Indian Journal of Unani Medicine
Vol. XVII, Issue 1, January-June, 2024, Pp. **62-82**
ISSN No.: **0974-6065**

https://doi.org/10.53390/IJUM.2024.17108

REGULATORY LANDSCAPE OF UNANI PRODUCTS UNDER D&C ACT AND RULES

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Review Paper

Received: **27.05.2024** Revised: **10.06.2024** Accepted: **18.06.2024**

ABSTRACT

The Unani System of Medicine (USM), deeply rooted in tradition, undergoes scrutiny in India under the Drugs and Cosmetics Act (D&C Act) for consumer safety. Regulated by the Central Drugs Standard Control Organization (CDSCO) and guided by the Ayurvedic, Siddha, and Unani (ASU) Drugs Technical Advisory Board, this framework ensures Unani product safety, efficacy, and quality. Manufacturers must comply with Good Manufacturing Practices (GMP), and the D&C Act establishes standards for labeling, packaging, and quality control—essential for marketing Unani products in India. The paper aims to analyze key D&C Act provisions related to Unani formulations, focusing on regulatory procedures. The study sheds light on specific requirements governing Unani drug import, manufacture, distribution, and sale, offering valuable insights into the regulatory framework. It systematically examines the D&C Act, emphasizing sections related to Unani products. Unani Drugs must adhere to prescriptions in the 14 recognized Unani texts (Schedule I of D&C Act). The Drugs and Cosmetics Rules of 1945 cover Unani Medicine in Parts 16 to 19, addressing licensing (Part 16), testing (Part 16A), labeling and packaging (Part 17), and quality control standards (Part 19). In conclusion, this paper provides a nuanced analysis of the regulatory landscape governing Unani products under the Drugs and Cosmetics Act. It elucidates legal intricacies, emphasizing challenges in compliance, standardization, and merging traditional knowledge with contemporary requisites. The insights contribute to understanding the regulatory environment surrounding Unani medicines, balancing cultural heritage preservation with ensuring efficacy and safety for consumers.

No. of Pages: 21 **References: 1**

Keywords: Drugs and Cosmetics Act; 1940; D&C Act; Unani System of Medicine; USM; D&C Rules.

Introduction

REGULATORY LANDSCAPE OF UNANI PRODUCTS UNDER D&C ACT AND RULES

In the dynamic realm of healthcare, traditional systems of medicine play a pivotal role in providing diverse therapeutic options. Among these, the Unani system stands as a venerable tradition with deep historical roots. As we navigate through the complex landscape of medicinal practices, it becomes imperative to analyse the regulatory framework governing Unani drugs. This paper delves into the intersection of Unani medicine and the Drugs and Cosmetics Act (1940), in order to understand

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the parameters that shape the regulatory landscape of Unani drugs in the contemporary healthcare scenario.

"Unani drugs" include all medicines intended for internal or external use for (or) in the diagnosis, treatment, mitigation or prevention of disease or disorder in human beings or animals, and manufactured exclusively in accordance with the formulae described in, the authoritative books of Unani Tibb system of medicine, specified in the First Schedule. A "patent or proprietary medicine" in the context of Unani Tibb system refers to formulations containing solely the ingredients outlined in the formulae specified within the authoritative books Unani Tibb system as detailed in the First Schedule. However, this definition excludes medicines administered by the parenteral route and formulations explicitly included in the authoritative books.

Unani Tibb System of Medicine along with Ayurveda and Siddha finds mention in Chapter IV-A, Sections 22, 23, 24, 25 of Chapter IV and First and Second Schedule of the Drugs and Cosmetics Act, Part XVI to Part XIX and Schedule T of the Drugs and Cosmetic Rules.

Brief overview of the Act, Rules and Schedules concerning Unani Drugs

Chapter IV-A consisting of 21 sections outlines provisions related to Ayurvedic, Siddha, and Unani drugs, focusing on the establishment of regulatory bodies, such as the Ayurvedic, Siddha and Unani Drugs Technical Advisory Board (ASUDTAB) and Ayurvedic, Siddha and Unani Drugs Consultative Committee (ASUDCC). It also covers aspects like misbranded, adulterated, and spurious drugs, regulations for manufacturing and sale, appointment of analysts and inspectors, penalties for offences, and the power of the Central Government to make rules. It also emphasizes on compliance and licensing.

Part XVI of the Drugs and Cosmetics Rules outlines regulations related to the manufacture and sale of Ayurvedic (including Siddha) or Unani (ASU) drugs. It covers aspects such as licensing, application procedures, fees, forms of licenses, and conditions for grant or renewal. Additionally, there are provisions for loan licenses, certificates of renewal, and guidelines for Good Manufacturing Practices (GMP) in Ayurveda, Siddha, and Unani drugs. It also includes conditions, requirements, and procedures for maintaining records, inspections, and the identification of raw materials.

Part XVI-A of the Drugs and Cosmetics Rules outlines the approval process for institutions to conduct tests on ASU drugs and their raw materials. Key points include the application procedure, conditions for approval, equipment requirements, and the duration of approval. The process involves inspections, compliance checks, and the possibility of renewal or withdrawal of approvals.

Part XVII of the Drugs and Cosmetics Rules delineates stringent guidelines for the **labelling, packing, and permissible alcohol content in ASU drugs.** The stipulated regulations encompass the obligatory disclosure of comprehensive ingredient lists, cautionary labels for substances listed in Schedule E(1), and specific requirements for medicines intended for internal use. Moreover, it mandates the inclusion of manufacturing particulars, batch numbers, date of manufacture, and distinct labelling criteria for externally applied medicines. Provisions for export are detailed, necessitating compliance with the importing country's specifications. Significantly, it also emphasizes the conspicuous display of the expiry date for these medicines, with categorized shelf life parameters for diverse Unani medicines.

