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AUTOMATIC ALERT GENERATION SYSTEM FOR STABILITY STUDIES OF PHARMACEUTICAL FORMULATIONS OF DRUGS

Dr. Sunil Rathod
Department of Computer Engineering,
Dr. D Y Patil School of Engineering, Lohegaon, Pune, India
sunil6kr@gmail.com

Dr. Soumitra Das
Department of Computer Engineering,
Indira College of Engineering and Management, Pune, India
soumitra_das@yahoo.com

Dr. Vikas Nandgaonkar
Department of Computer Engineering,
Indira College of Engineering and Management, Pune, India
vikas.nandgaonkar@gmail.com

ABSTRACT

The pharmaceutical industry relies on the stability of drug formulations to ensure the safety and efficacy of medicines. However, monitoring and managing the stability of pharmaceutical formulations is a complex and critical task. The Stability of pharmaceutical products is considered as pre-requisite for its acceptance and approval as a product. The product quality, safety and efficacy throughout the shelf life of drugs are important things to be maintain along with the stability. The study of product quality, safety, efficacy and the stability are required to be conducted in a planned way following the guidelines of International Council for Harmonization of Technical Requirements of Pharmaceuticals for Human Use (ICH), World Health Organization (WHO) or other local government agencies. Until now this task was done physically by the drug experts. This paper presents the development and implementation of an Automatic Alert Generation System for Stability Studies of Pharmaceutical Formulations of Drugs designed to streamline and enhance the stability monitoring process for pharmaceutical formulations. The application generates an alert automatically after detecting the shelf life of the given drug.

Keywords : Pharmaceutical formulations, stability studies, automatic alert system, drug stability, pharmaceutical industry

1. INTRODUCTION

In this day and age, when images serve as strong vehicles for communication, information distribution, and creative expression, making sure that is maintained is quite important. However, the worrying rise in image manipulation and forgeries brought about by the widely accessible sophisticated digital editing tools is raising doubts about the validity of visual media. To address this pressing issue, researchers and technicians have been working nonstop to create advanced forgery detecting systems. One of the most promising strategies is to use Convolutional Neural Networks (CNNs), which have demonstrated remarkable performance in image processing and detection of patterns applications.

By providing a novel CNN-based method for identifying image forgeries, this work seeks to

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support ongoing efforts to maintain the transparency of visual media. Using the well-known "CASIA v2.0" dataset, which is well-known for its meticulous benchmarking of image

alterations, the suggested method is thoroughly tested to see how accurate and useful it is in detecting a wide range of adjustments.

Pharmaceutical formulations are the backbone of the pharmaceutical industry, serving as the essential bridge between the **A**ctive **P**harmaceutical **I**ngredients (APIs) and the final medicinal products consumed by patients. These formulations encompass a diverse range of dosage forms, such as tablets, capsules, syrups, injections, creams, and more, each tailored to meet specific patient needs and drug delivery requirements. The primary goal of pharmaceutical formulations is to ensure the safe, effective, and convenient delivery of medicinal compounds to patients.

This involves several key considerations:

Drug Solubility and Bioavailability:
Formulators must determine the most suitable form for the drug, considering its solubility and how readily it can be absorbed by the body. Techniques such as micronization or use of solubilizers may be employed to enhance bioavailability.

Dosage Form Selection:
The choice of dosage form depends on factors such as the patient's age, medical condition, and preferences. For instance, liquids or chewable tablets may be preferred for paediatric patients, while elderly individuals might benefit from extended-release formulations.

Stability and Shelf-Life:
Maintaining the stability of the formulation over its shelf-life is critical to ensure that patients receive consistent and effective medication. This involves selecting appropriate excipients and packaging materials and conducting stability studies.

Drug Delivery Systems:
Advances in pharmaceutical science have led to the development of novel drug delivery systems, including controlled release, transdermal patches, and nanotechnology-based carriers. These systems can improve patient compliance and reduce side effects.

Regulatory Compliance:
Pharmaceutical formulations must adhere to strict regulatory guidelines and quality standards to ensure safety and efficacy. Regulatory bodies, such as the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA), play a crucial role in approving and monitoring pharmaceutical products.

Patient-Centric Considerations:
Formulations should also consider patient preferences and convenience, as these factors can impact medication adherence. For instance, paediatric formulations may need to be palatable, and elderly patients may require easy-to-swallow options.

