**DPSRU Innovation and Incubation Foundation (DIIF)**

Delhi Pharmaceutical Sciences & Research University

Pushp Vihar, Sector III, MB Road, New Delhi – 110 075

 **Start Up Proposal**

**A. Personal information**

|  |  |
| --- | --- |
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**B. Introduction to Ideation**

**1.   Broad Industry sector** : Pharma

**2.    What is your product / service**

Takrarishta is one of the most potent Ayurvedic formulation effective against GI infection for e.g. Food poisoning, Diarrhoea, Dysentry.

It is capable of destroying most of organism, which cause food poisoning such as *S.aureus, S.typhi, S.substilis, P.vulgaris, M.luteus, P.aeruginosa, B.cereus, E .coli, S.flexneri and C.perfringen.*

This preparation as it is disappeared from market due to very little customer acceptability owing to its obnoxious odor and dirty look. There are no measures to arrest the fermentation before administration to the patient or during storage . As a result the fermentation continues to take place even during storage, and hence therapeutic efficacy of the formulation keeps on varying. It is therefore very necessary to revise the procedure of preparation to overcome this disadvantage.

In the present study, we will try to establish the therapeutic potency and increase the shelf stability of traditional formulation by means of modern pharmaceutical techniques thereby converting a traditional formulation into an effective solid dosage form and aesthetically acceptable treatment for patient in food poisoning.

**3. Who is recipient / beneficiary of your product / service?**

The beneficiary of this product will be Infants, Pregnant lady, Old age peoples. The recipient who is suffering from Food Poisoning.

1. **What is the idea/innovation**

The commercial preparation available in the market was very little customer acceptability owing to its obnoxious odour and dirty look. The process of fermentation include continuous fermentation there is no methodology to arrest the fermentation before administration formulation to patient or during storage is included procedure as result the fermentation continuous to take place even during storage, and hence therapeutic efficacy of the formulation keeps on declines. It is therefore very necessary to revise the procedure of preparation to overcome disadvantages associated with the same. The modify formulation also exert very potent antioxidant activity

**4 a. Is it an idea or have you validated any proof of concept?**

Book publication on Takrarishta

Acharya Charka was the first person who mentioned Takrarishta during that period there is no discrimination in between Asava and Arishta. According to book of Charak Samhita, Takrarishta fermented medicament prepared by buttermilk is classical Ayurvedic formulation.There are abunded references of Takra (buttermilk) in various Ayurvedic classical of Charak Samhita..Their method of preparation, types qualities and benefits were also discussed in various chapter of the Samhitas and Sangraha granthas, where as, only two references are found with regards to Takrarishta. Both the references are found in Charaka Samhita i.e. Chikitsa Sathana of14th(Arsha Chikitsa) and 15th(Grahni Chikitsa) chapters respectively. Even though in both the references Takra is used as a common medium , the difference lies in the herbal ingredients which are uncommon in these formulation, But both are having common indication of Agnimandya, shodha and Arshas some references reported.

Tripathi(1991) translate Charak Samhita in hindi and published book of Charak Samhita in hindi by Choukhamba prakashan.

Archarya Dalhana published book as commentries of Sushruta Samhita by Choukhamba prakashan. According to his book, Charaka considered Takrarishta under Arishta kalpa itself though it is fermentation where boiling was not carried unlike other arishta.

Acharya Shodhana (1969) published 1st edition as Gadanigraha with Vidyotini Hindi Commentary Vol.II by Choukhamba prakashan.He refers this formulation in his text Gada Nigraha-Prooyoga Kandhaa in Asavadhikara, Here in place of Kunchika,sushavi is mentioned and other than this all the ingredients are same as per the references of Charaka Chikitsa .Here, some specificationn is given regarding Takra as Manda amla(mild acidic)and Katu Rasatmakatwala((Pungent taste).Here 'Katu rasatwa' of buttermilk appears vogue.Probably by the line"Tacchoornam Takra Samyutam"or "Mandamla katukam sthapayet",taste of whole buttermilk wort may be considered, as most of the drugs told in this recipe are of Katu rasatmakaand useful in Shodha, Gulma, Arsha, Krimi, Meha, Udara, etc.As it is told under Grahani Adhikara, surely it is the formulation of priority in this disease.

