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Quality Control and Evaluation of Herbal Product

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Abstract: ***Standardization of herbal formulation is important in order to assess of quality drug. The quality of herbal drug is the considerate all the factor which contribute directly or indirectly to the safety, effectiveness of the product Medicinal plant have been used to improve human health , increasing popularity global as drug , complementary and alternative medicines, food supplement, cosmetic as medical devices. The complexity of herbs and extracts supplied to such a wide range of markets and in different requlatory environment, raise major quality issues, increasing the need for appropriate analytical method for their identification, standardization &also for the detection of adulterants and contamination. Major limitation factors, such as herbal product naming, sampling and sample preparation are also discussed. The use of products of natural origin has remarkably increased in the global market, because of consumer becoming more health-conscious herbal medicines are considered safe by consumers and these product are generally less expensive than allopathic medicines.***
Keywords-Quality control, Herbal drugs, Medicinal plant & Standardization

I. INTRODUCTION

The traditional medicine is widely usedfor various human aliment. All plant in this planet is important because of its medicinal qualities. Traditional system of medicines has become significantly more popular all over the globe because of the effective and curative nature for chronic disease with less toxicity. Herbal medicines are not a simple task since many factors influence the biological efficacy and reproducible therapeutic effect. Standard herbal formulations are essential in order to assess of quality drugs, based on the concentration of their active principles, physico-chemical, and phyto-chemical, In-vitro, and In-vivo parameters. Customs laboratories are often confronted with herbal samples (herbal medicines, food supplements, tobacco, cannabis), thus facing many different questions that range from identity confirmation to contamination assessment, risk identification, classification problematics or legal issues. Significant advances have been made in recent years in the processing and study of medicinal plants, including modern extraction methods and identification of key components. Many analytical methods, often hyphenated, including chromatography, microscopy, spectrometry, spectroscopy, DNA barcoding etc., have been applied to determining the identification and quality of herbal products,. Moreover, modifications to published methods are continuously being added and improved , yielding an even wider variety of possible analytical choices. But the selection of a given method should be carefully pondered, according to the set analytical objectives. The quality assessment of herbal formulations is paramount importance in order to justify their acceptability in modern system of medicine. One of the major problems faced by the herbal pharmaceutical industry is the unavailability of rigid quality control profiles for herbal materials and their formulations.The present review describes possible analytical goals that can be set for herbal samples and their complexity, to help in the selection of analytical methods appropriate for each purpose.

A. The Importance Of Quality Monographs Compendia

Important analytical approaches are documented in international Pharmacopoeias for the quality control and analysis of recognised herbal medicines. These notably include the European. French, German , British , United States , Chinese , Japanese , and Taiwanese Pharmacopoeias. Within these compendia, individual monographs present guidelines for best practice in macro- and microscopical identification, and in determination of quality. Modern methods, outside of the current monographs, have also been developed; these can be needed for particular analytical purposes (application in regions with particular substituents or toxic contaminants) and may complement the methods described therein. An important consideration of Pharmacopoeias is that, depending on where analysis is being performed, some techniques that are simple, such as TLC and HPTLC, can be valuable if more sophisticated hyphenated techniques are not available. Obviously, there are many species for which there are no monographs, and many traditional medicine systems which do not have a written tradition, therefore orally passing down the knowledge of traditional healing plants. In these instances, guidelines need to be firmly established, building a dynamic monographing system

1) Set up criteria to define a "traditional use" (e.g. convergence of uses, interdicts, precautions,…) and select species with good chances of activities and probable low risks of toxicity;
2) Harvesti botanically identified voucher specimens to define analytical criteria (identification, assay, standardization); • Collect commercial samples and in-house samples from tradipraticians

3) Set up norms and analytical criteria; detect eventual problematic samples
4) Develop an iterative quality system by regularly collecting and analyzing samples