In the above considerations, shelf life of the product is very important factor to decide the stability

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of the drugs. The shelf life is the period for which the drug is kept to reduce it to 90% of its original concentration. Thus, the stability of the drug is evaluated using shelf life and in technical term it is expressed as expiry date of a drug. The various environmental factors on which expiry of the pharmaceutical dosage depends are temperature, humidity, light, radiations etc. There are many other factors like physical and chemical active substances used in the formulation, the nature of

container-closures and the storage conditions are also equally important.
The developmental stages of drugs include pharmaceutical analysis and stability studies that are important to determine and assure the identity, potency and purity of ingredients of the drugs.[2] The other factors that affect the stability if drugs are growth of microorganisms in non-sterile products and changes in preservative efficacy which are also important parameter to be considered.[3] The regulatory approval of any drug or formulation can be done based on data generated during the stability testing.[4]

The stability studies have been given significant importance because of following reasons. [1,5]

- Instability of the active drug product can lead to undermedication due to reduction of the drug in the dosage form.
- It can lead to toxic products during the breakdown of the drug or product.
- During marketing from one place to another during transport, the drug has the ability to change its physical properties.
- Instability can be caused by a change in physical appearance, as the principles of kinetics are used in predicting drug stability, it differs between kinetics and stability studies

Types of Stability Studies on Drug Substances: [1, 5,6]
A comprehensive Unified Pharmacopial Protocol (USP) has defined the criteria for acceptable levels of stability studies for various different types of stabilities which are discussed in this section.

Physical stability:
The original physical properties such as appearance, color, solubility, palatability, suspendability are preserved. Physical stability can affect the uniformity and rate of release and is therefore important for product efficacy and safety.

Chemical stability:
It is the tendency to resist its change or decomposition as a result of reactions that occur under the influence of air, atmosphere, temperature, etc.

Microbiological stability:
Microbiological stability of drugs is the tendency towards resistance to sterility and microbial growth. The antimicrobial substances used in the preparation retain their effectiveness within the specified limits. This microbiological instability could be dangerous for a sterile drug product.

Therapeutic stability:
The therapeutic effect (Drug Action) remains unchanged.

Toxicological stability:

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Toxicological stability has no significant increase in the toxicity occurs.

Types of stability studies [1]
To test the drug product for longer periods under varying conditions of temperature and Relative Humidity (RH), stability studies are very important. long term stability studies are of prime importance if the drug is to be distributed in different geographical regions and if shipping is required for transportation. Long term stability studies are carried out by testing the sample at specific time intervals by changing the conditions of external parameters accordingly, with the

objective to determine shelf-life of the drug product. Stability studies can be categorized mainly four types, i.e. Long-Term stability, Intermediate stability, Accelerated stability and In-use stability Studies. Table-1 depicts the type of stability studies and its storage conditions with respective time.

Table 1: Types of Stability Studies [23]

Types of Stability Studies	Storage Conditions	Minimum Time Period (Months)
Long-Term	25±2°C and 60±5% RH or 30±2°C and 65±5% RH	12
Intermediate	30±2°C and 65±5% RH	6
Accelerated	40±2°C and 75±5% RH	6

The stability studies depicted in table-1 are discussed chronologically in this section.

Long-Term stability:
Immediate stability tests are usually performed under long-term tests to allow significant degradation of the product under approved storage conditions by examining the run at 25°C / 60% RH or 30°C / 65% RH. Ideally, 12 months of data can be accepted for tests, but 6 months of data can also be sent to the registry, continuing until the end of its shelf life. The parenteral stability of the drug is ensured by storing it in the refrigerator at 28°C. The actual test should be performed at 20°C. [22]

Intermediate Stability Tests:
Interim studies of stability tests are performed at 30°C / 65% RH. These studies are designed to measure the degradation or physical change of the prepared drug over the period time. The drug can be stored at 25°C for a long time for examination. Fast runs are unacceptable under normal conditions (40°C / 75% RH). Ideally 6 months of information should be created for best analysis. [22]

A. Guidance of Stability Studies
Regulatory authorities in many countries have made safety guidelines for the manufacturers to ensure that the most stable drugs and medicinal products are produced, distributed and made available to the public. First such guidelines are published in the 1980s to covers basic security issues, secure application profiles, and steps for using them in manufacturing the medicinal products. The main goal of these regulatory guidelines is to ensure uniformity in testing among manufacturers. These are guidelines are made consistent (harmonised) with the International Council for Harmonization (ICH) with the aim of making a common registration of products in

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other countries thus reducing trade barriers. ICH established in 1991, is a collaboration of industry and regulatory bodies in the European Commission, the United States and Japan that establish distinct standards for the quality, safety and efficiency of APIs and products. These guidelines are called Q, S, E, and M guidelines as it includes Quality, Safety, Efficiency, and Multidisciplinary aspects.