Part XVIII of the Drugs and Cosmetics Rules outlines the duties and qualifications pertaining to government analysts, inspectors, and the functioning of laboratories involved in the oversight of ASU drugs. Key aspects include the responsibilities of inspectors to conduct regular inspections, report findings, and initiate legal actions for violations. The qualifications for State Drug Licensing Authorities and the establishment of the Pharmacopoeia Laboratory

for Indian Medicine as a Central Drugs Laboratory are highlighted. The procedures for dispatching samples for analysis, recording conditions of seals, and reporting results are detailed, along with the stipulated fees for testing. The qualifications and duties of Government Analysts, including their role in analyzing samples and forwarding reports for publication, are also specified. Finally, the qualifications required for inspectors are outlined, encompassing educational backgrounds and practical training in the relevant systems of medicine.

Part XIX of the Drugs and Cosmetics Rules outlines standards for ASU drugs, including permitted excipients, natural coloring agents, and artificial sweeteners. It emphasizes compliance with existing pharmacopoeias and acts, labeling requirements, and responsible use of additives. Notably, it supersedes any previous notifications issued by the Department of AYUSH on the use of excipients, additives, or preservatives in these medicines.

The Schedule T legislates Good Manufacturing Practices (GMP) for ASU medicines, covering aspects like factory premises, hygiene, water supply, waste disposal, container cleaning, storage, machinery, batch records, distribution, quality control, and sterile product manufacturing. It emphasizes the need for adherence to specific standards, cleanliness, and documentation to ensure the quality and safety of the manufactured medicines. Exemptions are mentioned for registered practitioners not selling their own prepared medicines. Furthermore, this schedule also establishes guidelines and requirements for the manufacturing of different categories of Unani medicines, along with recommended machinery and equipment. It also includes specifications for in-house quality control sections, covering both chemistry and pharmacognosy aspects. Additionally, supplementary guidelines for manufacturing herbomineral-metallic (*kushtajaat)* compounds are detailed. It spotlights the need for good manufacturing practices, quality control, record-keeping, and employee medical examinations. Specific area requirements and equipment recommendations for different medicine categories are also outlined. It concludes with the mention of possible modifications at the discretion of the Licensing Authority.

THE DRUGS AND COSMETICS ACT, 1940
Chapter IV-A
PROVISIONS RELATING TO ASU DRUGS

Section 33C
This section establishes the Ayurvedic, Siddha and Unani Drugs Technical Advisory Board by the Central Government. The Board's primary purpose is to provide technical advice to both the Central and State Governments on matters related to Ayurvedic, Siddha, and Unani drugs. It is endowed with functions outlined in this Chapter and is officially constituted through a notification in the Official Gazette. The composition of the Board includes ex officio members such as the Director General of Health Services and the Drugs Controller, India. Additionally, it incorporates nominated members, representing various expertise areas like pharmacognosy, phyto-chemistry, and education in traditional medicine systems. The Board's composition also includes members from Ayurvedic, Siddha, and Unani pharmacopoeia committees, industry representatives, teachers in relevant fields, and practitioners of Ayurvedic, Siddha, and Unani Tibb systems. The Central Government appoints a Chairman from the Board's members, and nominated members serve a three-year term, with eligibility for reappointment. The Board has the authority to make bye-laws with the Central Government's approval, regulating its procedures and conduct. A Secretary is appointed by the Central Government, and the Board is provided with necessary clerical and staff support. In essence, this section establishes a specialized advisory board to offer technical guidance on matters concerning Ayurvedic, Siddha, and Unani drugs, ensuring a well-rounded approach involving professionals from different relevant domains.

Section 33D
It introduces the formation of the Ayurvedic, Siddha and Unani Drugs Consultative Committee (ASUDCC), granting authority to the Central Government for its establishment. This advisory committee serves a pivotal role by offering guidance and counsel to the Central Government, State Governments, and the [Ayurvedic, Siddha and Unani Drugs Technical Advisory Board]. Comprising two representatives nominated by the Central Government and additional representatives from each State nominated by their respective State Governments, the committee acts as a platform for collaborative decision-making. It convenes as needed, providing flexibility in addressing matters related to the administration of the Act, particularly concerning Ayurvedic, Siddha, and Unani drugs. The committee operates autonomously, regulating its own procedures, which enables it to establish rules and internal processes tailored to the dynamic landscape of traditional medicine practices. Overall, Section 33D establishes a consultative mechanism to ensure informed decision-making and uniformity in the application of regulations governing Ayurvedic, Siddha, and Unani drugs across different jurisdictions within the country.

Section 33E
It defines the criteria for deeming an ASU drugs as misbranded. The section outlines various conditions under which a drug falls into this category. Firstly, if the drug is colored, coated, powered, or polished in a manner that conceals damage or makes it appear of greater therapeutic value than it truly possesses, it is considered misbranded. Additionally, misbranding includes situations where the drug is not labeled in the prescribed manner, or if the label, container, or any accompanying material bears false or misleading statements, designs, or devices that make inaccurate claims about the drug.

Section 33EE
This section defines the conditions under which an ASU drug is deemed adulterated. If the drug contains filthy, putrid, or decomposed substances, or if it has been prepared, packed, or stored under unsanitary conditions leading to contamination, it is considered adulterated. Further, if its container is composed, either wholly or in part, of any poisonous or deleterious substance, or if it contains a color other than the prescribed one for coloring purposes, it falls into the category of adulterated drugs. Adulteration also includes the presence of harmful or toxic substances that may render the drug injurious to health, or if any substance has been mixed to reduce its quality or strength.