II. STANDARDIZATION OF HERBAL MEDICINES

Generally, all medicines, whether they are synthetic or of plant origin, should be fulfill the basic requirements of being safe and effective. The term "herbal drugs" denotes plants or plant parts that have been converted into phyto pharmaceuticals by me simple processes involving harvesting, drying, and storage. Hence they are capable of variation. This variability is also caused by differences in growth, geographical location, and time of harvesting. Standardization of herbal medicines is the set of standards or inherent characteristics, constant parameters, definitive qualitative and quantitative values that carry an assurance of quality, efficacy and safety. It is the process of developing and agreeing upon technical standard. Specific standards are worked out by experimentation and observations, which would lead to the process of prescribing a set of characteristics exhibited by the particular herbal medicine. Hence standardization is tools in the several problems not applicable to synthetic drugs often influence the quality of herbal drugs. For instance

1) Herbal drugs are usually mixtures of many constituents.
2) The active principle(s) is (are), in most cases unknown.
3) Selective analytical methods or reference compounds may not be available commercially.
4) Plant materials are chemically and naturally variable.
5) Chemo-varieties and chemo cultivars exist.
6) The source and quality of the raw material are variable. The methods of harvesting, drying, storage, transportation

III. HERBAL DRUGS AND THEIR PREPARATIONS

Herbal drugs, that are described as traditional medicines, include aerial parts, flower, fruit, leaves, seed, stem and subterranean parts (such as roots, bulbs, tubers, rhizomes) . They are presented in raw form, fresh or dried, extracts, sometimes whole dried plants and have considerable importance for global international trade. Their clinical, economic, health and pharmaceutical worth is becoming increasingly valued, rightly or wrongly, and their market is steadily growing. Nevertheless, data on the quality, safety and efficacy of many plants, their extracts, preparations, and active compounds are still limited. Controlling their quality is crucial for ensuring their efficacy and safety

A. Need of Quality Control

Modern system of medicine is based on sound experimental data, toxicity studies and human clinical studies. But, Pharmacopoeial standards on raw material/finished products are not available. cGMP for herbal industry are not well defined nor the barest minimum standards of medicinal plant products are maintained or regulated. The lack of quality standards has resulted in mild to serious adverse effects ranging from hepato toxicity to death. Hence, herbal ingredients require tools for determining identity, purity and quality and tools have to be technically sufficient, rapid and cost effective with GMP requirements. World health organization has set specific guidelines for the assessment of safety, efficacy and quality of herbal medicines. Quality control of herbal drug is not an easy task as numerous factors influence the bio-efficacy, reproducible therapeutic effect. In order to obtain quality oriented herbal product care should be taken right from the proper identification of plants, season, area of collection, their extraction and purification of polyherbal drugs [9] .

B. Quality Control of Herbal Crude Drugs

Processes and procedures According to WHO [10, 11], quality control of herbals is the process involved in the physicochemical evaluation of crude drug covering aspects, such as selection and handling of crude material, safety, efficacy and stability assessment of finished product, documentation of safety and risk based on experience, provision of product information to consumer and product promotion. Authentication- Each and every step has to be authenticated, area of the collection, parts of the plant collection, the regional situation, botanical identity, microscopic and histological analysis (characteristic features of cell walls, cell contents, starch grains, calcium oxalate crystals, hairs, fibers, vessels etc.) taxonomic identity, foreign matter, loss on drying, swelling index, foaming index, ash values, extractive values, chromatographic and spectroscopic evaluation, determination of heavy metals, pesticide residues, microbial contamination and radioactive contamination. The parameter stability of herbal formulations that includes pharmacognostic parameters, physicochemical parameters, phyto-chemical parameters, microbiological assay and chromatographic analysis:

IV. ASSESSMENT OF QUALITY

All procedures should be in accordance with good manufacturing practices.