The ICH guidelines do not cover the extreme weather conditions observed in many countries, so the World Health Organization (WHO) updated these guidelines in 1996 and included only new medicines and products. In addition to the guidelines of WHO and ICH, in June 1997, the United States Food and Drug Administration (USFDA) also issued an advisory as guidelines, titled as "Exclusion Date for Metal- Containing Oral Products". The ICH guidelines were later extended to

include veterinary medicinal products. The Association of Pharmaceutical Manufacturers of India (APMI) also has similar guidelines on the safety of drugs and medicinal products available in India subcontinents. Information on active medicinal substances, medicinal products or preparations and supplements contains different conditions and regulations. The codes and topics covered by the ICH Guides are shown in Tables 2 and 3. The Committee on Clinical Practice (CPMP) of the European Agency for Medicines Evaluation (EMEA) has also introduced guidance on safety measures to support those seeking marketing authorization for medicines in the EU, as noted in the comments. [1,23]

Table 2: Codes and Titles used in ICH Guidelines.

ICH Codes	Guideline Titles
Q1A	Stability testing of new drug substances and products (second revision)
Q1B	Photo stability testing of new drug substances and products
Q1C	Stability testing of new dosage form
Q1D	Bracketing and Matrixing Designs for the 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 for biotechnological/ biological products
Q6A	Specifications: Test Procedures and Acceptance Criteria for New Drug Substances and New Drug Products: Chemical Substances
Q6B	Specifications: Test Procedures and Acceptance Criteria for New Drug Substances and New Drug Products: Biotechnological/Biological Products

Table 3: CPMP Guidelines for stability studies.

CPMP Codes	Guideline Titles
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 Zone III and IV to be marketed in the EU

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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 Shelf Life of the Finished Dosage Form
CPMP/QWP/2934/99	Note for the 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

B. Climatic Zones for Stability Studies [1,3, 13, 14]

The stability studies are performed worldwide these stability studies cannot be performed at one place as the temperature and other factors vary from country to country and place to place. Due, to this purpose the world has been divided into four zones depending on their climatic conditions so

that the degradation of the product and the shelf life could be predicted accurately. Based on this data the real-time stability testing and accelerated stability testing have been derived. The standard climatic zones for the use of pharmaceutical products stability studies have enumerated and break-up of the environmental conditions derived from long term storage condition has given by WHO are also been presented in Table 4.

Table 4: Climatic Zones and Long-term stability conditions

Climatic Zones	Climate	Countries	MAT*	Long-Term Testing Conditions
I	Temperate	United Kingdom, Russia, USA	<15C/<11hPa	21°C/45%RH
II	Subtropical and Mediterranean	Japan, Southern Europe	>15-22°C />11-18hPa	25°C/60%RH
III	Hot and Dry	Iraq, India	>22°C/<15hPa	30°C/35%RH
IV a	Hot and Humid	Iran, Egypt	>22°C/>15-17hPa	30°C/65%RH
IV b	Hot and very humid	Brazil, Singapore	>22°C/>27hPa	30vC/75%RH

*MAT - Mean annual temperature measured in open air. [1, 3, 13, 14, 15]

C. Protocol of Stability Study

Stability study which determines the shelf life of the medicinal drugs or products is one of the drug development processes. The storage and packaging information of products planned in large quantities is determined from security studies and their analysis.[21]

For security research, the security process or a protocol wherein the written document containing a description of security management and quality control are given as guidelines of the processes to

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be followed. The packaging of drugs and medicinal products depends on the type of medication. This packaging process may also depend on drugs and new preparations available in the market. [24]

The process should reflect the areas identified by ICH. A proper safety study should include the following information:

1. Number of Batch.
2. Containers and Seals.
3. Container storage condition.
4. Sampling time period.
5. Test storage conditions.
6. Test parameters.

1. Batch Number:

As it is difficult to perform the stability step of all the batches in one go, they are divided into groups and group stability study is carried out only for that products which are stable and without any side effect.

For licensing of drugs, safety studies are categorized as stable products or unstable products. Three groups are considered for each stable products and unstable products. For unstable products, the relevant six products are tested for stability and if stability does not re-establish, all products from that groups are discarded as unmanageable products. The testing of stability is not to be done all products, rather the first three groups need to be tested after approval. Data collected directly from the laboratory is not considered to be preliminary safety data so the random sampling of samples from the population of a pilot or production batch are taken for the stability test.

2. Containers and seals:

The selection of containers and seals is very important for the safety and long life of drugs are little investigated when goods are to be packed in suitable box. Packaging material to be used are aluminium tape packaging, bubble wrap, aluminium foil packaging, HDFE bottles and the like. The secondary packing is also important but, in many cases, it is a concern of the distributers of the drugs.

The packed drugs are also tested for the stability as the inappropriate container will get contaminated and may affect the shelf life of the medicine.

3. Container storage condition:

The stability testing of the sample of solutions and semi-solid drug products should be done by ensuring that the product comes into contact with the container. This helps us to understand that does the drug changes its chemical properties or degrades the quality of drugs.