Sen Gupta(1991)published book as commentries of Charka Samhita.According to this book Takrarishta appears as a type of arishta Kalpana(fermented product).

Reddy(1998) published book as Bhaishajyavijnyana. In his book hewrote the basic principles of Bhaishajyakalpanaand' Yoganamak aranasiddhanta'. According to Bhaishajya vijnyana,Takrarishta appeares as a type of ArishtaKalpana(fermented product).As the media used is Takra(butter milk),He also explain, Takrarishta this name was given by our ancient Acharyas.Inspite of their good knowledge regarding Amala Sandhana, consideration of Shukta Sandhana (Amala Sandhana) in the name of Arishta(a type of Madyasandhana), still appears a surprising fact.

National and International research work of Takrarishta

Krishnamurthy(2012) carried out Pharmaceutico-analytical study on Takrarishta. He carried to achieved pharmaceutically acceptable 18 samples, as part of standardization, with different ingredients and fermenting agents. Six different methods were adapted ,to find out the best pharmaceutical way to prepare Takrarishta. The available successful sample were subjected for physic- chemical analysis and reported standards for Takrarishta like specific gravity, refractive Index, pH, alcohol, Total Sugar content, Ascorbic Acid content .Free fatty Acid content, Total Protein content ,Qualitative test result :Presence of functional groups like tannin, saponin, flavanoids, glycosides, triterpenoid and sterroides, carbohydrates.

Krishnamurthy et al(2011) worked on critical study of Takrarishta and reported that fermented product and refermentation of the some more salts and herbal drugs yield more stable product containing little amount of alcohol and dominant character of acidic fermentation which has been substantive through the biochemical values.

Krishnamurthy et al(2011) studied the effect of Takrarishta on blood profile and concluded that Takrarishta is helpful for marginal increase of Hb% and significant decrese of SGOT,SGPT and serum alkaline phosphatese. The study also discloses potent Grahi action of Takra.

Abdolhossein Moghbel(2011) reported "Study of Compressibility Properties of yogurt Powder in Order to prepare a Complementory Formulation". In this studies he formulated tablet from curd .

Nag A.(2011) submitted thesis on topic ‘Development of a microencapsulation technique for probiotic bacteria Lactobacillus casei 431 using a protein-polysaccharide complex’. In this studies, he successfully entrapped lactobacillus casei 431 cell into this gel matrix. He decided appropriate combination of ingredients on the basis of final elastic modules to attain adequate gel strength. This combination resulted in a very fine and uniform capsule size distribution and upto 89% encapsulation efficiency was achieved.

Bhardwaj (2005 )reported in vitro antibacterial activity of Takrarishta against 10 bacterial species using standard drug Amoxycillin(10ug/ml).The formulation as well as individual component exhibited antibacterial activity has been suggested to be useful in G.I. infection and in food poisoning. He also attempted modifications of the formulation and procedure of preparing this formulation but was successfully to the extend of prolonging the shelf life only to about and one month only.

Chandramouli (2004) reported ‘An improved method of microencapsulation and its evaluation to protect Lactobacillus spp.in stimulated gastric conditions’. In this studies, An improved method of microencapsulation was developed to increase the efficacy of capsules in protecting the encapsulated bacteria under stimulated gastric condition. Thus the encapsulation method describe in this study may be effectively used to protect the lactobacillus from adverse gastric condition.

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**4 b.  If you have started any work on it, has it generated any revenue?**

Yet any work has been started

1. **Any other information on status of your idea / start-up (interms of technology)**

*Takrarishta* is classified as *Arishta* in *Ayurvedic* system of medicine and is prescribed against Dysentry, Piles, haemorrhoides, intestinal worm ,hepatic disorder, oedema, spleenic disorder, loss of appetite, irritable bowel syndrome and abdominal disorder. During the present investigations sample of Takrarishta shall be prepared using herbs, salts and buttermilk with specification given by Charak 4.

The aim of present study to prepare an oral Pellets/Tablet/ Capsule from liquid Takrarishta by reforming the physical properties for easy transportation, long term storage to overcome its disadvantages of Takrarishta like obnoxious odor , dirty look and continuous fermentation.

Formulation by using more rational and more scientific techniques shall be proving its stability and shelf life. This preparation shall effective measure against G4.I disorders. The solid dosage form shall be homogenized by a 12 mesh size sieves. Some tests such as Carr’s compressibility index, Hausner ratio and the angle of repose will be evaluating the flow ability of Takrarishta powder. Study of the deformation of particals forcing will be done by calculation of the elastic recovery index.

