TERMS OF REFERENCE FOR THE R&D PROJECT

[Medical Laboratory Instruments Sectional Committee MHD 10
Medical Equipment and Hospital Planning Department]

1. **Title:** Study of Platelet Incubator with Agitator

2. **Background:**

Platelet incubators with agitators are essential equipment used in the storage and preparation of platelet concentrates for transfusion in the field of healthcare. These devices play a crucial role in maintaining the quality and safety of platelet products, and their specifications have a significant impact on the effectiveness and reliability of these operations. To ensure their endurance and reliability, the development of precise standards is imperative. This study focuses on crafting comprehensive specifications for Platelet incubators and accessories, material composition, design, calibration, and quality control. These specifications will bolster consistency, product quality, and ultimately elevate the standard of care in the medical industry. Recognizing the significance of this topic, it's worth noting that currently, there are no established national or international standards for Platelet incubators. Nevertheless, the criticality of investigating Platelet incubators specifications is underscored by their pivotal role in attaining dependable outcomes. To guarantee such endurance and reliability, the formulation of rigorous and exacting specifications becomes an imperative necessity.

3. **Objective:**

To collect and analyse the relevant data and information from both primary and secondary sources in regard to performance characteristics of Platelet incubators with agitators.

4. **Scope:**

1. Comprehensive collection of data regarding:
   1.1. Assessment the current status of indigenous manufacturing and import of Platelet incubators.
   1.2. Gather information regarding the specifications of Platelet incubators from various of manufacturers.
   1.3. Information about minimum required QC measures being followed currently.
   1.4. Determine the quantities of production and usage of Platelet incubators.
   1.5. Solicit feedback on user experiences with Platelet incubators.
2. Comprehensive literature review of existing standards and guidelines.
3. Collection of scale-wise data on manufacturing base through government sources (websites, reports) or industry associations
4. Collect data of manufacturing base, testing facilities available
5. Collection of data on the following through visits to two industries each of large manufacturer, MSME and one each of government and NABL accredited private testing facility:
   a) Type of raw materials
   b) Varieties manufactured

c) Manufacturing processes
d) In process quality controls
e) Manufacturing facilities (Automation, Industry 4.0)
f) Quality parameters
g) In-house test facilities
h) Parameters tested
i) Marking and labelling
j) Packaging
k) Finished materials quality parameters
l) Sampling plans
m) Sustainability practices [energy consumption, renewable energy sources, sustainable practices, 3Rs (Reuse, Reduce and Recycle), waste management and disposal mechanisms, carbon footprints], future plans.

However, the final plan for physical visits will be made after the data of manufacturing base and testing facilities available has been shared by the proposer to the Nodal Officer of BIS.

6. Consultation with medical and laboratory experts to gather insights and recommendations.
7. Testing data to assess the performance and suitability of different materials and designs.
8. Benchmarking and industry visits to identify best practices in Platelet incubators.
9. Generation of data after testing the product for important characteristics and establishing parameters for Platelet incubators such as:

- **Comprehensive specifications:** Develop clear and comprehensive specifications for Platelet incubators, addressing critical system parameters and performance criteria.
- **Material, Design, and Manufacturing Requirements:** Identify the essential material requirements, design features, and manufacturing standards that are crucial for ensuring sterility, safety, and operational efficiency of Platelet incubators.
- **Reliability:** Investigate how optimized specifications and adherence to quality control (QC) methods can significantly improve the reliability of Platelet incubators.
- **Promote Longevity and Maintenance Efficiency:** Explore how specifying design features and maintenance requirements can extend the lifespan of Platelet incubators and enhance their cost-effective maintenance.

5. Research Methodology:

The project will involve the following research methodologies:

1. Study the literature and analyse it in respect to the scope.
2. Survey the market through structured questionnaires for collecting information in respect tothe scope (manufacturers, QA/QC professional, End users etc).
3. Contact the relevant organizations and associations (Industry/ user associations) for gathering the data.
4. Visits to the manufacturing units to observe and collect data as per the scope.
5. Discussion with focused groups (Quality control personnel and person responsible formanufacturing) through structured questionnaires

6. Samples shall be tested in such a manner that there is sufficient data to compare the performance and the range of varieties being manufactured by any manufacturer. For this purpose, samples from the lowest, middle, highest range shall be preferably considered for testing. In case of non-availability of samples during the visit or tests are time consuming in nature, the test results of the samples already tested and documented by the manufacturer may be collected for the purpose of analysis.
7. Comprehensive reporting on all aspects.

6. Expected Deliverables:

a) A comprehensive report consisting of outcomes of the study covering all aspects of the scope, shall be submitted in both paper and digital formats.
b) Along with the final report the survey formats and responses, questionnaires, results of testing,reports of visits, other relevant documents/ information to be appended.

7. Delivery Milestones and Review Process:

a) The duration of the project shall be three months from the date of award of the project.
b) An interim report indicating the review of the literature, desktop research and sampling plan shall be submitted in 15 days from award of the project.
c) Draft report shall be submitted by the end of 60 days from award of the project.
d) Final report shall be submitted within 90 days from award of project.

8. Support from BIS:

Upon specific request, the following support will be extended:

- Access to a pool of experts necessary for conducting research project activities.
- Access to the pertinent published standards essential for conducting research project activities.

9. Nodal Point:

Member Secretary, MHD 10 may be contacted for more clarification on the R&D project (Email address: mhd10@bis.gov.in)