A. *Crude Plant Material*

The botanical definition, including genus, species and authority, description, part of the plant, active and characteristics constituents should be specified and, if possible content limits should be defined. Foreign matter, impurities and microbial content should be defined or limited. Voucher specimens, representing each lot of plant material processed, should be authenticated by a qualified botanist and should be stored for at least a 10-year period. A lot number should be assigned and this should appear on the product label. Plant preparations the manufacturing procedure should be described in detail. If other substances are added during manufacture in order to adjust the plant preparation to a certain level of active or characteristics constituents or for any other purpose, the added substances should be mentioned in the manufacturing procedures. A method for identification and, where possible, assay of the plant preparation should be added. If identification of an active principle is not possible, it should be sufficient to identify a characteristic substance or mixture of substances to ensure consistent quality of the preparation. Finished Product The manufacturing procedure and formula, including the amount of excipients, should be described in detail. A finished product specification should be defined to ensure consistent quality of the product. The finished product should comply with general requirements for particular dosage forms. Stability the physical and chemical stability of the product in the container in which it is to be marketed should be tested under defined storage conditions and the shelf-life should be established. Safety Assessment Herbal medicines are generally regarded as safe based on their long-standing use in various cultures. However, there are case reports of serious adverse events after administration of herbal products. In a lot of cases, the toxicity has been traced to contaminants and adulteration. However, some of the plants used in herbal medicines can also be highly toxic. As a whole, herbal medicines can have a risk of adverse effects and drug-drug and drug-food interactions if not properly assessed. Assessment of the safety of herbal products, therefore, is the first priority in herbal research. These are various approaches to the evaluation of safety of herbal medicines. The toxic effects of herbal preparation may be attributed mainly to the following: Inherent toxicity of plant constituents and ingredients and Manufacturing malpractice and contamination. Evaluation of the toxic effects of plant constituents of herbal formulation requires detailed phytochemical and pharmacological studies. It is, however, safe to assume that, based on human experiences in various cultures, the use of toxic plant ingredients has already been largely eliminated and recent reports of toxicity could largely ne due to misidentification and overdosing of certain constituents [23] . Toxicity Assessment Toxicity investigation will also be required because the analysis alone is unlikely to reveal the contributions to toxicity itself. In assessing toxicity of an herbal medicine, the dose chosen is very important [24] . Toxicity assessment involves one or more of the following techniques- In vivo & vitro techniques, cell line techniques, micro- array and other modern technique.

B. *Pharmacognostic Evaluation*

It includes color, odor, taste, size, shape, micro scopical characters, and histological parameters.

C. *Physico-chemical Parameters*

It includes foreign matter, total ash, acid-insoluble ash, swelling and foaming index, assay, extractive values, moisture content, viscosity, pH, Disintegration time, friability, hardness, sedimentation, alcohol content.

D. *Chemical Parameters*

It includes limit tests, chemical tests etc.

E. *Chromatographic and Spectroscopic Analysis*

It includes TLC, HPLC, HPTLC, GC, UV, IR, AAS, FTIR, LC-MS, and GC-MS etc.

F. *Microbiological Parameters*

It includes the full content of viable, total mould count, total coliforms count. Limiters can be used as a quantitative tool or semi quantitative to determine and control the amount of impurities, such as reagents used in the extraction of various herbs, impurities ships directly from the manufacturing and solvents etc [12, 13]

G. Chromatography and Chemical Fingerprints of Herbal Medicines

In general, the methods for quality control of herbal medicines involve sensory inspection (macroscopic and microscopic examinations) and analytical inspection using instrumental techniques such as thin layer chromatography, HPLC, GC–MS, LC–MS, near infrared (NIR), and spectrophotometer, etc. [38].

On the other hand, the methods of extraction and sample preparation are also of great importance in preparing good fingerprints of herbal medicines.

In this review article, however, we shall only focus our attention on how to construct reasonably the chromatographic fingerprints and their reasonable and efficient evaluation for the purpose of quality control.

As a single herbal medicine may contain a great many natural constituents, and a combination of several herbs might give rise to interactions with hundreds of natural constituents during the preparation of extracts, the fingerprints produced by the chromatographic instruments, which may present a relatively good integral representation of various chemical components of herbal medicines, are mainly concerned in this review.

V. THIN LAYER CHROMATOGRAPHY

TLC was the common method of choice for herbal analysis before instrumental chromatography methods like GC and HPLC were established. Even nowadays, TLC is still frequently used for the analysis of herbal medicines since various pharmacopoeias such as American Herbal Pharcopoeia (AHP) (Upton, Santa Cruz, US, 2002), Chinese drug monographs and analysis (Wagner, Kotzting/Bayer, Wald, ¨ Germany, 1997), Pharmacopoeia of the People's Republic of China (Chemical Industry Press, Beijing, 1997), etc. still use TLC to provide first characteristic fingerprints of herbs. Rather, TLC is used as an easier method of initial screening with a semiquantitative evaluation together with other chromatographic techniques.

