Probiotics is a broad term used for friendly bacteria, more appropriately defined as live microorganisms, which when administered in adequate amounts confer a health benefit on the host. These are increasingly used in present scenario due to their wide range of health benefits accompanied with low cost and negligible side effects. Theoretically these beneficial microorganisms can be used to treat a range of clinical conditions that have been linked to gastrointestinal problems like irritable bowel syndrome, traveler’s diarrhea, inflammatory bowel disease, oral diseases like tooth decay and periodontal disease, various other infections including vaginal infections, possibly skin infections and could also conceivably be used for preventing autoimmune like disorders.

Despite of having beneficial effect of probiotics, status of the probiotics as a component of food is not clear in health industry whether they are used as preventive or curative therapy as most of probiotic bacteria are sold over-the-counter as dietary supplements or in food products such as yogurt, as well as in the pharmaceutical preparations too. What so ever be the category of probiotic products, industry based on these products has witnessed tremendous growth in the market around the globe which necessitated encountering formidable challenges posed due to lack of appropriate studies required for the development of probiotics as modern therapeutic drugs. Currently probiotic based industries are flooding the market with a range of commercial probiotic products and these probiotics are much more preferred over the conventional dosage forms due to their wide therapeutic benefits with negligible side effects but lack of standardization is becoming a major threat while establishing the credibility of probiotic based products. Bringing harmonization of standards for global acceptance will regulate these products with quality control and assurance which ultimately leads to increase in probiotic market value without false claiming on probiotic products as a less expensive alternative of many medicines.

For acceptance of probiotics based products with uniform quality, greater safety of patients, with established scientific evidences for holistic therapeutic benefits in treatment of various ailments, drafting of comprehensive regulatory guidelines is the need of the hour. So in this context, already prescribed guidelines from various xxx
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countries have been collected for common point selection and reviewed critically. It
has been reviewed that probiotics are categorized under various categories like dietary
supplements, natural health products; food supplements etc. in different countries and
most of the countries have established the guidelines for probiotic food instead of
probiotic drugs as their use as food products is well established. Along with this it has
been reviewed that most of the countries have framed the guidelines in accordance to
the products manufactured in that country particularly and majority are considering it
under functional foods. But therapeutic effect intended by probiotic food articles is
beyond the limit of ordinary food articles and hence it is strongly felt that the use of
these products must be strictly regulated by establishing all the necessary guidelines.
With respect to probiotics, not even a single country has covered all the aspects
including identification, evaluation, manufacturing, approval, identifying and defining
data for substantiating health claims, and safety assessment studies. Hence to bring
harmonization of standards, a modified appropriate definition, categorization of
probiotics, a draft document for identification up to genus/species/strain level of
probiotic microbes followed by a draft document for evaluation of probiotic
formulations, for the production of the probiotics formulation including GMP aspects
as well as for approval process related to Investigational New Drug approval and New
Drug approval on the basis of GRAS probiotic, live microbes other than GRAS and if
new microbe with probiotic potential has been compiled. Another compiled
associated draft documents include identifying & defining data for substantiating
health claims for deciding dose and duration of probiotic use, viability at target site
and effectiveness, In vitro tests suitable for evaluation of probiotics as well as their
safety assessment.
So draft of comprehensive regulatory guidelines for probiotics has been compiled,
which can have international acceptance. The proposed guidelines are framed to clear
existing ambiguities related to status and approval process for probiotic based
products by covering all related aspects like identification and evaluation of
microorganisms with probiotic potential up to strain level, good manufacturing
processes for production, quality control parameters, dossier development and related
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documentations for clinical trials and approval of probiotic products as per their intended use, marketing and labeling requirements etc.
The proposed work is to take lead in current international scenario by framing a comprehensive and harmonized guideline to be accepted universally. The guidelines so developed will result in harmonization of standards for global acceptance, strictly regulated probiotic based products with quality control and assurance, single definition of probiotics and consistent terminology, clear cut demarcation of regulatory probiotic categorization, increased customer acceptance and commercial success of probiotic product, no false claiming on probiotic products, a less expensive alternative of many medicines with negligible or no side effects, increased customer acceptance, which ultimately leads to increase in probiotic market value, reduced flooding of international market with misbranded & counterfeit products, awareness of the products quality, safety and efficacy