Section 33EEA
This section addresses the categorization of spurious ASU drugs. A drug is deemed spurious under several conditions outlined in this section. Firstly, if it is sold or offered for sale under a name that belongs to another drug, or if it is an imitation or substitute for another drug in a manner likely to deceive, it is classified as spurious. Additionally, if the label or container bears the name of a fictitious or non-existent individual or company as the manufacturer, or if the drug has been wholly or partially substituted by another substance, it falls into the category of spurious drugs. Furthermore, if a drug purports to be the product of a certain manufacturer when it is not genuinely so, it is also considered spurious.

Section 33EEB
This section focuses on the regulation of the manufacture for sale of ASU drugs. It stipulates that no person shall manufacture these drugs for sale or distribution unless it aligns with the prescribed standards.

Section 33EEC
It addresses the prohibition and regulation of the manufacture and sale of certain ASU drugs. It empowers the State Government, through a notification in the Official Gazette, to specify the date from which the manufacturing and sale of certain categories of drugs will be prohibited. These categories include misbranded, adulterated, or spurious Ayurvedic, Siddha, or Unani drugs. Additionally, the section mandates that individuals or entities must not manufacture

these drugs without a valid license issued under the chapter. The provision extends to the manufacturing of patent or proprietary medicines, requiring a clear display of all ingredients on the label or container. The section ensures that the manufacturing and sale of Ayurvedic, Siddha, and Unani drugs comply with the stipulated regulations, contributing to the overall safety and quality control in the traditional medicine industry. The exceptions provided for Vaidyas and Hakims manufacturing drugs for their own patients, as well as for small quantities for examination or analysis.

Section 33EED
Empowers the Central Government to exercise its authority in the interest of public safety concerning ASU drugs. If the Central Government, based on available evidence, concludes that the use of any such drug poses a risk to human beings or animals, or that the drug lacks the therapeutic value claimed, it can prohibit the manufacture, sale, or distribution of that particular drug. This provision highlights the government's responsibility to safeguard public health by intervening when there are concerns about the safety or efficacy of specific ASU drugs. The power to prohibit the circulation of such drugs underscores the commitment to ensuring that only medicines meeting established safety and efficacy standards are available in the market, aligning with the broader objective of protecting public welfare.

Section 33F
Establishes the role of Government Analysts in the regulatory framework for ASU drugs. Both the Central Government and State Governments have the authority to appoint individuals, meeting the prescribed qualifications, as Government Analysts for designated areas. These analysts play a crucial role in testing and analyzing the composition of these drugs. Importantly, the section imposes a restriction, ensuring that no person with a financial interest in the manufacture or sale of any drug can be appointed as a Government Analyst.

Section 33G
The section outlines the appointment of Inspectors by both the Central Government and State Governments for the purpose of regulating and overseeing ASU drugs. These appointed individuals must meet specified qualifications. The section grants these inspectors powers and duties as prescribed, allowing them to conduct inspections and ensure compliance with relevant regulations. Importantly, individuals with any financial interest in the manufacture or sale of drugs are prohibited from being appointed as inspectors, reinforcing the impartiality and integrity of the inspection process. Inspectors are deemed public servants, and their actions are subject to the oversight of the government authority appointing them.

Section 33H
This section extends the application of certain provisions, namely sections 22, 23, 24, and 25 of Chapter IV of the D&C Act, along with any rules made under these sections, to Inspectors and Government Analysts appointed under this chapter. These provisions, which typically apply to inspections, search and seizure, and analysis, are modified to encompass the context of ASU drugs. The section ensures that the powers, duties, and limitations specified in these provisions are tailored to the roles of Inspectors and Government Analysts dealing specifically with traditional medicinal products.

Section 22 of Chapter IV
The section delineates the powers bestowed upon inspectors within the designated jurisdiction. Inspectors, subject to specified rules, can inspect premises involved in the manufacturing, sale, or distribution of drugs and cosmetics. This includes scrutinizing manufacturing processes, testing methodologies, and places where these products are stocked or exhibited. They are authorized to take samples from manufacturing units, sellers, or distributors. Furthermore, inspectors can execute searches on persons, premises, or vehicles they believe are linked to offenses under the Act. They may also seize drugs or cosmetics, along with

substances or articles used for offenses. The section empowers inspectors to examine records and documents related to drug or cosmetic activities, and they can seize such materials if they are deemed to provide evidence of an offense.

Section 23 of Chapter IV This section details the procedural aspects governing the actions of inspectors. When inspectors take samples of drugs or cosmetics, they are required to tender the fair price and may seek a written acknowledgment. If the tendered price is refused or when inspectors seize a stock, a receipt in the prescribed form must be provided. When taking samples for testing, inspectors must inform the concerned party in writing, divide the sample into portions, seal and mark them, allowing the party to add their seal and mark. The section stipulates the disposal of sample portions – one sent to the Government Analyst, another produced in court, and if applicable, a third sent to the person whose details were disclosed under section 18A *[18A. Disclosure of the name of the manufacturer, etc.—Every person, not being the manufacturer of a drug or cosmetic or his agent for the distribution thereof, shall, if so required, disclose to the Inspector the name, address and other particulars of the person from whom he acquired the drug or cosmetic.]*. In cases of contravention, inspectors need to promptly ascertain compliance and, if no contravention is found, revoke their order or take necessary actions for the return of seized stock. Additionally, if a contravention is remediable by the possessor, the inspector should revoke the order upon satisfaction of remedy. The section also outlines the procedure for seizing records or documents, involving informing a Judicial Magistrate and seeking their orders regarding custody.

Section 24 of Chapter IV
This section establishes the obligation of individuals in charge of premises where drugs or cosmetics are manufactured, stored, or distributed. When requested by an inspector, these individuals are legally bound to disclose the location where the drug or cosmetic activities are taking place. This provision ensures transparency and cooperation in regulatory efforts, enabling inspectors to ascertain compliance with the Act by gaining access to the specific premises involved in the production or storage of drugs and cosmetics. The legal obligation imposed by this section underscores the importance of collaboration between industry stakeholders and regulatory authorities to uphold the standards and regulations outlined in the Act, contributing to the overall safety and quality of pharmaceutical and cosmetic products in the market.

