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ICH Stability Study Regulations and Comparison Studies with Indian Stability Studies

RUNNING TITLE

Harmonizing ICH Stability Study Guidelines: A Comparative Analysis with Indian Stability Studies

ROOPASHREE G L

ABSTRACT

In the pharmaceutical industry, stability testing is of paramount importance, ensuring that drug products maintain their quality and efficacy over time. Factors like temperature, humidity, light exposure, and packaging materials can influence the stability of pharmaceuticals. The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) plays a crucial role by establishing globally recognized guidelines for stability testing and promoting harmonization between regulatory authorities and the industry. In India, the Central Drugs Standard Control Organisation (CDSCO) outlines specific regulations for stability testing, emphasizing parameters, storage conditions, sampling methods, and analytical procedures. While adhering to CDSCO guidelines, pharmaceutical companies operating in India benefit from conducting stability studies in line with ICH standards, enhancing the global acceptance of their products and facilitating smoother registration processes in multiple countries. Rigorous stability testing ensures that pharmaceuticals consistently meet quality standards, remain safe, and remain effective throughout their shelf life.

KEYWORDS

ICH, stability study regulations, pharmaceutical products, drug development, shelf-life

ABBREVIATIONS:

ICH - International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use

CDSCO - Central Drugs Standard Control Organisation

CTD - Common Technical Document

MedDRA - The medical dictionary for regulatory activities

ESTRI - Electronic Standards for the Transfer of Regulatory Information

GMP - Good Manufacturing Practice

INTRODUCTION

Stability studies are an essential part of the medication development process because they evaluate the effects of external conditions on the potency, quality, and shelf life of pharmaceuticals[1]. These studies provide essential data for establishing product expiration dates and storage conditions[2].The ICH guidelines, particularly the ICH Q1A(R2) guideline, outline the requirements for conducting stability studies on new drug substances and products[3]. They cover aspects such as study design, storage conditions, sample analysis, and data evaluation [4]. Compliance with these guidelines ensures adherence to global standards and facilitates regulatory compliance in various regions[5].

Comparing the ICH stability study regulations with the Indian stability study practices reveals both similarities and differences. Areas of comparison include study design, storage conditions, sample analysis, and data evaluation.

Understanding these variations is crucial for pharmaceutical companies in India as they strive to harmonize their stability study practices with global standards. Harmonizing stability study practices with the ICH guidelines may pose challenges for companies in India[6]. They must carefully assess the differences between the ICH and Indian guidelines and adjust their study protocols accordingly. Compliance with international standards not only ensures regulatory compliance but also enhances the credibility of the data generated during stability studies[7].

OVERVIEW OF ICH GUIDELINES

The International Council for Harmonisation (ICH) is a global endeavor that unites regulatory bodies with the pharmaceutical sector to create norms for the creation, registration, and post-approval of pharmaceutical products[6]. The creation of recommendations for the stability assessment of pharmaceutical goods is one of ICH's primary areas of interest[8]. The rules, which are founded on the ideas of Good Manufacturing Practises (GMP), mandate that stability tests be carried out on pharmaceutical goods at certain points during their shelf life to guarantee that they continue to be safe, effective, and of a satisfactory caliber [6,8].

The criteria for assessing the outcomes of these studies, as well as the kinds of stability studies that ought to be carried out, such as long-term and accelerated stability studies, are outlined in the ICH guidelines[8]. The guidelines also provide guidance on the testing conditions, sample size, and statistical analysis required for stability testing. The ICH standards are accepted by regulatory bodies in the US, Europe, and Japan and apply to all kinds of pharmaceutical goods, including medications, biologics, and vaccines[9]. Global regulatory agencies typically demand compliance with the ICH principles, and new pharmaceutical product approval frequently depends on it[10]. A stability study is frequently used to suggest the best ways to store products. It also emphasizes the need for the potency period or expiration date of the drug to be displayed on the outside of the drug's packaging for marketing purposes[11]. This suggests that the drug is safe and effective up until the date specified on the outside of the packaged product and that shelf life may be indicated on the label to verify that the drug is safe and effective for the duration of its shelf life[12]. Stricter regulations are implemented to get the best possible outcome in all possible situations where the medication may be used within its shelf life. Therefore, stability studies can be carried out using sound scientific concepts, after thoroughly understanding the current laws governing the subject, and while considering climate zones [13,14].

