TERMS OF REFERENCE FOR THE R&D PROJECTS

1. Title: Development of the Performance parameters for commercial Potentizer in Homoeopathy.

2. Background

2.1 Drug dynamization or potentization is the process of the reduction of crude, inert, or poisonous medicinal substances to a state of harmless therapeutic activity. The process involves the dilution of drug substances according to the different scales followed by frictions, either by trituration or by continuous shaking called succussion. The succussion implies powerful, mechanical strokes produced in an identical manner between each dilution to generate the inherent curative power of the drug. As the total number of strokes is incredibly high in higher potencies, a mechanical Potentizer is used for the purpose by the manufacturers.

2.2 The difficulty associated with these potentizers is lack of accuracy, uniformity of impact, and non-standardization.

2.3 The gap thus identified; it is imperative to develop performance parameters of Homoeopathic Potentizer. This R&D project will serve as a basis for developing a uniform standard based on the analysis of developed parameters, which will benefit both the industry and the consumers.

3. Objective

The project's objective is to collect technical data and scientific evidence for various performance parameters of commercial Potentizers used by the homoeopathic industry based on literature review/desk study, survey, industry visit, testing results of the samples, and user feedback.

4. Scope of the project

The scope of this project aims for a comprehensive understanding through the following key components:

4.1. Literature Review:

An extensive review of existing literature, research papers, international standards, and other published information related to using potentizers for succussion in preparing homeopathic dilutions. This review will focus on the types and functionalities of potentizers, performance parameters and standardization efforts, scientific evidence related to the impact of potentization, and existing regulations and guidelines relevant to potentizers.

4.2. Import/Export Analysis:

Collect import/export details of potentizers, including Product specifications and technical regulations of exporting and importing countries, market trends and potential impact on Indian industry, and identification of potential benchmark standards for performance parameters.

4.3. Feedback:

Develop a questionnaire to assess the suitability of potentizers for inputs from manufacturing units, pharmaceutical industries, and laboratories.

4.4. Industry Visits and Focused Group Discussions:

- Observe the potentization process (succussion and trituration),
- Understand the methods and regulations followed by different manufacturers,
- Collect technical data and information on scope, principle, apparatus/equipment, test preparation, testing procedure, instrument diagram, calibration, calculation of results,
- Conduct focused group discussions with industry stakeholders to identify key issues and challenges.

4.5. Manufacturing Base:

Provide technical data and information for developing and validating test methods in the Indian Context based on literature survey, International Standards, manufacturer's practices, lab visits, etc. The technical data shall include but not be restricted to the following information:

- **Scope**: Clearly define the intended use of the developed test methods (e.g., quality control, performance evaluation, research purposes).
- **Terms and Definitions**: Establish consistent terminology for key concepts related to potentization and testing methods. Reference established standards and guidelines.
- **Scientific Principles:** Analyse the scientific rationale behind existing potentization methods and historical practices. Clearly distinguish theoretical assumptions from experimentally validated claims.
- **Apparatus and Reagents:** Identify suitable equipment and reagents for the chosen test methods. Consider factors like accuracy, precision, sensitivity, and cost-effectiveness.
- **Instrument Properties:** Investigate the instruments and components' physical, chemical, and mechanical properties to ensure reliability and reproducibility of testing results. Consider maintenance needs, lifespan, and potential issues like erosion, corrosion, and leaching.
- **Testing Procedures:** Develop detailed and standardized procedures for sample preparation, testing steps, extraction, and filtration, ensuring consistency and repeatability.
- **Calibration and Results:** Establish instrument calibration procedures and clearly define methods for expressing and calculating results. Provide clear interpretations of the generated data.
- **Test Report Format:** Design a standardized format for reporting test results, including essential information like sample details, methods used, results obtained, and data analysis.

- **Additional Considerations:** Explore advanced testing methods like spectroscopic techniques, particle size analysis, and surface characterization techniques, where applicable. Consider factors like environmental conditions, user expertise, and data storage/management.