Section 25 of Chapter IV
This focuses on the reports provided by Government Analysts regarding samples of drugs or cosmetics submitted for testing or analysis. Upon receiving a sample, the Government Analyst delivers a signed report in triplicate to the submitting inspector. The inspector then distributes copies, providing one to the entity from which the sample was taken and another to any person whose details were disclosed under section 18A. The third copy is retained for potential use in legal proceedings. The report signed by a Government Analyst serves as conclusive evidence of the stated facts unless the concerned party notifies, within twenty-eight days of receiving the report, their intention to present evidence contradicting it. In such cases, the court may order the sample to be sent to the Central Drugs Laboratory for further testing, and the resulting report from the Laboratory becomes conclusive evidence. The cost of this additional test is directed by the court, either to be paid by the complainant or the accused, depending on the court's decision.

Section 33I
Outlines penalties for offences related to the manufacture, sale, or distribution of ASU drugs. The section classifies offences into two categories. Firstly, offences related to misbranded, adulterated, or spurious drugs, or

the manufacture of drugs without a valid license, are punishable by imprisonment for a term extending up to one year and a fine not less than twenty thousand rupees or three times the value of the confiscated drugs, whichever is more. Secondly, the manufacture and sale of drugs in contravention of notifications issued under Section 33-EED *(The drugs prohibited from manufacture under Section 33EED are specified by the Central Government through notifications based on concerns related to risks to human beings or animals and the claimed therapeutic value)* is subject to imprisonment for up to three years and a fine extending to fifty thousand rupees or three times the value of the confiscated drugs, whichever is more.

Section 33J
This section addresses subsequent offences under this chapter, detailing enhanced penalties for individuals convicted more than once. The section outlines specific consequences based on the nature of the offence. For convictions related to misbranded, adulterated, or spurious drugs, or the manufacture without a valid license, subsequent offences lead to imprisonment for a term up to two years and a fine not less than fifty thousand rupees or three times the value of the confiscated drugs, whichever is more. For offences related to contravention of notifications issued under Section 33-EED, subsequent convictions may result in imprisonment for up to three years and a fine extending to one lakh rupees or three times the value of the confiscated drugs, whichever is more. The section provides flexibility for the court to impose lower penalties based on adequate and special reasons mentioned in the judgment, emphasizing the severity of repeated offences and aiming to deter individuals from engaging in unlawful practices related to Ayurvedic, Siddha, or Unani drugs.

Section 33K
Stipulates that upon conviction under this chapter, the stock of ASU drugs associated with the contravention shall be liable to confiscation. This means that if a person is found guilty of offences outlined in the chapter, the drugs involved in the violation may be seized by the authorities. Confiscation serves as a punitive measure, aiming to deter illegal activities related to the manufacturing, sale, or distribution of these traditional medicinal products.

Section 33KA
Mandates that any individual, excluding the manufacturer or their distribution agent, must disclose specific details to an Inspector if requested. These details include the name, address, and other particulars of the person from whom the individual acquired an ASU drug. The purpose of this disclosure requirement is to enhance transparency in the supply chain of these traditional medicinal products. By ensuring that individuals involved in the distribution of these drugs provide essential information about their sources, Section 33-KA facilitates effective regulatory oversight, helping authorities track and verify the origin of Ayurvedic, Siddha, and Unani drugs.

Section 33KB
It imposes obligations on individuals holding a manufacturer license pertaining to Ayurvedic, Siddha, or Unani drugs. According to this provision, license holders are required to keep and maintain records, registers, and other documents as prescribed by the relevant regulations. Additionally, the section mandates license holders to furnish necessary information to any officer or authority empowered under the Act.

Section 33L
Outlines the application of the provisions of this chapter, excluding section 33K related to confiscation, to government departments engaged in the manufacture, sale, or distribution of ASU drugs. It ensures that the regulatory framework established by this chapter, which includes licensing requirements, quality standards, and other stipulations, is applicable to government departments in a manner similar to private entities. However, unlike other provisions, it explicitly excludes the application

of section 33K, which deals with the confiscation of drugs upon conviction, thereby outlining a distinction in the enforcement mechanism concerning government departments.

Section 33M - Cognizance of offences
Addresses the initiation of prosecutions under this chapter. It stipulates that no prosecution can be instituted except by an Inspector and requires the previous sanction of the authority the inspector is subordinate to. This places a controlled and authorized mechanism for legal actions, ensuring that prosecutions are carried out with the official approval of the designated authority. Additionally, the section specifies that no court inferior to that of a Metropolitan Magistrate or a Judicial Magistrate of the first class shall try an offence punishable under this chapter, thereby establishing a higher judicial threshold for cases related to ASU drugs.

Section 33N
It delineates the substantial authority vested in the Central Government to promulgate rules, a power instrumental in enforcing the provisions of this chapter pertaining to ASU drugs. This regulatory framework is contingent upon consultation with or recommendations from the Board, emphasizing collaborative decision-making. The provision mandates prior publication of rules in the Official Gazette, ensuring transparency and public awareness. The rules, diverse in scope, cover crucial aspects such as the establishment of testing laboratories, qualifications and duties of Government Analysts and Inspectors, methods for testing drug authenticity, identification of poisonous substances, licensing procedures for drug manufacture and sale, including processed drugs, and conditions for cancellation or suspension of licenses. Additionally, the rules address packaging standards, labeling regulations, and the colors permitted for these traditional drugs. Importantly, the provision authorizes the prescription of standards for Ayurvedic, Siddha, or Unani drugs, reflecting a comprehensive approach to quality control. The inclusion of records and registers under Section 33KB highlights the emphasis on documentation and record-keeping, ensuring accountability and traceability in the manufacturing and sale of these traditional medicines.