4. Sampling Time Period:

Determining the stability properties of new drugs in specific time interval is crucial factor. The specific time period is also called as sampling time point. The products have the shelf life of a few months in the first year, six months in the second year, and an estimated shelf life for each

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subsequent year. In case of accelerated stability there are at least three time points such as 0, 3 and 6 months respectively for first year, second year and the next subsequent years. In this three time points the same product is taken with different strengths, sizes, etc. and tested for its stability. Retained stability testing can be used to reduce the stability testing time period. These reduced testing plans are based on the bracketing and matrixing statistical designs. Bracketing is the design used only when the samples on the certain design factors such as strength and package size are tested at all the three time points as in full design. The matrixing is done in case the factors are the strength, batches, container sizes, and intermediate time points. The environment, sampling time and there selective climatic zones [4,17] are shown in Table 5.

Table 5: Test Schedule for stability testing of new products

Environment	Sampling Time Points (Months)	Method & Climatic zone
25°C/60% RH	3, 6, 9, 12, 18, 24,36	Long term for zones I and IV
30°C/35% RH	3, 6, 9, 12, 18, 24,36	Long term for zones III
30°C/65% RH	3, 6, 9, 12, 18, 24,36	Long term for zone IVa, or intermediate condition for zones I and II
30°C/75% RH	3, 6, 9, 12, 18, 24,36	Long term for zone IVa, or intermediate condition for zones I and II
40°C/75% RH	3, 6, 9, 12, 18, 24,36	Accelerated condition for all zones

5. Test storage conditions:

The storage conditions are to be selected on the basis of the climatic zones in which the product has to be marketed. General recommendation on the storage conditions has been given by ICH, CPMP, and WHO. The ICH and WHO Stability studies storage conditions for drug products [8, 14, 17] are shown in Table 6.

Table 6: Stability studies storage conditions for drug products.

Intended Storage Condition	Type of Stability Studies	Storage Conditions for					
		ICH			WHO		
		Temperature (°C)	RH* (%)	Time (Month)	Temperature (°C)	RH* (%)	Time (Months)
Room Temperature	Long term	25±2°C	60±5%	12	25±2°C	60±5%	12
		30 ± 2°C	65±5%				
	Intermediate	30 ± 2°C	65±5%	6	--	--	--
	Accelerated	40 ± 2°C	75±5%	6	--	--	--
Refrigerator	Long term	5 ±3°C	--	12	5 ±3°C	--	--
	Intermediate	25±2°C	60±5%	6			
Freezer	Long term	-20±5°C	--	12	20±5°C		

*Relative Humidity (RH)

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6. Test parameters:

The test parameters used in the stability studies must be evaluated using the stability samples. The test conducted on these sample mainly includes the quality, purity, efficacy, and identity which may be dependent on the climatic conditions. Therefore appearance, assay, degradation products, microbiological tests include sterility, preservative measures etc. The stability testing batches should also reach the testing parameters including the heavy metals, residue of ignition, residual solvents, etc. These tests are also being discussed in the ICH guidelines (QA6).

2. LITERATURE SURVEY

The Literature survey is an important first step in our research, In pharmaceuticals, stability studies are crucial for ensuring product efficacy and safety over time. These studies monitor parameters like temperature and humidity. Understanding these fundamentals is vital for designing an effective automatic alert system tailored to pharmaceutical formulations.

In paper [25], Olga González-González, Irving O. Ramirez, in “Drug Stability: ICH versus Accelerated Predictive Stability Studies”, the stability studies of pharmaceutical products are essential processes carried out by pharmaceutical companies to ensure the quality, safety, and efficacy of drugs throughout their shelf life. These studies involve the evaluation of the chemical, physical, and microbiological properties of a pharmaceutical product under various environmental conditions such as temperature, humidity, light, and other factors that it might be exposed to during storage, transportation, and usage.
The main objectives of stability studies are to determine the shelf life of a pharmaceutical product,

establish storage conditions, and provide evidence for the product's quality and performance over time. These studies are crucial for regulatory compliance and are conducted according to guidelines provided by regulatory agencies such as the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH).

During stability studies, pharmaceutical products are subjected to accelerated and long term stability testing. Accelerated stability testing involves exposing the product to high stress conditions, such as elevated temperatures and humidity, to predict its behavior over a short period. Long term stability testing, on the other hand, involves storing the product under normal storage conditions and monitoring its stability over an extended period, typically up to the proposed shelf life of the product.

The stability studies assess various parameters like the drug's chemical integrity, potency, purity, dissolution rate, and physical characteristics such as appearance, color, and texture. Additionally, microbial contamination and preservative effectiveness are also evaluated, especially for products susceptible to microbial growth. Based on the results of these studies, pharmaceutical companies can determine appropriate storage conditions, packaging materials, and shelf life for their products. Stability data are submitted to regulatory authorities to obtain product approval, and any changes in the manufacturing process or formulation are informed by these studies to maintain product quality and patient safety.