Note - The technical/scientific data collected shall not violate copyright/patent rights (if any) on the proposed subject.

4.6. Data Analysis:

Preparation of a comprehensive but analytical project report covering all the above and below information.

a) Types of instruments/materials used
b) Manufacturing process followed
c) Designing and moulding requirements
d) In-house test facilities available
e) Types of test methods used
f) Performance parameters* – Grade wise
g) Frequency of testing employed
h) In-process quality control – Checks
i) Marking requirements
j) Packaging requirements
k) Data on domestic consumption/export
l) Post-manufacturing quality control tests
m) Users' feedback (after identifying user base)
n) Patents/IPR if any.

* Performance parameters may consist of, but are not limited to, nature of strokes (number, time gap between strokes, velocity, direction of movement, etc.), mechanical (type of prime mover electrical motor/electromagnet/etc., height, angle, etc.), container used (shape, size, dimensions, level of filling, etc.), accuracy and consistency of dilutions across multiple runs.

5. Methodology

5.1. Collect existing data / Information (refer to 4.1 & 4.2): Identify relevant reports, databases, or studies.

5.2. Collect feedback (refer to 4.3): Design and distribute structured questionnaires to industries/stakeholders/Manufacturing units/Laboratories**.**

5.3. Conduct site visits (refer to 4.4): Schedule visits to pharmaceutical industries/Manufacturing units/Laboratories, etc., to collect data.

5.4. Prepare technical data (refer to 4.5 & 4.6): Generate technical data, test instrument samples, and validate methods.

5.5. Analyse findings and write reports: Use appropriate tools to analyze data and prepare a comprehensive project report.

6. Sampling Plan

Three sample data of the performance parameters shall be collected.

7. Deliverables

- **Study Report:**
  - **Format:** Soft and hard copy versions.
  - **Content:** Comprehensive literature review, international standards, and industry practices related to potentizers. Detailed analysis of identified performance parameters and their impact on product quality and consistency. Development and validation of test methods for evaluating these parameters, including procedures, equipment specifications, and data analysis methods. Discussion of limitations and potential future research directions.
- Questionnaire and user feedback, reports of visits, testing/validation results, focussed group discussion reports, and other relevant documents and information shall be appended to the project report.
- A comparative detail of different potentizers used in Homeopathy.

8. Timelines and Delivery Milestones

The project's duration is 150 days (05 months) from the date of the project award. The stage-wise indicative timelines are as follows:

Method of progress	Activities	Timeline
• Collection from books/magazines/research journals/government reports/ laboratory reports/ national and international standards/regulations and studying standards to execute the project with appropriate knowledge on the subject.	Literature review, desk study	0-30 days (1 month)
• Collection of Technical data/information on test methods and validation (Note: - The test method shall be reviewed by the technical committee AYD 07 before purchase of samples and validation process.)	Visit testing labs	30-75 days (1.5 months)
• Testing of samples/Inter-laboratory validation of test of 3 different samples	Sample collection/purchase, testing	75-105 days (1 month)
• Visiting/consulting or Taking feedback through the questionnaire. • Analysis of all the data collected	Feedback collection, data analysis	105-135 days (1 month)

• Preparation and submission of draft report to BIS		
• Submission of Final report (Draft report to be submitted 15 days before the final report submission).	Final report submission	135-150 days (0.5 month)
NOTE — In case of delay in submission of the final report, the awardee shall give the justification for consideration by the Sectional Committee.		

9. Support from BIS

- Access to all the relevant Indian/ISO Standards or any other standards required during the project.
- Facilitate/introduce the project leader/organization to relevant Industry and industry associations, testing labs, institutes, academia, users, regulators/ministries.
- Facilitate testing of samples in BIS Lab/BIS Recognized Lab.
- Financial assistance as per the R&D Guideline of the BIS.
- Coordination and further assistance from the member secretary, if required, shall be provided.

10. Nodal Person

Dr Kumar Vivekanand
Scientist D and Member Secretary of AYD 07
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