Section 33O
This section grants the Central Government the authority to modify the First Schedule associated with ASU drugs. To enact such changes, the Central Government must engage in consultation with the Board, ensuring collaborative decision-making. The process involves issuing a notification in the Official Gazette, providing a minimum of three months' notice before implementing any amendments. Through a subsequent notification of similar nature, the Central Government can either add to or modify the entries in the First Schedule. Once this amendment process is completed, the First Schedule is considered officially amended according to the alterations made.

THE FIRST SCHEDULE

1. Qarabadin Qadri
2. Qarabadin Kabir
3. Qarabadin Azam
4. Ilaj-ul-Amraz
5. Al Qarabadin
6. Biaz Kabir Vol. II
7. Qarabadin Jadid
8. Kitab-ul-Taklis
9. Sanat-ul-Taklis
10. Miftah-ul-Khazain
11. Madan-ul-Aksir
12. Makhzan-ul-mufradat
13. National Formulary of Unani Medicine
14. Unani Pharmacopoeia of India

THE DRUGS AND COSMETICS RULES, 1945
The Drugs and Cosmetics Rules, 1945, are a set of rules that govern the import, manufacture, distribution, and sale of drugs and cosmetics in India. These rules are made under the authority of the Drugs and Cosmetics Act, 1940, and are designed to ensure the safety, efficacy, and quality of drugs and cosmetics sold in the country. The rules cover various aspects,

including the licensing of drug manufacturers and importers, the registration of drugs, the testing and analysis of drugs, the labeling and packaging of drugs and cosmetics, and the prohibition of certain drugs. The rules also provide for the establishment of a Central Drugs Laboratory to analyze and test drugs, as well as the appointment of drug inspectors to enforce the rules. Part XVI to Part XIX of the Drugs and Cosmetics Rules are related to the regulation of ASU Drugs.

PART XVI
MANUFACTURE FOR SALE OF ASU DRUGS

Rule 151 mandates that in the manufacturing process of ASU drugs, if operations extend to multiple premises, each site must secure an individual license. This provision ensures that each manufacturing location undergoes independent evaluation and regulatory scrutiny, promoting adherence to stringent safety, quality, and hygiene standards.

Rule 152 pertains to the appointment of Licensing Authorities by the State Government for the purpose of overseeing the manufacturing and sale of ASU drugs within specified areas. These Licensing Authorities are responsible for granting licenses and enforcing regulations outlined in the rules. The State Government designates these authorities through official notification in the Official Gazette.

Rule 153 outlines the procedures for applying for a license to manufacture ASU drugs for sale, as well as the associated fees. To initiate the licensing process, applicants must submit a formal application, utilizing Form 24-D, to the designated Licensing Authority. Alongside the application, a fee of one thousand rupees is required.

It also delineates provisions for license renewal, permitting applicants to seek renewal before the expiration of their existing license or within one month following its expiry. Renewal applications submitted within this timeframe incur a fee of one thousand rupees. However, renewal applications submitted later, within three months of expiry, are subject to an additional fee of six hundred rupees.

Furthermore, the section specifies the fee for obtaining a duplicate copy of a license, set at three hundred rupees.

Rule 153A delineates the procedures for obtaining a loan license to manufacture and sell ASU drugs, along with the associated fees. A loan license enables an applicant without manufacturing facilities of their own to utilize the production infrastructure owned by a licensee possessing a manufacturing license in Form 25-D.

Applicants seeking a loan license must submit a formal application, using Form 25-E, to the designated Licensing Authority. Alongside the application, a fee of six hundred rupees is required. Similar to the provisions for license renewal outlined in Rule 153, applicants may apply for loan license renewal before expiry or within one month following its expiration. Renewal applications within this timeframe incur a fee of six hundred rupees. However, renewal applications submitted later, within three months of expiry, are subject to an additional fee of three hundred rupees.

Additionally, the section specifies the fee for obtaining a duplicate copy of a loan license, set at one hundred and fifty rupees.

Rule 154 outlines the procedure for issuing a license to manufacture ASU drugs for sale, as well as the form of the license. To qualify for a license, applicants must ensure that the conditions specified in Rule 157 are met.

Once these conditions are fulfilled, a license to manufacture and sell ASU drugs is issued in Form 25-D. This license is granted within a period of three months from the date of receipt of the application by the Licensing Authority. Additionally, the grant of this license involves consultation with an expert in the relevant

system of medicine, as approved by the State Government.

Rule 154A pertains to the issuance of a loan license for the manufacture and sale of ASU drugs and specifies the form of this license.

Under this section, a loan license is granted in Form 25E to individuals or entities who do not possess their own manufacturing facilities but intend to utilize the manufacturing infrastructure of another licensee holding a manufacturing license in Form 25D.

The issuance of a loan license is subject to consultation with an expert in the relevant system of medicine, as approved by the State Government. Additionally, before granting a loan license, the Licensing Authority must ensure that the manufacturing unit has adequate equipment, staff, capacity for manufacture, and testing facilities to fulfill the manufacturing requirements on behalf of the applicant.

Rule 155 specifies the requirement for a certificate of renewal for a license to manufacture and sell ASU drugs. This certificate, issued in Form 26-D, serves as official confirmation of the renewal of the license. Upon completion of the renewal process, the Licensing Authority issues this certificate within the prescribed time frame, ensuring that the licensee maintains authorization to continue manufacturing and selling the specified drugs.

Rule 155A outlines a similar provision for the renewal of a loan license, which permits the manufacturing and sale of ASU drugs without possessing a manufacturing facility. A certificate of renewal, issued in Form 26-E, confirms the extension of the loan license. This certificate is provided by the Licensing Authority within the designated period, enabling the licensee to continue utilizing manufacturing facilities for the specified period.

