content of allicin in microwave assisted garlic powder and aqueous garlic extract was found to be 1242.29 µg/gm of garlic powder and 552.26 µg/gm of garlic bulbs respectively by Solid phase extraction–UV method. Minimum inhibitory concentrations of microwave assisted garlic powder and aqueous garlic extract was found to be 268.33 µg /ml and 249.6 µg /ml respectively. From the minimum inhibitory concentration (MIC) obtained, the microwave assisted garlic powder and aqueous garlic extract were then incorporated at different percentages into shampoo formulations. The shampoo formulations were evaluated for two months at room temperature and 40C. Aqueous extract containing shampoo showed inhibitory action for 1 week (7 days) but growth was observed after 2 weeks (14 days) at both temperature conditions.

Microwave assisted garlic powder containing shampoo when kept at 40C showed inhibitory action up to 4 weeks (28 days) but growth was observed after 5 weeks (35 days) and shampoo formulations kept at room temperature showed inhibitory action up to 5 weeks (35 days) but growth was observed after 6 weeks (42days). Study shows that microwave drying technique helps in improving the stability of allicin. Whereas Storage at refrigerator temperature has no role in stability improvement of allicin in the formulation.

10. Thorakkattu,P.; Khanashyam,A.C.; Shah,K.; Babu,K.S.;ShankerMundanat,A.; Deliephan,A.; Deokar,G.S.; Santivarangkna, C.; Nirmal,N.P. Postbiotics:Current Trends in Food and Pharmaceutical Industry. Foods 2022, 11, 3094.https://doi.org/10.3390/foods11193094 (Collaborative work with Mahidol University,Thailand)(Review article) https://www.mdpi.com/2304-8158/11/19/3094

Abstract

Postbiotics are non-viable bacterial products or metabolic byproducts produced by probiotic microorganisms that have biologic activity in the host. Postbiotics are functional bioactive compounds, generated in a matrix during anaerobic fermentation of organic nutrients like prebiotics, for the generation of energy in the form of adenosine triphosphate. The byproducts of this metabolic sequence are called postbiotics, these are low molecular weight soluble compounds either secreted by live microflora or released after microbial cell lysis. A few examples of widely studied postbiotics are short-chain fatty acids, microbial cell fragments, extracellular polysaccharides, cell lysates, teichoic acid, vitamins, etc. Presently, prebiotics and probiotics are the products on the market; however, postbiotics are also gaining a great deal of attention. The numerous health advantages of postbiotic components may soon lead to an increase in consumer demand for postbiotic supplements. The most recent research aspects of postbiotics in the food and pharmaceutical industries are included in this review. The review encompasses a brief introduction, classification, production technologies, characterization, biological activities, and potential applications of postbiotics.