Formulation studies shall involve developing preparation of the solid dosage form which is both stable and acceptable to the patient.

**6. What is the problem you are trying to solve**

In G.I infection where use of antibiotics is harmful, in that conditions administration of Takrarishta may be useful. The formulation also exert very potent antioxidant activity It is common experience that presently available antibiotics are rapidly getting exhausted as the organism are developing resistance against them. Shigella dysenteriae, Salmonella and Pseudnomas show high level of resistance14.The formulation also exerts very potent antioxidant activity.

*Takrarishta* is very useful in curing food poisoning. In certain pathophysiological conditions, e.g. during pregnancy or infant Diarrhoea the administration of antibiotics is not beneficial in that case administration of *Takrarishta* will be useful.

This preparation as its available today in market was very little customer acceptability owing to its obnoxious odor, dirty look and continuous fermentation so that overcome this disadvantage there is necessity to formulate its Solid dosage form.

Formulation studies shall consider stability studies and such factors as partical size, polymorphism, pH and solubility, as all these influence bioavailability and hence the activity of a drug. The resultant final dosage form shall be combined with inactive additives by a method which will ensures that the quantity of a drug present in each dosage unit e,g each tablet. The final dosage form shall be in uniform appearance, with an acceptable taste, tablet hardness or capsule disintegration

1. **What experiments you will like to do?**

# Objective

1. To prepare *Ayurvedic* recipe called *Takrarishta* by adding Go-*Takra, Amala, Harda, Marich* along with minerals
2. To carry out antimicrobial activity of *Takrarishta*, *Takra* and plant extract in Vitro.
3. To convert original liquid formulation into dry form.
4. To evaluate antimicrobial activity of the resultant dry form.
5. To convert resultant dry form in solid dosage form to enhance therapeutic efficiency of Formulation by doing necessary modification
6. To study stability studies for antimicrobial efficacy and prolonged shelf life of resultant solid dosage form

**Proposed plan and methodology**

# Phase I

Takrarishta shall be prepared according to the method prescribed . Their shall be isolation and identification of chemical by HPLC and UV. and antimicrobial activities shall be tested against concerned organism by cup plate method.

# Phase II

The original formulations, which are in liquid dosage forms, shall be converted into solid form by

a. Vacuum distillation

b. Spray drying

c. Freeze drying.

The antimicrobial activity of the resultant dry form shall be evaluated.

# Phase III

The resultant dry form shall be converted into suitable solid dosage form. i.e. Pellets

# Phase IV

Evaluation of solid dosage form and determination of shelf life.

1. **What will be requirement to get idea conceptualized**

 Infra Red Spectrophotometer (Hitachi)

 Double beam UV visible spectrophotometer (Shimadzu)

 HPLC (Binary pump) with UV-visible detector (Shimadzu)

 HPTLC (Camag)

 Mass Spectrophotometer

 Differential Scanning calorimeter (Perkin-Elmar)

 Atomic absorption spectrometer

 Gas liquid chromatography

 Elisa reader

 Fourier transform-Infra Red spectrophotometer

 Nuclear magnetic resonance instrument

 HS-Counter current chromatography

 Green house

 Herbal garden

 Dissolution apparatus

 Disintegration apparatus

 PH meter

 Extrusion and Spheronization apparatus

 Stability Chember

 Tablet filling

 Capsule filling

 Single punch

 Multiple punch

 Rotatory pan coater

 Bed coater

 Atomic force microscope

Aseptic room

Laminar air flow.

Soxhlet Apparatus.

Column Chromatography.

TLC

Bacterial Cultures

Hardness tester

Refractometer

Spray drier

Lyophilizer

**C: Strategy**

1. **What if you do not get incubation support from DIIF**

If I do not get incubation support from DIIF then I will complete this project self financially.

1. **What if you get incubation support from DIIF**

It will be very much helpful for me. I will get all facility as well as financial support at DPSRU.