Table 1: Stability Zones Climatic Condition[14]

Stability Zones	*Climatic Condition*
Zone I	Temperate Zone
Zone II	Mediterranean /Sub-tropical Zone
Zone III	Hot Dry Zone
Zone IV A	Hot Humid Tropical Zone
Zone IV B	Hot/Higher Humidity

GUIDELINES FOR STABILITY STUDIES

Guidelines: To specify the stability data that is required for the registration of new drug substances and products within the ICH regions, several guideline documents were created. According to these guidelines, stability studies conducted in support of product registration should be compliant[15].

The guidelines of ICH are broadly categorized into four types.

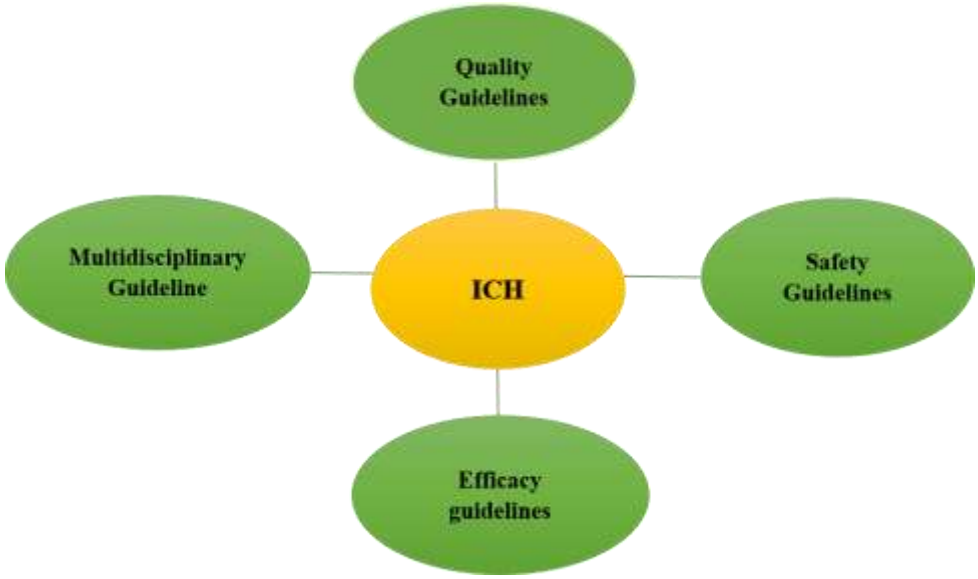

Figure 1: The Guidelines of ICH Categorization[16]

"Q" Guidelines: These are standards for quality. The accomplishments of harmonization within the standard area include significant turning points such as how to interpret studies on the stability of medications, establish minimum thresholds needed to test for impurities in the medications under study, and evaluate the quality of products produced by Good Manufacturing Practice (GMP) risk management[17].

S" Guidelines: A thorough set of safety guidelines has been developed by ICH to identify possible hazards such as carcinogenicity, genotoxicity, and reprotoxicity. A non-clinical testing approach for determining the QT interval prolongation liability—the main reason behind drug withdrawals in recent years—has just been discovered[18].

E" Guidelines: Effectiveness guidelines guiding the process of planning and conducting studies, the safety precautions followed, and the report submission about the clinical trials conducted. Furthermore, it regulates the several significant categories of pharmaceuticals obtained through the application of diverse biotechnological techniques. Furthermore, the application of pharmacokinetics and pharmacogenomics methodologies in the production of optimal pharmaceuticals[19].

"M" Guidelines: Cross-cutting topics that don't work clearly inside the standard groups overseeing the Safety and efficacy groups are known as multidisciplinary guidance. It consists of the Common Technical Document (CTD), and the International Conference on Harmonization of Medical Terminology Medical. The Medical Dictionary for Regulatory Activities (MedDRA), and the creation of Electronic Standards for the Transfer of Regulatory Information (ESTRI)[20].

