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Perspective

Global Comparison of Sustainability Evaluation Factors and Techniques for Finished Herbal Products

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DESCRIPTION

Achieving consistent quality for herbal goods is difficult due to their physiochemical complexity and inherent variabilities. Quality consistency of drug products is crucial to provide predicted therapeutic actions. For stability testing parameters and testing practices for herbal products maintained under suggested circumstances, regulatory agencies from all over the world have established regulations or guidelines. The guidelines and regulations issued by five international organizations and 15 nations, namely the Association of Southeast Asian Nations (ASEAN), the Eurasian Economic Commission (EEC), the European Medicines Agency (EMA), and the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use, detail the testing parameters and procedures for finished herbal products (ICH).

The testing parameters (temperature and relative humidity) used for long-term, expedited, or intermediate testing were included in the rules and regulations. Physical, chemical, and biological stability tests were compared between various dosage forms. For the international harmonization of herbal product quality evaluations, comparisons of foreign rules and standards addressing stability testing are essential. This review contributes to our awareness of the global context for verifying the quality of herbal products in relation to storage.

To ensure therapeutic activity, the quality of herbal products must be maintained during storage. Herbal products are subjected to rigorous storage conditions that are stressed by heat, moisture, light, oxygen, different physical and chemical conditions (such as vibration or freezing), and container-related factors. Stability testing is used to assess how herbal products maintain their properties under these conditions. Because herbal products can be created in a variety of dosage forms (such as tablets, powders, or liquids for oral administration or as creams for external application), it is necessary to use the right techniques when testing the stability of different dosage forms.

Testing for properties susceptible to storage conditions, such as physical (organoleptic characteristics, physical condition, particle size, etc.), chemical (assays of active components, pH, identification, etc.), microbial, and toxicological properties can be used to determine the stabilities of finished herbal products.

Stability testing should be used to evaluate the shelf life of herbal products because these attributes can all impact their quality, safety, or efficacies.

Furthermore, as herbal products are typically designed to comply with national standards, several stability techniques are employed in various nations. Recently, the need of global stability testing harmonization has been highlighted in the context of developing herbal drugs, but acceptance of worldwide standards can only be made possible by exchanging national knowledge and experience.

The guidelines and regulations issued by international organizations, such as the Association of Southeast Asian Nations (ASEAN), the Eurasian Economic Commission (EEC), the European Medicines Agency (EMA), the International Council for Harmonization of Technical Requirements for the Pharmaceuticals for Human Use (ICH), and the World Health Organization (WHO), are therefore detailed in the present study.

To maintain the quality of finished herbal products (traditional medicines) in designated containers that adhere to advised storage conditions and periods, ASEAN sets stability testing recommendations. According to these recommendations, final products' physical, chemical, and microbiological properties must be taken into consideration. The following are the dose form specifications: Pills (coated and uncoated; organoleptic characteristics, assay, hardness, friability, dissolution, disintegration, water content, and microbial content); oral powders (organoleptic characteristics, assay, water content, and microbial content); hard capsules (organoleptic characteristics, assay, dissolution, disintegration, water content, and microbial

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content); soft capsules (organoleptic characteristics, assay, dissolution, disintegration, and microbial content, granules or particle-size variation, and resuspendability); suspensions (organoleptic characteristics, assay, viscosity, pH, and microbial content); solutions (organoleptic characteristics, assay, viscosity, pH, and microbial content); emulsions (organoleptic characteristics, assay, viscosity, pH, and microbial content); semisolid preparations (ointment, cream organoleptic characteristics, assay, water content, and microbial content).

CONCLUSION

For herbal medical preparations to be registered under the EEC's rules for pharmaceutical substances and medicinal products, storage stability tests must be completed. Preservative contents (such as antioxidants and antibacterial preservatives) and delivery device capabilities (such as dose distribution system) are all evaluated as part of the stability testing process.

All medicinal items must be tested for their appearance, active ingredients, degradation products, preservatives, and antioxidants according to the requirements. According to the note for guidance on stability testing of new drug substances and products (CPMP/ICH/2736/99), the "Guideline on stability testing of new veterinary drug substances and medicinal products (CVMP/VICH/899/99)," and the "Guideline on stability testing of existing active substances and related finished products (CPMP/QWP/122/02 and EMEA/CVMP/846/," the EMA mandates product-specific storage stability testing of herbal medicinal products for quality assurance.