Rule 155B introduces the concept of a certificate of Good Manufacturing Practices (GMP) for manufacturers of Ayurvedic, Siddha, or Unani drugs. This certificate, issued to licensees who comply with the GMP requirements specified in Schedule T of the rules, serves as recognition of adherence to quality manufacturing standards. The certificate is valid for a period of five years from the date of issuance of the license, ensuring ongoing compliance with GMP regulations and promoting the production of safe and effective pharmaceutical products.

Rule 156 delineates the duration of validity for an original license to manufacture and sell ASU drugs. Such a license, issued in Form 25-D, remains valid for a period of five years from the date of its issuance, provided it is not suspended or canceled earlier. Additionally, the section outlines provisions for license renewal, allowing licensees to apply for renewal before the expiration of their existing license or within one month following its expiry. If the renewal application is submitted within this timeframe, the license continues to remain in force until a decision is made on the renewal application. However, failure to apply for renewal within three months of expiry results in the license being deemed expired.

Rule 156A outlines the duration of validity for a loan license. An original loan license, issued in Form 25-E, or a renewed loan license, issued in Form 26-E, remains valid until the 31st of December of the year following the year in which it is granted or renewed. Similar to the provisions for original licenses, failure to apply for renewal within three months of expiry results in the license being deemed expired.

Rule 157 outlines the conditions that must be met for the grant or renewal of a license. Before a license is granted or renewed, applicants must ensure compliance with the specified conditions. These conditions include:

I. Ensuring that the manufacturing of ASU drugs is conducted in premises and under hygienic conditions as specified in Schedule T of the rules.

II. Compliance with Good Manufacturing Practices (GMP), as verified by the Licensing

Authority, and issuance of a GMP certificate simultaneously with the grant or renewal of the license.

III. Prohibition on using prefixes or suffixes with the names of ASU drugs, except as described in authoritative books specified in the First Schedule of the Act.

IV. Restrictions on using the names of ASU drugs for naming any patent or proprietary medicine, except for single plant-ingredient based formulations.

V. Requirement for licensees to seek renewal with appropriate names for drugs not conforming to specified rules within one year of the commencement of the Drugs and Cosmetics (4th Amendment) Rules, 2015.

VI. Imposition of penalties under section 33-I of the Act for contravening the specified rules.

Additionally, the section outlines requirements for competent technical staff involved in the manufacturing process, specifying qualifications and experience criteria for individuals directing and supervising the manufacture of ASU drugs:

- Degree/Diploma in relevant system of medicine or Pharmacy.
- Minimum 2-8 years' experience in drug manufacturing.
- Registration as Vaid/Hakim or Pharmacist as required.

Rule 157A mandates licensed manufacturing units of ASU drugs to maintain records of raw materials used in the preceding financial year. These records must be kept in the prescribed format provided in Schedule TA. Each manufacturing unit must submit these records to the State Drug Licensing Authority of ASU drugs and to the National Medicinal Plants Board or any designated agency by the 30th day of June of the succeeding financial year.

Rule 158 outlines the conditions that must be adhered to by license holders manufacturing ASU drugs. These conditions include:

- Maintenance of proper records detailing the manufacturing process and any tests conducted on raw materials and finished products.
- Authorisation for inspectors appointed under the Act to access manufacturing premises, inspect facilities, and obtain samples for testing.
- Maintenance of an Inspection Book to facilitate recording of inspectors' observations and identified defects during inspections.

Rule 158A imposes additional conditions on loan license holders manufacturing ASU drugs. These conditions include:

- The loan license is deemed cancelled or suspended if the manufacturing license of the entity providing manufacturing facilities is suspended or cancelled.
- Compliance with the provisions of the Act and rules, including any further requirements specified in subsequent rules under Chapter IV-A of the Act.
- Maintenance of proper records detailing the manufacturing process and any tests conducted on raw materials and finished products.
- Authorisation for inspectors appointed under the Act to access manufacturing premises, inspect facilities, and obtain samples for testing.
- Maintenance of an Inspection Book to facilitate recording of inspectors' observations and identified defects during inspections.

Rule 158B provides guidelines for issuing licenses pertaining to ASU drugs. These guidelines include:

- Definition of Ayurveda, Siddha, or Unani medicines under section 3(a) and patent or proprietary medicines under section 3(h).
- Criteria for issuing licenses for various types of medicines, including those mentioned in the First Schedule of the Act.

- Requirements for safety studies and evidence of effectiveness for different types of medicines.
- Specific conditions for issuing licenses for medicines promoting positive health, beauty products, medicinal plant extracts, and other formulations.
- Standard protocols published by Central Research Councils and other relevant bodies to be considered during the licensing process.
- *Rule 158C* pertains to the issuance of Free Sale Certificates (FSC) and Non-Conviction Certificates (NCC) for ASU drugs manufacturers. This section mandates the State Drug Controller or Licensing Authority to issue these certificates upon request by the manufacturer, within 15 days from the date of application.
- The Free Sale Certificate, available in Form 26 E2-I for original license holders and Form 26 E2-II for loan license holders, confirms that the products manufactured by the licensee comply with regulatory standards and are approved for sale in the domestic and international markets.
- The Non-Conviction Certificate, available in Form 26 E3, certifies that the licensee has not been convicted of any drug-related offences. These certificates are essential for manufacturers to demonstrate compliance with regulatory requirements and facilitate the export of Ayurvedic, Siddha, and Unani drugs to various countries.
- Category Ingredient (S) Indication (s) Safety studyExperience/Evidence of Effectiveness Published Literature Proof of Effectiveness(A) ASU drugs, given in 158 B as referred in 3(a)As per textAs per textNot RequiredRequiredNot Required(B) Any change in dosage form of ASU drugs, as described in section 3 (a) of the Drugs and CosmeticsAs per textAs per textNot RequiredRequiredNot RequiredASU drugs, referred in 3(a) to be used for new indication. As per textNewNot Required If Required. For issue of licence to the medicine with respect to Ayurvedic, Siddha and Unani, the conditions relating to safety study and the experience or evidence of effectiveness.