In paper [1], Sneha Aashigari, Ramya Goud G, in “Stability studies of pharmaceutical products”

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are fundamental in ensuring the safety, efficacy, and quality of medications throughout their shelf life. These studies employ two primary methodologies: one based on the guidelines provided by the International Council for harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH) and the other involving Accelerated Predictive Stability Studies. ICH guidelines offer a standardized and globally recognized framework, encompassing long term and accelerated testing protocols.

By adhering to ICH guidelines, pharmaceutical companies can establish a product's shelf life and storage conditions, ensuring compliance with regulatory standards and facilitating international market access. On the other hand, Accelerated Predictive Stability Studies expedite the process by subjecting pharmaceutical products to extreme environmental conditions, allowing researchers to predict a product's stability over a shorter period. While these studies provide faster results, they may not always precisely replicate real world scenarios. Both methods play a pivotal role in evaluating a drug's chemical, physical, and microbiological properties, as well as its potential degradation pathways.

Stability testing within these studies involves a comprehensive analysis of various parameters such as appearance, color, potency, and dissolution rate, enabling pharmaceutical companies to make informed decisions about formulation adjustments, packaging materials, and storage conditions. Ultimately, stability studies and testing are integral components of pharmaceutical research and development, ensuring that patients receive safe and effective medications that maintain their quality and efficacy from production to consumption. For the transfer learning models, the authors used three pretrained models: ResNet50; SeNet50; VGG16. Our results are comparable with the state of the art models; however, the models are more efficient in performance.

In paper [26], Yilong Yang, Zhuyifan Yein, in “Deep learning for in vitro prediction of pharmaceutical formulations “ have explored on the ML role in the stability alert prediction on the

given pharmaceutical data. Deep learning techniques have revolutionized the field of pharmaceutical formulation by offering innovative solutions for predicting in vitro behavior. Leveraging artificial neural networks, deep learning algorithms process vast and diverse datasets related to pharmaceutical formulations, incorporating variables such as drug properties, excipient compositions, manufacturing processes, and even environmental factors like temperature and humidity. These algorithms can automatically extract intricate patterns and correlations from the data, enabling accurate predictions of how different formulations will behave under various conditions.

This predictive capability is invaluable in optimizing drug delivery systems, ensuring stability, and enhancing efficacy. By significantly reducing the need for extensive laboratory experimentation, deep learning expedites the formulation development process, saving time and resources. Moreover, these models can handle complex, nonlinear relationships within the data, providing a nuanced understanding of how different components interact.

This deeper insight aids researchers in designing formulations with enhanced bioavailability, controlled release, and improved overall performance. Consequently, the application of deep learning in pharmaceutical formulations not only accelerates the development of new drugs but also facilitates the continuous improvement of existing pharmaceutical products, ultimately benefiting

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both the industry and patients by ensuring the delivery of safe, effective, and high-quality medications.

Table 7: Literature of review

Sr. No.	Title of Paper	Year	Author	Key Points	Limitations
1.	Stability studies of pharmaceutical products	2018	Sneha Aashigari, Ramya Goud G	Stability Studies, Pharmaceutical Products and Stability Testing	It does not provide guidance on how to choose the right type of stability study for a particular product.
2.	Drug Stability: ICH versus Accelerated Predictive Stability Studies	2022	Olga González-González, Irving O. Ramirez	Stability extemporaneous compounding ASP.	The paper does not discuss recent advances in APS
3.	Deep learning for in vitro prediction of pharmaceutical formulations	2019	Yilong Yang, Zhuyifan Ye	Pharmaceutical formulation Deep learning	Imbalanced dataset, Lack of validation.

3. METHODOLOGY

The user interface shall be designed with usability principles in mind, catering to both novice and experienced users.

In the Literature review section, we have elaborated the details of the drug stability processes and the issues. Even though a lot of theoretical work has been done on the drug stability but until now there is no computerized automated system is available in the market for stability studies of pharmaceutical formulations of drugs.

The efforts have been put in designing the system which will help the drug experts to get an alert on the email and on the mobile phone as SMS.

The contribution in the work is elaborated in the table-8 below. The focus of the research is on the automation of the drug stability process against the manual process which is followed in the pharmaceutical industry.

The data in the table-8 shows that the existing systems are the manual systems and no automation work was done on the stability studies of pharmaceutical formulation of drugs. The proposed system is going to address the following issues of the existing systems like:

1. Data Visualization
2. Customizable alert thresholds
3. Real-time Monitoring
4. Stability Study alerts

The practical and the actual real time model and its implementation is explained in the next section.