Table 2: Codes and titles used in ICH Guidelines[21]

ICH Code	Guideline title
Q1A	Stability testing of New Drug Substances and Products (Second Revision)
Q1B	Stability testing: Photostability testing of New Drug Substances and Products
Q1C	Stability testing of New Dosage Forms
Q1D	Bracketing and Matrixing Designs for stability testing of Drug Substances and Products
Q1E	Evaluation of stability data
Q1F	Stability data package for Registration Applications in Climatic Zones III and IV
Q5C	Stability testing of Biotechnological/Biological Products

Table 3: CPMP Guidelines for Stability[22]

CPMP code	Guideline title
CPMP/QWP/576/96 Rev. 1	Guideline on Stability Testing for Applications for Variations to a Marketing Authorization
CPMP/QWP/6142/03	Guideline on Stability Testing for Active Substances and Medicinal Products Manufactured in Climatic Zones III and IV to be marketed in the EU
CPMP/QWP/609/96 Rev. 1	Note for guidance on Declaration of Storage Conditions for Medicinal Products Particulars and Active Substances
CPMP/QWP/122/02 Rev. 1	Note for Guidance on Stability Testing of Existing Active Substances and Related Finished Products
CPMP/QWP/072/96	Note for Guidance on Start of Shelf Life of the Finished Dosage Form
CPMP/QWP/2934/99	Note for Guidance for In-Use Stability Testing of Human Medicinal Products
CPMP/QWP/576/96	Note for Guidance on Stability Testing for a Type 2 variation to a Marketing Authorization
CPMP/QWP/ 159/96	Note for Guidance on Maximum Shelf-Life for Sterile Products after First Opening or Following Reconstitution

Climatic Zone and Stability Study Conditions as per ICH Guidelines

Traveling the world causes the climate to shift, resulting in varying climate conditions in different parts of the world[23]. Climate has an impact on a medicinal product's stability. The pharmaceutical product's stability study must therefore be conducted while considering the nation's climate. Zone I, II, III, and IV of the ICH stability study criteria classify the world's climate into four distinct zones. Zone IV A and Zone IV B are the two further divisions of Zone IV[24].

Table 4: Long-Term Stability Testing Conditions [25]

Stability Zone	Temperature	Humidity	Minimum Duration
Zone I	21°C ± 2°C	45%RH ± 5% RH	12 Months
Zone II	25°C ± 2°C	60%RH ± 5% RH	12 Months
Zone III	30°C ± 2°C	35%RH ± 5% RH	12 Months
Zone IV A	30°C ± 2°C	65%RH ± 5% RH	12 Months
Zone IV B	30°C ± 2°C	75%RH ± 5% RH	12 Months

Since the world's temperatures and humidity vary widely, distinct regions are classified as different climatic zones. According to the stability zone, ICH has established various stability conditions for investigations[26]. The following is a description of the drug product's stability research condition:

Table 5: Intermediate and Accelerated Stability Testing Condition:[27]

Study	Storage Condition	Minimum Duration
Intermediate Term	30°C±2°/65% RH ± 5%RH	6 Months
Accelerated	40°C ± 2°C/75%RH ± 5%RH	6 Months

Table 6: Drug Products intended for storage in a refrigerator:[27]

Study	Storage Condition	Minimum Duration
Long Term	5°C± 3°C	12 Months
Accelerated	25°C ± 2°C/60%RH ± 5%RH	6 Months

Table 7: Drug Products intended for storage in a freezer:[27]

The drug product's shelf life, the drug substance's retest period, and the ideal storage conditions are all determined by successful stability research. Ensuring patients receive safe and effective medication is another important aspect of a successful stability study[28].

THE DESIGN AND CONDUCT OF THESE STABILITY STUDIES

Ensuring the safety, efficacy, and quality of pharmaceutical goods over their whole shelf life depends heavily on the planning and execution of ICH stability studies[29]. Here are some key factors to consider in designing and conducting ICH stability studies:

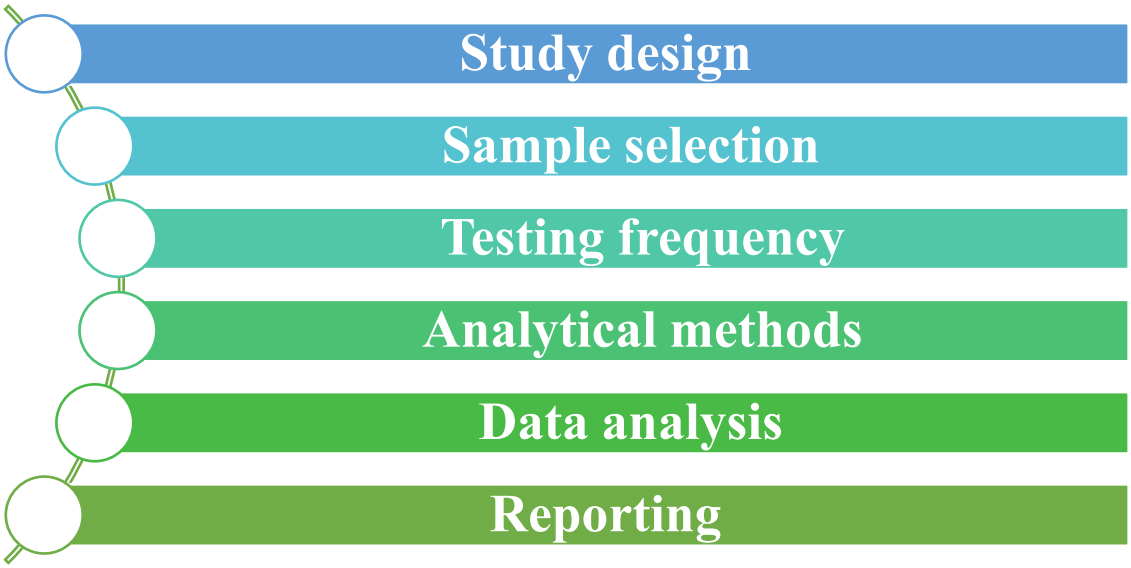

Figure 2: Key factors to consider in designing and conducting ICH stability studies [30]

Study design: The study design should be based on the ICH guidelines and consider the product's characteristics and intended use. The study should be conducted over a sufficient duration to evaluate the product's stability under different environmental conditions[30].

Sample selection: The samples chosen should reflect the range of batches and package configurations used in the drug product's production process. Samples ought to be kept in controlled environments, with documentation of the storage circumstances required[31].

Testing frequency: The stability profile and intended use of the product should determine how frequently it is tested. Depending on the product's shelf life, stability testing is usually done at various intervals, such as 0, 3, 6, 9, 12, 18, 24, and 36 months[32].

Analytical methods: Drug stability should only be assessed using approved analytical techniques with the right amount of accuracy, specificity, and sensitivity. Any modifications to the drug product, such as degradation products or potency alterations, should be detectable by the procedures[33].

Data analysis: To assess the product's stability in various environmental settings, the data gathered from the stability studies should be examined. The product's shelf life and storage requirements should be determined using the findings[34].

Reporting: Documentation and reporting of the stability study results to regulatory bodies are required. The study design, sample selection, testing frequency, analytical techniques, and data analysis should all be covered in the report[35].

OVERVIEW OF STABILITY STUDIES IN INDIA

In India, the term "stability studies" refers to the scientific study of the physical, chemical, and microbiological characteristics of pharmaceuticals to make sure that their effectiveness, safety, and quality are maintained throughout time[36]. Stability studies are essential to the creation and approval of novel medications as well as to the post-approval surveillance of goods that are already on the market[37]. All new drug products must undergo stability studies, according to the CDSCO, an Indian regulatory body. The findings of these studies must be included in the drug registration dossier[38]. Drug products are usually subjected to a variety of environmental factors, including temperature, humidity, and light, and their physical and chemical properties are tracked over time as part of stability studies[39]. Finding any deterioration or modifications to the drug's characteristics that might compromise its efficacy or safety is the aim. ICH rules, which offer a uniform framework for carrying out stability studies and reporting the results, regulate stability studies in India[36]. The number of batches, testing frequency, storage conditions, and approval criteria are just a few of the minimal requirements for stability studies that are outlined in the ICH recommendations[37].

There are typically three types of stability studies conducted in India, as per the guidelines provided by CDSCO. These are:

Accelerated Stability Studies: The purpose of these investigations is to produce a faster pace of drug substance and/or drug product breakdown. The objective is to identify the mechanisms of degradation and assess how degradation affects the drug product's efficacy, safety, and quality. To simulate degradation that might take place over an extended period, these experiments are carried out at higher temperatures and humidity levels than the real storage conditions[40]

Intermediate Stability Studies: The ambient storage conditions used in these investigations are 25°C ± 2°C in terms of temperature and 60% ± 5% in terms of relative humidity. These investigations aim to determine the drug product's shelf life, detect any possible degradation, and assess the effect of storage on the drug product. [41]

Long-Term Stability Studies: These tests are carried out over longer periods using storage parameters, such as humidity and temperature. The objective is to ascertain the drug product's degradation routes, assess the stability of the product over its shelf life, and establish the product's shelf life. These investigations are carried out under the product's suggested storage setting[42].