❖ *Rule 159* addresses the cancellation and suspension of licenses issued under the Act. This section empowers the Licensing Authority to cancel or suspend a license if the licensee fails to comply with any of the conditions of the license or violates any provisions of the Act or the rules made thereunder.

Before taking such action, the Licensing Authority must provide the licensee with an opportunity to show cause within a specified period, which shall not be less than fifteen days from the date of receipt of the notice. The licensee can present their defense and provide reasons why the license should not be cancelled or suspended.

If the licensee's license is suspended or cancelled, they have the right to appeal to the State Government within three months from the date of receiving the order. The State Government will consider the appeal and make a decision accordingly. CategoryIngredient (S)Indication (s)Safety studyExperience/Evidence of EffectivenessPublished LiteratureProof of Effectiveness(A) AqueousAs per textAs per textNot RequiredNot RequiredNot Required(A1) AqueousAs per textNew IndicationNot RequiredNot RequiredRequired(B) Hydro AlcoholAs per textAs per textNot RequiredIf RequiredNot Required(B1) HydroAlcoholAs specifiedNew IndicationRequiredIf RequiredRequiredOther than Hydro/ Hydro-AlcoholAs specifiedAs specifiedRequired Acute, Chronic, mutagenicity and teratogenicityIf RequiredRequiredFor issue of license with respect to extract of medicinal plant (dry or wet) CategoryIngredient (S)Indication (s)Safety studyExperience/Evidence of EffectivenessPublished LiteratureProof of EffectivenessPatent or Proprietary medicineAs per textTextual RationaleNot RequiredOf IngredientsPilot study as per relevant protocol for

Category	Ingredient (S)	Indication (s)	Safety study	Experience/Evidence of Effectiveness	
				Published Literature	Proof of Effectiveness
(A) ASU drugs, given in 158 B as referred in 3(a)	As per text	As per text	Not Required	Required	Not Required
(B) Any change in dosage form of ASU drugs, as described in section 3 (a) of the Drugs and Cosmetics	As per text	As per text	Not Required	Required	Not Required
ASU drugs, referred in 3(a) to be used for new indication	As per text	New	Not Required	If Required	Required

For issue of licence to the medicine with respect to Ayurvedic, Siddha and Unani, the conditions relating to safety study and the experience or evidence of effectiveness

Ayurveda, siddha and Unani drugsASU drugs with any of the ingredients of Schedule E(1) of the Drugs and Cosmetics Act, 1940As per textExistingRequiredRequiredRequiredFor issue of license with respect to Patent or Proprietary medicine. The condition relating to Safety studies and experience or evidence of effectiveness.

Rule 160 delineates the process for **identifying raw materials** used in the preparation of ASU drugs. This section mandates that raw materials must be identified and tested for genuineness where applicable. Records of these tests and the methods used must be maintained.

Category	Ingredient (S)	Indication (s)	Safety study	Experience/Evidence of Effectiveness	
				Published Literature	Proof of Effectiveness
Patent or Proprietary medicine	As per text	Textual Rationale	Not Required	Of Ingredients	Pilot study as per relevant protocol for Ayurveda, siddha and Unani drugs
ASU drugs with any of the ingredients of Schedule E(1) of the Drugs and Cosmetics Act, 1940	As per text	Existing	Required	Required	Required

For issue of license with respect to Patent or Proprietary medicine. The condition relating to Safety studies and experience or evidence of effectiveness

Category	Ingredient (S)	Indication (s)	Safety study	Experience/Evidence of Effectiveness	
				Published Literature	Proof of Effectiveness
(A) Aqueous	As per text	As per text	Not Required	Not Required	Not Required
(A1) Aqueous	As per text	New Indication	Not Required	Not Required	Required
(B) Hydro Alcohol	As per text	As per text	Not Required	If Required	Not Required
(B1) HydroAlcohol	As specified	New Indication	Required	If Required	Required
Other than Hydro/ Hydro-Alcohol	As specified	As specified	Required Acute, Chronic, mutagenicity and teratogenicity	If Required	Required

For issue of license with respect to extract of medicinal plant (dry or wet)

PART XVI (A)
APPROVAL OF INSTITUTIONS FOR CARRYING OUT TESTS ON ASU DRUGS AND RAW MATERIALS USED IN THEIR MANUFACTURE ON BEHALF OF LICENSEES FOR MANUFACTURE FOR SALE OF ASU DRUGS

Rule 160A outlines the application process for obtaining approval to conduct tests on ASU drugs, as well as their raw materials.

- Application Procedure: Entities seeking approval to perform tests on these drugs must submit an application in Form 47 to the Licensing Authority appointed by the State Government. This authority is referred to as the "approving authority" under this section.
- Inspection Fee: Along with the application, an inspection fee of six thousand rupees is required for testing the specified drugs listed in the First Schedule to the Act. If the approval renewal is sought within six months of its expiry, an additional fee is applicable.
- Additional Information: Applicants may be required to furnish additional information as requested by the approving authority in connection with the application.

Rule 160B elaborates on the form and conditions for granting approval to institutions for conducting tests on ASU drugs on behalf of licensees involved in manufacturing these drugs :

- **Approval Form:** Approval for conducting tests on these drugs is granted in Form 48.
- Conditions for Approval:
- Premises Requirements: The premises where the tests are conducted must be well-lit, properly ventilated, and, if necessary, air-conditioned to maintain accuracy and enable specialized tests.
  - **Space Requirement:** Adequate space must be provided for various sections such as Chemistry, Pharmacognosy, Microbiology, etc., with proper partitions. The minimum required area is 800 sq. ft.
  - **Expert Staff:** The applicant must provide a list of qualified experts such as chemists, botanists, and specialists in Ayurveda/Siddha/Unani or pharmacy, with specified degrees and experience.
  - **Equipment:** Adequate equipment essential for conducting tests must be provided, as per pharmacopoeial or other available standards. A detailed list of recommended equipment is provided for

Chemistry, Pharmacognosy, and Microbiology sections.