As there is relatively less change in the simple TLC separation of herbal medicines than with instrumental chromatography, only a brief summary is given here, and for further details about TLC the readers could consult references [39–40]. TLC has the advantages of many-fold possibilities of detection in analyzing herbal medicines. In addition, TLC is rather simple and can be employed for multiple sample analysis.

For each plate, more than 30 spots of samples can be studied simultaneously in one time. Thus, the use of TLC to analyze the herbal medicines is still popular [41–50,221–224]. With the help of the CAMAG video store system (CAMAG, Switerland) and TLCQA-UV methods [51], it is possible to get useful qualitative and quantitative information from the developed TLC plate. One can observe that, in reference [51], the four samples of Cordycepsinensis from the joint products of China and Japan cooperation have more valuable medical effect compared to others as they contained the most effective component cordycepin. Moreover, with the help of image analysis and digitized technique developed in computer science, the evaluation of similarity between different samples is also possible.

In summary, the advantages of using TLC to construct the fingerprints of herbal medicines are its simplicity, versatility, high velocity, specific sensitivity and simple sample preparation. Thus, TLC is a convenient method of determining the quality and possible adulteration of herbal products.

It is worth noting that the technique of TLC is also being updated in progress. A recent paper [52] gave a very good review on this respect. It summarized the progress in forced-flow planar chromatography (FFPC) and demonstrated the importance of the different techniques like rotation planar chromatography (RPC), overpressured-layer chromatography (OPLC), and electroplanar chromatography (EPC).

A simple, but powerful preparative forced-flow technique was also reported; in this technique hydrostatic pressure is used to increase mobile-phase velocity.

Parallel- and serially-coupled layers open up new vistas for the analysis of a large number of samples (up to 216) for high throughput screening and for the analysis of very complex matrices. Some applications, relating to different classes of substances, were given to demonstrate the versatility of the various FFPC techniques [52].

VI. GAS CHROMATOGRAPHYAND VOLATILE COMPONENTS IN HERBAL MEDICINES

It is well-known that many pharmacologically active components in herbal medicines are volatile chemical compounds. Thus, the analysis of volatile compounds by gas chromatography is very important in the analysis of herbal medicines. The GC analysis of the volatile oils has a number of advantages. Firstly, the GC of the volatile oil gives a reasonable "fingerprint" which can be used to identify the plant.

The composition and relative concentration of the organic compounds in the volatile oil are characteristic of the particular plant and the presence of impurities in the volatile oil can be readily detected.

Secondly, the extraction of the volatile oil is relatively straightforward and can be standardized and the components can be readily identified using GC–MS analysis. The relative quantities of the components can be used to monitor or assess certain characteristics of the herbal medicines.

Changes in composition of the volatile oil may also be used as indicators of oxidation, enzymatic changes or microbial fermentation.

The advantages of GC clearly lie in its high sensitivity of detection for almost all the volatile chemical compounds.

This is especially true for the usual FID detection and GC–MS. Furthermore, the high selectivity of capillary columns enables separation of many volatile compounds simultaneously within comparatively short times.

Thus, over the past decades, GC is a popular and useful analytical tool in the research field of herbal medicines [53–62]. Especially, with the use of hyphenated GC–MS instrument, reliable information on the identity of the compounds is available as well (see next section for more detail).

However, the most serious disadvantage of GC is that it is not convenient for its analysis of the samples of polar and non-volatile compounds.