COMPARISON OF ICH WITH INDIAN STABILITY STUDIES

Table 8: Comparison of ICH with Indian Stability Studies

Criteria	ICH Stability Studies	Indian Stability Studies
Scope	Global[55]	India-specific[56]
Temperature	25°C/60% RH, 30°C/65% RH, 40°C/75% RH[57]	30°C/65% RH, 30°C/75% RH, 40°C/75% RH[58]

Humidity	Different humidity levels are used[59]	Humidity levels are the same as in ICH studies[60]
Time period	Long-term (12 months), intermediate-term (6 months), and accelerated (3 months)[61]	Long-term (12 months), intermediate-term (6 months), and accelerated (3 months)[61]
Products tested	Pharmaceuticals, biopharmaceuticals, and medical devices[54]	Pharmaceuticals, biopharmaceuticals, and medical devices[54]
Regulatory bodies	FDA, EMA, and other global regulatory agencies[55]	Drug Controller General of India (DCGI)[55]
Container Closure	Multiple container types allowed (e.g., glass, plastic)[62]	Only one container type (e.g., HDPE) allowed[63]
Light Exposure	Required for photosensitive drugs[64]	Not required for all drugs[65]
Sample Size	Minimum of 12 units per time point[66]	Minimum of 6 units per time point[67]
Excursion Testing	Not required, but recommended if applicable[68]	Required for all batches[67]
Intermediate Testing	Optional[66]	Required for all batches[67]
Stability Indicating Method	Required[56]	Not required for all drugs[56]
Forced Degradation Studies	Required[54]	Not required for all drugs[54]
Reporting	Detailed stability data and statistical analysis required[57]	Less detailed reporting required[54]

Case Study:

Suppose a pharmaceutical company wants to conduct stability studies for a new drug product for registration in India and global markets. The company can conduct stability studies following the guidelines set by ICH or Indian regulatory bodies[43].

If a company chooses to follow the ICH guidelines, they conduct stability experiments in three distinct humidity and temperature ranges:

Table 9: ICH Stability Guidelines[44]

Study	Storage Condition	Minimum Duration
Long Term	25°C/60%RH	12 Months
Intermediate Term	30°C/65%RH	6 Months
Accelerated	40°C/75%RH	3 Months

The purpose of these studies is to evaluate the product's stability over a specified period and under varying environmental conditions, simulating real-life storage and transportation scenarios[45].

On the other hand, if a company chooses to follow the guidelines specific to India, they may conduct stability studies at slightly different conditions. The Indian guidelines recommend stability studies at,[46]

Table 10: Indian Stability Guidelines[47]

Study	Storage Condition	Minimum Duration
Long Term	30°C/65%RH	12 Months
Intermediate Term	30°C/75%RH	6 Months
Accelerated	40°C/75%RH	3 Months

Regulatory requirements and the market in which the drug is intended for marketing may influence the decision to follow Indian or ICH criteria[48]. Adherence to relevant guidelines is crucial for the company to guarantee the drug's quality, safety, and efficacy during its entire shelf life[49].

During stability studies, samples of the drug product are stored under controlled conditions, and regular testing is performed at predetermined intervals to assess various parameters. These parameters may include physical appearance, chemical composition, impurity profile, potency, and other relevant quality attributes[50]. The collected data allows for the evaluation of the product's stability profile and the determination of appropriate storage and expiration conditions[51].

Stability studies provide valuable information to regulatory authorities, ensuring that the biosimilar product remains stable and maintains its quality throughout its shelf life[52]. These studies contribute to the establishment of storage and handling instructions and assist healthcare professionals in making informed decisions regarding product usage, storage, and expiration[53].

Both sets of stability studies would provide important information about the stability of the drug product under different storage conditions and help ensure that it is safe and effective for patients[54].

CONCLUSION

In conclusion, the pharmaceutical sector must comprehend the rules and policies guiding stability studies to guarantee the efficacy, safety, and caliber of its goods. Stability studies in India are conducted by the ICH principles, which offer a uniform framework with some modifications. By considering the unique climatic conditions and product diversity in India, the regulatory authorities aim to establish robust stability testing programs. Pharmaceutical companies operating in India must navigate these guidelines and meet the specific requirements to ensure compliance and deliver safe and effective products to the market.

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