I am doing Part time Ph.D and doing job as Guest faculty at DIN Dayal College of Pharmacy. So Workstation, office space, lab facility, internet facility, Labs, are essential for me doing this project. That are part of infrastructure. So Good infrastructure will be helpful for me.Requirement of meeting room will be helpful for me for meeting and discussion of topic

1. **How do you plan to scale up your start-up**

a)Preparation of Takrarishtra*:* During the present investigations sample of Takrarishta shall be prepared using herbs salts and buttermilk with specification given by Charak 4.

 b)To isolate & characterize the chemical constituents from fermented Takrarishta.

Characterization of compounds

TLC studies, UV, IR, Mass, 1H, 13C NMR, 2D NMR

Fermentation broth

Filtration

Fractionation

Counter current, Vacuum, Flash, open column chromatography

Isolation & purification of compounds

Column chromatography, prep TLC, prep HPLC, crystallization

c) To perform the quality control parameters for above formulations.

Formulation

pH

Specific gravity

Total solids

Total phenolics

Assay

Alcohol content

Absence of methanol

Sugar content

d) To develop the method for standardization of the formulation Takrarishta..

Formulation

HPTLC, HPLC with respect to the isolated constituents

Preparation of extracts

e) Standardization of Antibacterial activity of Takrarishta and Takra in comparison to standard drug (Amoxycillin)

i) Bacterial cultures and their maintenance.

 Test Organisms

*Staphylococcus aureus, Salmonella typhi, Bacillus subtilis* (MTCC 441)

*Pseudomonas aeruginosa* (MTCC 424), *Proteus vulgaris* (MTCC 1771)

*Micrococcus luteus* (MTCC 1541), *Bacillus cereus* (MTCC 430)

*Escherichia coli* (MTCC 739), *Shigella flexneri* (MTCC 1457)

*Clostridium perfringens* (NCIM 2677)

 Maintain on nutrient agar except *C.perfringens* (Reinforced Clostriduium agar.

 Incubation in b/w 30ºC to 37ºC for 24 hr.

ii) Studies of antibacterial activity.

Takraristra

Takra

Studies of antibacterial activity

Preparation of 75% ,50%,25%, &10% concentration by using sterile distilled water.

Amoxycillin (10 µg / ml)

**Phase II :**

The original formulation which is in liquid dosage forms shall be converted into solid form.

Studies of antibacterial activity.

Vacuum distillation

Spray drying

Freeze drying

Solid dosage forms

Liquid dosage forms

Preformulation Studies

Preformulation studies of resultant dry form

**Stabiity Analysis**

Solid State Stability

Compalibility

(Drug expient interaction studies)

**Solubility Analysis**

PH Solubility profile

Dissolution studies

In Vitro.

**Bulk Characterization**

Taste ,Odour, Melting point, Crystallinity, Hygroscopicity, Fine particle Characterization, Powder flow Properties(Carr’s index, Hausner ratio, Angle of repose

**Phase III:** The resultant dry form shall be converted into sustained release solid dosage form i.e.Pellets

1. Preparation of Pellets by Extrusion Techniques.

Solid dry Takrarishta + Polymer(1.8% Alginate+5% Starch)

 Introducing a mixture into an Extruder.

Dropping the mixture into Cacl2 Solution

 Recovering of gel

Microsphere

Coating(0.4% Chitosan)

Characterization of Microspherei.e Partical size and shape,Release study,Density Determination

 **Phase IV:** Interaction between the ingredients and adjuvant shall be studied. The final formulation shall be decided on the basis of antibacterial efficacy and prolong shef life.

Stability Testing

Physical Stability

Chemical Stability

Microbiological Stability

Compatibility

 Light, Color, OdorTexture,PH,Temperature Microscopic analysis,Humidity, Dissolution method in Vitro,Disintegration studies,Particle analysis

Hydrolysis

Oxidation

Photolysis

Temperature

Toxicological Strategy-

Contamination with bacteria, mold & yeast.

Between the contents and container

Resultant dosage form i.e Pellets

1. **What are the challenges you are facing now and you foresee in next 2 years**

As concern as challenges regarding this project are as

1. There is no financial assistant.
2. University .has been newly opened So there is no advanced instrument facility.

**D. Requirements**

1. **Infrastructure required**
2. **Justification of infrastructure required.**

I am doing Part time Ph.D and doing job as a Principal at Din Dayal College of Pharmacy. So Workstation, office space, lab facility, internet facility, Labs are essential for me doing this project. That are part of infrastructure. So Good infrastructure will be helpful for me.