For this, it is necessary to use tedious sample work-up which may include derivatization. Therefore, the liquid chromatography become an another necessary tool for us to apply the comprehensive analysis of the herbal medicines. 2

VII. HIGH-PERFORMANCELIQUID CHROMATOGRAPHY

HPLC is a popular method for the analysis of herbal medicines because it is easy to learn and use and is not limited by the volatility or stability of the sample compound. In general, HPLC can be used to analyze almost all the compounds in the herbal medicines. Thus, over the past decades, HPLC has received the most extensive application in the analysis of herbal medicines [63–76]. Reversed-phase (RP) columns may be the most popular columns used in the analytical separation of herbal medicines. It is necessary to notice that the optimal separation condition for the HPLC involves many factors, such as the different compositions of the mobile phases, their pH adjustment, pump pressures, etc. Thus, a good experimental design for the optimal separation seems in general necessary [73,76].

In order to obtain better separation, some new techniques have been recently developed in research field of liquid chromatography. These are micellar electrokinetic capillary chromatography (MECC) [77], high-speed counter-current chromatography (HSCCC), low-pressure size-exclusion chromatography (SEC) [78], reversed-phase ion-pairing HPLC (RP-IPC-HPLC) [79,80], and strong anion-exchange HPLC (SAX-HPLC) [81].

They will provide new opportunities for good separation for some specific extracts of some herbal medicines. On the other hand, the advantages of HPLC lie in its versatility for the analysis of the chemical compounds in herbal medicines, however, the commonly used detector in HPLC, say single wavelength UV detector, seems to be unable to fulfill the task, since lots of chemical compounds in herbal medicines are non-chromophoric compounds.

Consequently, a marked increase in the use of HPLC analysis coupled with evaporative light scattering detection (ELSD) in a recent decade demonstrated that ELSD is an excellent detection method for the analysis of non-chromophoric compounds [82–84]. This new detector provides a possibility for the direct HPLC analysis of many pharmacologically active components in herbal medicines, since the response of ELSD depends only on the size, shape, and number of eluate particles rather than the analysis structure and/or chromophore of analytes as UV detector does. Especially, this technique is quite suitable for the construction of the fingerprints of the herbal medicines. Moreover, the qualitative analysis or structure elucidation of the chemical components in HM by simple HPLC is not possible, as they rely on the application of techniques using hyphenated HPLC, such as HPLC–MS, HPLC-NMR, for the analysis of herbal medicines. This topic will be further discussed later on.

VIII. SAFETY ASSESSMENT

Herbal medicines are generally regarded as safe based on their long-standing use in variouscultures. However, there are case reports of serious adverse events after Administration of herbal products. In a lot of cases, the Toxicity has been traced to contaminants and adulteration.

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IX. CONCLUSION

Herbal drug standardization is massively wide and deep. Strict guidelines have to be followed for the successful production of a quality herbal drug. Among them are proper botanical identification, phytochemical screening, and standardization. Quality control and the standardization of herbal medicines involve several steps.

The source and quality of raw materials, good agricultural practices and manufacturing processes are certainly essential steps for the quality control of herbal medicines and play a pivotal role in guaranteeing the quality and stability of herbal preparations. Standardization of herbal drugs comprises total information and controls to essentially guarantee consistent composition of all herbals including analytical operations for identification, markers and assay of active principles. There is no legal control model over medicinal plants.

Different countries define medicinal plants or products derived from them in different ways and have adopted different approaches to licensing,

The advancement of analytical techniques will serve as a rapid and specific tool in the herbal research, thereby, allowing the manufacturers to set quality standards and specifications so as to seek marketing approval from regulatory authorities for therapeutic efficacy, safety and shelf life of herbal drugs.

The applications of high-technology oriented advanced hyphenated techniques will serve as a rapid and unambiguous tool in the herbal research, thereby, enefiting the entire harmaceutical industry. Quality control of Herbal Medicines has not only to establish reasonable analytical methods for analyzing the active constituents in Herbal Medicine s, but many other factors should be concerned, such as pesticides residue, aflatoxine content, the heavy metals contamination, good agricultural practice (GAP), good manufacturing practice (GMP), etc.

There is need for development of techniques which includes both traditional methods of evaluation and modern methods of evaluation. This will improve the quality of the drug and also motivates the practitioners to get more involved in the standardization process. Overcoming the various problems, the vast knowledge of the important herbs found in India and widely used in ayurvedic formulation should be explored in collaboration with the new standardization techniques.

