TERMS OF REFERENCE FOR THE R&D PROJECTS

AYUSH DEPARTMENT, BIS

1. **TITLE**: Analysis of Safety and Quality parameters for Kudineer Tablet (Tablet from Decoction).

2. **BACKGROUND**:

2.1 Many pharma companies manufacture ready to use tablet of "Kabasura Kudineer" decoction, which are made from powdered raw drug ingredients whereas the appropriate procedure is to prepare tablets from the decoction itself. The gap thus identified requires establishment of a standard operating procedure is to be addressed by formulation of an Indian Standard on the subject.

2.2 Safety and quality requirements/parameters are needed to be identified as this is a new dosage form that has been started to be manufactured during the COVID times for easy use and palatability in reaching the masses.

2.3 As many Indian manufacturers are producing these Kudineer tablets since COVID pandemic, this research will identify the Quality and Safety parameters to be included in the Standard.

2.4 Analysis and incorporation of essential parameters in the Standard will benefit both the Industry and Consumers.

3. **OBJECTIVES:**

The Objective of the study is to collect the data/information from primary and secondary sources for Safety and Quality parameters of Kudineer Tablet (Tablet from Decoction).

4. **SCOPE:**

The scope of the project is multifaceted, aiming for a comprehensive understanding of Safety and Quality parameters of Kudineer Tablet (Tablet from Decoction). The Project encompasses the following key elements:

4.1 Literature review:

- To undertake the in-depth study of the existing literature with regard to the Published Documents on Kudineer tablets, regulatory bodies such as PCIM&H, PLIM guidelines, Indian Pharmacopeia guidelines, WHO-GMP guidelines,
- Regulations of Foreign countries such as, Malaysian, Singapore, France, European, American Standards, Sri Lanka, etc to analyse safety and quality parameters of kudineer tablet.
- Analyse Research papers published on the subject, studies conducted by industry or organizations, and any other relevant literature.
- Relevant information on the Database can be taken from the Websites of Ministry of Commerce and Ministry of Ayush.

4.2 Import and Export Analysis:

- Scrutinize the import/export dynamics of the raw materials/products involved in the manufacturing process.
- Investigate the technical regulations governing the product in countries with significant import/export activity.

4.3 Manufacturing Base:

- Study and compile data on the manufacturing base of in India, covering production processes, facilities, and distribution networks
- Gather insights into production capacities, technological capabilities, regulatory compliance, and market dynamics within the Indian context.

4.4 Feedback:

- Construction of a structured questionnaire on the specific requirements of the Kudineer tablet for inputs/feedback from Pharma industries, end users, major exporters and laboratories.
- Conduct Focus Group Discussions and Interviews to collect first-hand information on the practical aspects, and challenges.

4.5 Visit to the Manufacturing Industries (Small, Medium, Large, Micro) and End Users:

- Conducting visits to the 3 manufacturing industries of Kudineer Tablets and the end users covering a spectrum from large-scale to micro-level manufacturers
- Identify and document the diverse manufacturing processes employed for the product
- Investigate and catalogue the testing facilities available for the product

4.6 Labs Visit:

- Visit at least 2 Government approved/NABL Accredited/BIS recognised Laboratories to gain insights into ongoing research, testing methodologies, and innovative practices.
- Document the technological advancements and best practices observed in the Lab visits.

4.7 Data Analysis:

- Analyse the data collected from the literature review, manufacturers' visits, end users, import/export analysis, lab visits, and interviews.
- Identify current patterns and critical insights relevant to the safety and quality parameters of Kudineer Tablets.

5. METHODOLOGY:

In respect of the areas covered under the scope, the methodology encompasses the following:

5.1 Study and comparative analysis of the literature and analyse it.

5.2 Framing and Sending Structured Questionnaires to the relevant industries/ Stakeholders/Consumer Organizations/ End Users for feedback.

5.3 Visiting three Industrial manufacturing units - Observation of the Process facilities and Processes; Visiting at least 2 Government approved/NABL Accredited/Ministry of Ayush recognized Laboratories; Experts' Focus Group Discussion with the help of structured Format; It is anticipated that the research will involve a minimum of 5 visits.

5.4 During the visits, the following information are to be collected:

i. Types of raw materials used
ii. Manufacturing process followed
iii. In – house Test facilities available
iv. Types of test methods used
v. Quality Parameters – Grade wise, if any
vi. Safety and performance Parameters
vii. Frequency of testing employed
viii. In process Quality Control – Checks in Manufacturing Units
ix. Marking requirements
x. Packaging requirements
xi. Shelf Life of the product
xii. Data on domestic consumption /export
xiii. Post Manufacturing Quality Control Tests
xiv. Users feedback is very essential (after identifying user base)
xv. Sustainable procedures followed during production
xvi. Steps taken for energy conservation/efficiency– for e.g., Waste management, by products management, sources of energy used in the manufacturing; use of solar power; etc. (Reduce -Recycle- Reuse)
xvii. Preparing an analytical report on the data/information collected as above.

5.5 Sample testing of the product

5.6 Specifying safety and quality parameter essential for the standard formulation.

5.7 Assessment of test facilities available in the Country.

6. DELIVERABLES:

Considering the scope and objectives, the research shall be taken up by the proposer and prepare a report on the following deliverables:

6.1 Project Report covering all aspects of scope. It shall be a detailed review report specifying safety, quality parameters along with their test methods.

6.2 The following reports shall be appended to the final study report:

6.2.1 Questionnaire report
6.2.2 Users Feedback report
6.2.3 Focus Group Discussion report
6.2.4 Sample Tests report

7. TIMELINES:

The duration of the Project shall be 4 months. The timeline of the project shall start from the date of issue of sanction letter by BIS. The details are as follows:

Time line	Stage
1 month	• Literature review/Desktop Study- collection from books/magazines/ national and international standards/regulation and studying standards to execute the project with appropriate knowledge on the subject. • To devise sampling plan one sample from large, medium and small-scale industry) of each variety of the product
1 month	• Visiting of industrial Manufacturing units and testing labs to collect information • Focus Group Discussions – quality control personnel with the industry/consumer organizations/stakeholders
1 month	• Visiting/Consulting or taking feedback from at least 3 Govt/Private hospitals/clinics. • Examining the results of samples tested • Analyzing data collected through visits and literature survey/desktop Study and questionnaire.
15 Days	Consolidation of data, Submission of analytical report of the project. Draft report to be submitted 15 days before the submission of the final report.
15 Days	Submission of Final report

NOTE: Progress reviews will be conducted as needed to track developments, and to make timely adjustments. In case of delay in submission of final report, justification shall be given by the awardee for consideration by the sectional committee.

8. SUPPORT BIS WILL PROVIDE:

a) To provide National/International ISO standards relevant to traditional Medicine
b) Letters to relevant stakeholders for support to the research project.
c) Coordination and further assistance if required from the member secretary shall be provided.

8. NODAL OFFICER:

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