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Table 8: Comparison of the existing systems with the proposed system

Parameters → System ↓	**Data Visualization**	**Customizable alert thresholds**	**Real-time Monitoring**	**Stability Study alerts**
Drug Stability: ICH versus Accelerated Predictive Stability Studies	X	X	X	X
Stability studies of pharmaceutical products	X	X	X	X
Deep learning for in vitro prediction of pharmaceutical formulations	X	X	X	X
Automatic Alert Generation System for Stability Studies of Pharmaceutical Formulations of Drugs	✓	✓	✓	✓

The research gap can be easily observed in the table-8 of the research paper. The overall operations happening the proposed system are shown in the architecture diagram shown in Figure-1.

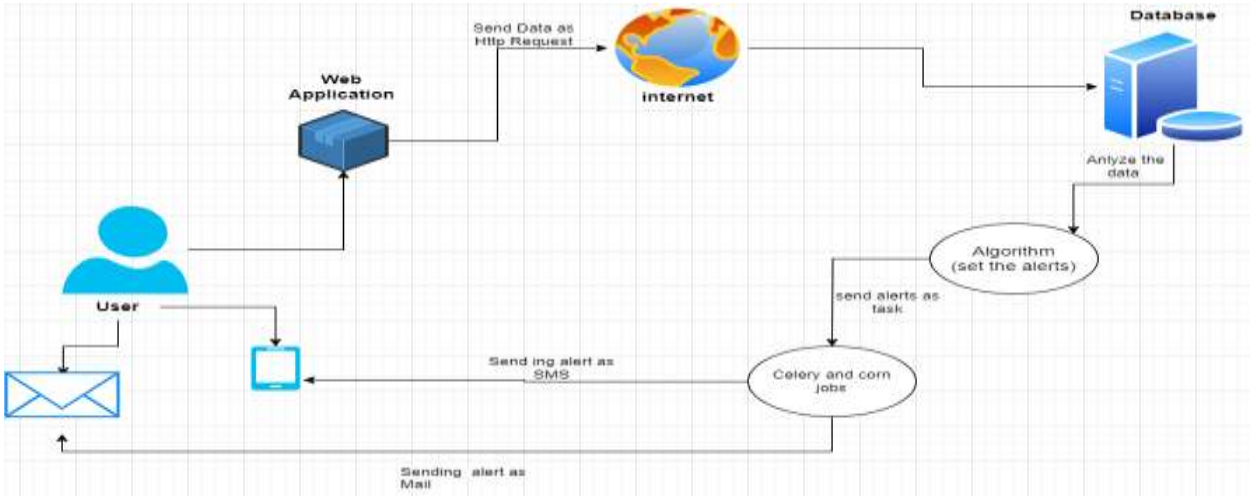

Figure-1: The proposed system architecture

4. RESULTS

The Automatic Alert Generation System for Stability Studies of Pharmaceutical Formulations of Drugs, has been designed and implemented using Django Python Framework. The user interface is made simple and easy to use so that the user of the system need not to worry about the exhaustive training of the system along with the botheration of unnecessary customer support.

The user of the system is a drug expert and he provided the details of the drugs as an essential information for the automatic generation of alert. The interaction of the user happens through web

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interface where the essential information is passed on to the server as HTTP request. The server stores the data in the database. The data is continuously monitored by the server for the analysis of the drugs condition. The analysis program gives the details of the alter to the messenger modules of the system.

The messenger modules then generate appropriate messages as SMS alter which is sent to the registered mobile of the user and an email message which is sent to the registered email of the user.