Advancement on this path will help us authenticate quality of traditionally important herbs thereby reducing further problems. Quality if ensured at the starting point will eliminate all problems in quality control of herbal formulations to obtain better formulations. Moreover the society will be benefitted with safer drugs at affordable price, leading to the Goal of WHO “Health for All”

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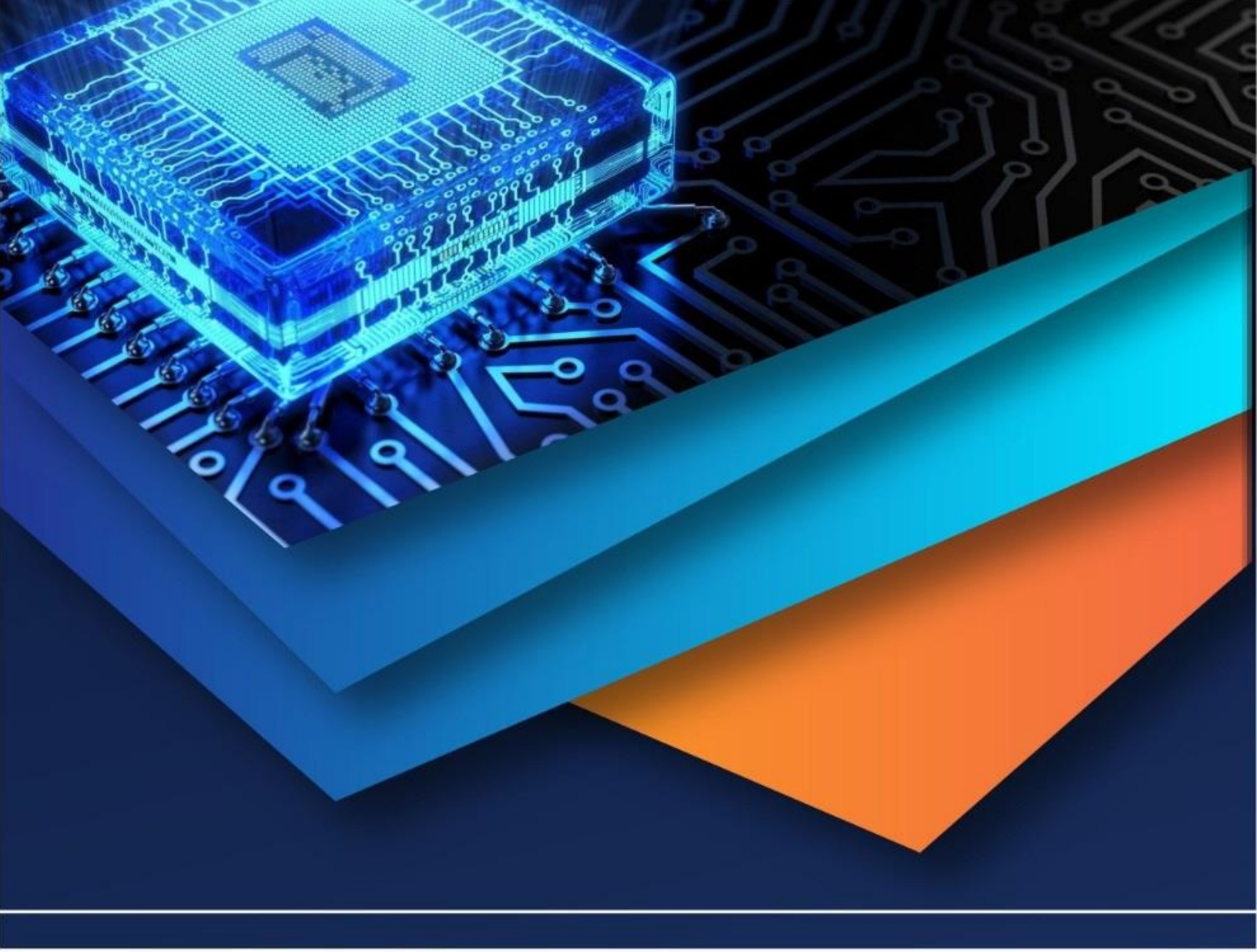

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