1. **Requirement of meeting room (Frequency of meetings being held /month)**

Yes, Requirement of meeting room will be helpful for me for meeting and discussion of topic.

1. **Funds required upto 2 years:**

**Forteen Lacs and Twenty Nine Thousand only**

1. **Assistance required upto 2 years:**

Financial assistant will very helpful for complete this project.

**Justification for budgetary requirements-**

**Felloship-To assist myself financially.**

**Consumable** - Proposed work involves preparation of *Takrarishta* and identification of Novel Pharmacophores from *Takrarishta* and shall be develop standardization method of *Takrarishta* on the basis of chemical constituents as well as standardization of antibacterial activity as compare to standard drug shall be done. So that 10 bacteria which are responsible for Food Poisoning that will be purchased. Nutrient media shall be required for the growth of bacteria. The second purpose of this studies is to do develop formulation and evaluation of analogous Ayurvedic preparation (*Takrarisht*a) for prolonged therapeutic efficiency and Stability in treatment of GI infection including Diarrhea, Dysentry, Food Poisoning.

Preformulation involves the characterization of a drug’s Physical Chemical, and Mechanical properties in order to choose what other ingredients (known as excipient) shall be used in the `preparation for formulation of solid dosage form i.e. Pellets.

Bioavailability of Pellets shall be studied by dissolution and PH solubility method in Vitro that shall be useful to understand availability of drug in systemic circulation.

Shelf life of Pellets shall be decided on the basis of Prolonged therapeutic efficiency and stability.

That all process will require good amount of *Takra*, Herbal drugs i.e. *Amala ,Harda, Marich, Ajowain*, salts, chemicals and glassware’s.

**Travel-**The fund allotted for travel will be used for literature survey outside Jamia Hamdard and presenting the finding of project in national level conferences and seminars.

**E .Abstract/ Summary of proposal (Maximum 200 words)**

Asavas /Aristas are traditional formulations prepared after fermentation of either infusion or decoction of herbs. Takrarishta is classified as Arishta in Ayurvedic system of medicine and is prescribed against Dysentry, Piles, haemorrhoides, intestinal worm, hepatic disorder, oedema, spleenic disorder, loss of appetite, irritable bowel syndrome and abdominal disorder. During the present investigations sample of Takrarishta shall be prepared using herbs i.e Amla(Emblica officinalis Geartn), Harad(Terminalia chebula Retzr), Marich(Piper nigrum Linn), Ajowan(Carum copticum Hiren.), Marich(Piper nigrum Linn) along with minerals salt like Saindhava, Sauvarcala, Audbhida, Bida, Samudra along with Takra commonly called as buttermilk, many variation of in the formulation are recommended in this topic as per specification given by Charak.

 The formulation will be prepared using traditional method & quality control parameters for all the formulations will be evaluated as per the guidelines of Ayurvedic Pharmacopoeia of India.

A method will be developed to standardize the formulation based on isolated constituents before and after fermentation which may lead to develop and optimize the modern biotechnological method for the preparation of Takrarishta.

Takarishta is one of the most potent ayurvedic formulation effective against GI infection for e.g. Food poisoning, Diarrhoea, Dysentry.

It is capable of destroying most of organism, which cause food poisoning such as *S.aureus, S.typhi, S.substilis, P.vulgaris, M.luteus, P.aeruginosa, B.cereus, E .coli, S.flexneri and C.perfringen.*

Bhardwaj. S performed antibacterial activity of Takrarishta and suggested this Ayurvedic preparation in G.I infection including Diarrhea and Food Poisoning.

In certain pathophysiological conditions,e.g.during pregnancy or infant Diarrhea the administration of antibiotics is not permissiblel.In that case administration of Takrarishta will be usefull

The point of advantage over the commonly used antibiotics is that It is free from toxicity, which is generally exhibited by commonly employed antibiotics.

The commercial preparation available in the market was very little customer acceptability owing to its obnoxious odour and dirty look. The process of fermentation include continuous fermentation there is no methodology to arrest the fermentation before administration formulation to patient or during storage is included procedure as result the fermentation continuous to take place even during storage, and hence therapeutic efficacy of the formulation keeps on declines. It is therefore very necessary to revise the procedure of preparation to overcome disadvantages associated with the same. The modify formulation also exert very potent antioxidant activity.