Figure-2: The SMS alter to the user using proposed system

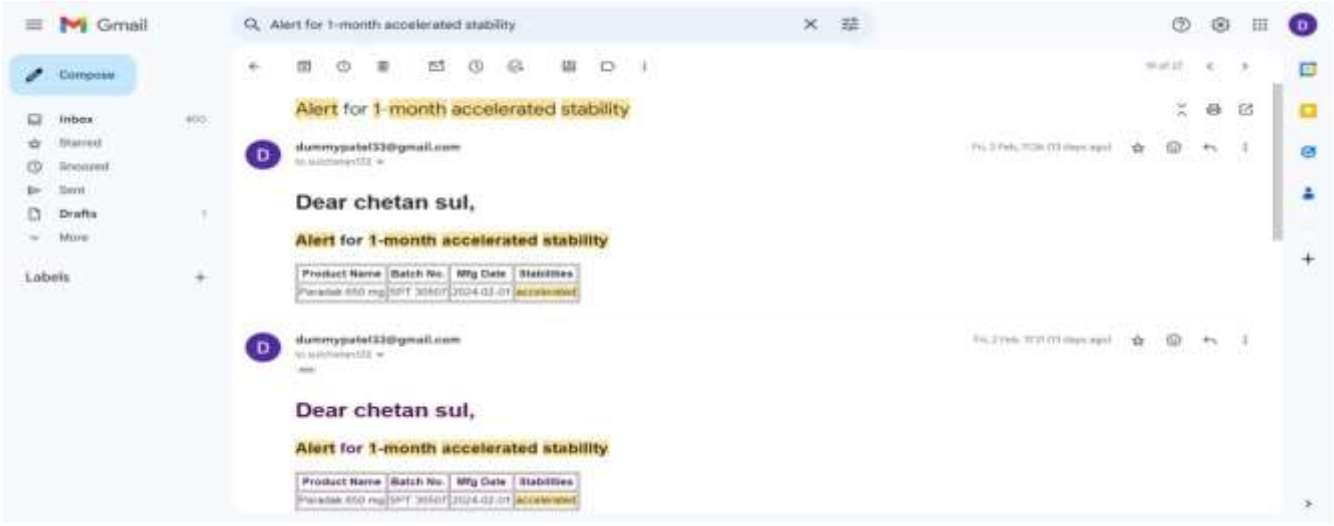

Figure-3: The email alters to the user using proposed system

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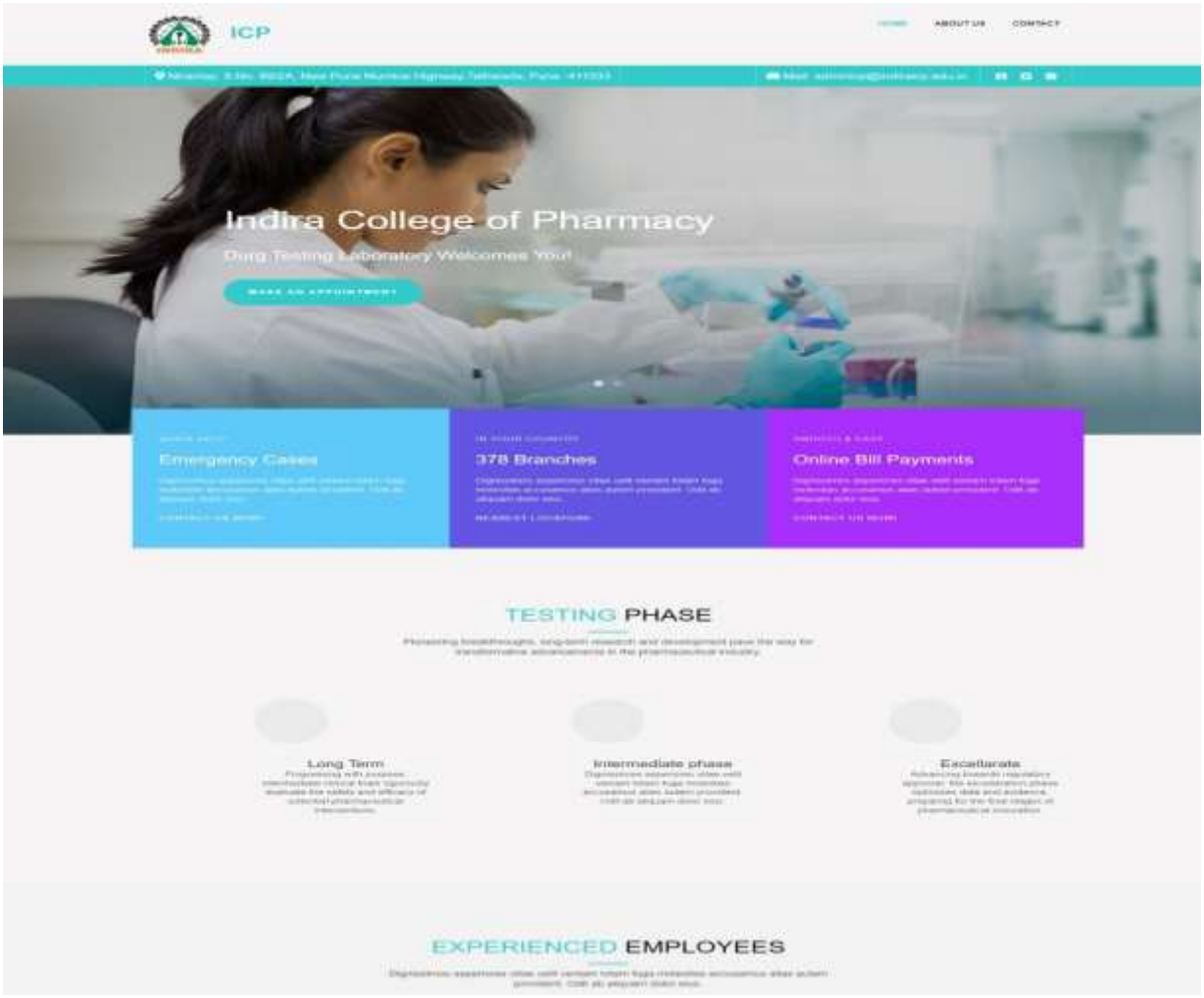

Figure-3: The home page of the proposed system

Figure-4: The appoint today interface of the proposed system

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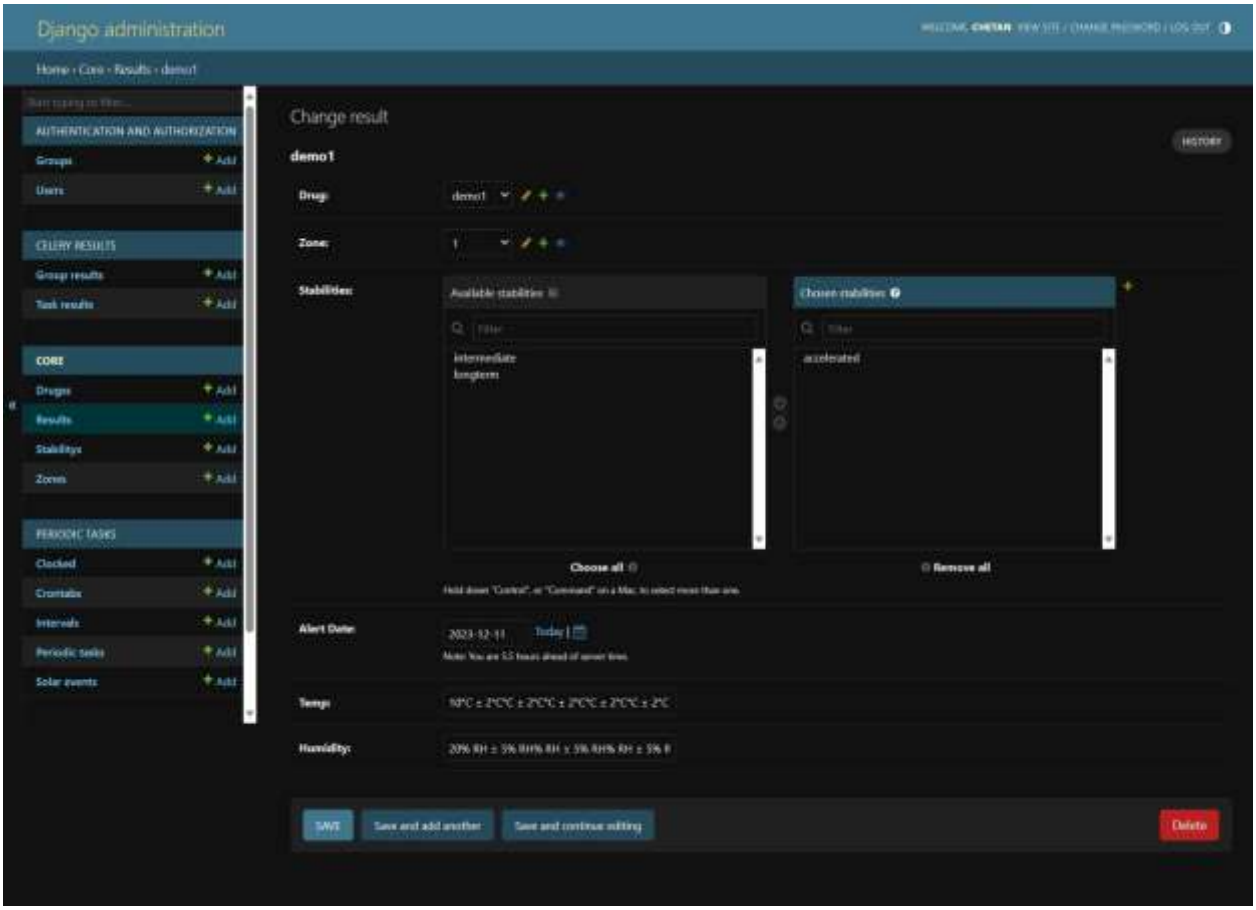

Figure-4: The backend of the proposed system

5. CONCLUSION

In this paper the thorough study of the stability of the medicinal drugs. The existing researchers have explored on the pharmaceutical drugs whose stability is done using traditional.

There are too many limitations of the manually maintained drug stability studies as the records are maintained using the physical records of the drugs.

Automatic Alert Generation System for Stability Studies of Pharmaceutical Formulations of Drugs, is a critical tool for ensuring the quality and safety of drug formulations.

The system can help pharmaceutical companies monitor and analyze stability data in real-time, identify any stability issues or trends, and provide early warnings and alerts to prevent any quality issues from occurring.

As the system is developed using web technology, it is accessible anywhere world. The system is simple with easy to use interface so that with a little or no training the user may use the system. The system sends alerts to the pharma experts as SMS to the registered mobile number and the email to the registered email ID.

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