Chemistry Equipment:

- Apparatus for determination (alcohol, volatile oil, boiling point, melting point)
- Analytical instruments (refractometer, polarimeter, viscometer, UV spectrophotometer)
- Laboratory furnaces and ovens (muffle furnace, hot air oven)
- Glassware and supplies (distillation apparatus, sieves, crucible)
- Miscellaneous equipment (water bath, heating mantle, centrifuge machine)
- Testing apparatus for tablets (disintegration, friability, dissolution)
- Others (pH meter, gas cylinder, dehumidifier, etc.)

Pharmacognosy Equipment:

- Microscopy equipment (microscope, microtome)
- Laboratory supplies (chemical balance, slide cabinet, trays)
- Heating equipment (hot plates, oven)
- Storage facilities (refrigerator)
- Miscellaneous supplies (LPG cylinder, camera lucida, micrometers)

Microbiology Equipment:

- Sterilisation equipment (autoclave, incubators)
- Microscopy equipment (microscope)
- Laboratory supplies (water bath, colony counter)
- Others (laminar air flow bench)

Rule 160C outlines the duration of approval granted to institutions for conducting tests on ASU drugs:

- **Validity Period:** An approval granted or renewed in Form 48 or Form 49, respectively, is valid for a period of three years from the date of issuance or renewal.
- **Renewal Procedure:** If an application for renewal is submitted before the expiry of the approval, or within six months after expiry along with the additional inspection fee, the approval continues until a decision is made on the renewal application. Failure to apply for renewal within six months of expiry results in the approval being deemed expired.

Rule 160D delineates the conditions attached to approvals granted to institutions conducting tests on ASU drugs :

- **Institutional Requirements:** Institutions, referred to as approved laboratories, must ensure they possess and maintain adequate staff, premises, and equipment as specified in Rule 160B.
- **Storage Facilities:** Approved laboratories are mandated to provide proper storage facilities to preserve the properties of the samples intended for testing.
- **Record-Keeping Obligations:** The approved laboratory is required to maintain comprehensive records of tests conducted on all samples of ASU drugs, along with the test results and protocols. These records must be retained for a specified period, depending on the expiry date of the substances.
- **Inspection and Compliance:** The approved laboratory must permit inspectors appointed under the Act to enter the premises, inspect the equipment, and review testing procedures. They are also obliged to provide necessary information to inspectors for compliance verification.
- **Reporting Obligations:** The laboratory is responsible for reporting any changes in personnel, premises, or equipment to the approving authority. They must also furnish test reports in the prescribed format.
- **Quality Compliance:** The approved

laboratory must adhere to the provisions of the Act and rules made thereunder, along with any additional requirements specified under Chapter IV-A of the Act.

- **Inspection Book:** An inspection book must be maintained by the approved laboratory to facilitate recording of inspector impressions or identified defects.

Rule 160E: This section mandates a pre-approval inspection conducted by designated inspectors appointed by both the Central and State Governments. The purpose of this inspection is to thoroughly examine the premises and equipment intended for testing ASU drugs. Additionally, the qualifications of the expert staff employed by the laboratory are scrutinized to ensure they meet the required standards.

Rule 160F: Following the inspection conducted as per Section 160E, inspectors appointed by the Central Government are required to submit a detailed report of their findings to the approving authority. This report encompasses a comprehensive assessment of the laboratory premises, equipment intended for drug testing, and the qualifications of the expert staff employed by the institution.

Rule 160G: Upon receiving the inspection report specified in Section 160F, the approving authority conducts further inquiry, if necessary, to ensure compliance with the rules under the Act. Based on their assessment, the approving authority either grants approval in Form 48 if satisfied with compliance or rejects the application if not satisfied. In case of rejection, the applicant is informed of the reasons for rejection, providing them with clarity on areas needing improvement or rectification.

Rule 160H: If an application for approval is rejected, the applicant has six months to inform the approving authority that the conditions for approval have been met and to deposit a specified inspection fee. Subsequently, the approving authority may conduct another inspection to verify compliance with the conditions for approval. If satisfied with the outcome of the further inspection, the approving authority may grant approval in Form 48, allowing the applicant to proceed with conducting tests on ASU drugs.

Rule 160I: This section details the renewal process for approvals granted under Section 160G. Upon receiving an application for renewal, the approving authority conducts an inspection to ensure continued compliance with the rules under the Act. If satisfied with compliance, the approving authority issues a certificate of renewal in Form 49, extending the validity of the approval for another specified period.

Rule 160J addresses the withdrawal or suspension of approvals by the approving authority if the approved laboratory fails to comply with the conditions specified under the Act or the rules made thereunder. The approved laboratory is provided with an opportunity to show cause why such an order should not be passed before the approval is withdrawn or suspended. Additionally, the approved laboratory may appeal against the withdrawal or suspension of approval within a specified period.

PART XVII
LABELLING, PACKING AND LIMIT OF ALCOHOL IN ASU DRUGS

Rule 161: Labelling and Packing Requirements:

- Comprehensive Labelling Practices: Rule 161 mandates comprehensive labelling practices for ASU drugs, ensuring transparency and consumer safety. Key provisions include the disclosure of all ingredients used in the preparation, referencing authoritative texts for the method of preparation, and the inclusion of cautionary labels 'Caution: To be taken under medical supervision' for medicines containing Schedule E (1) substances.
- Essential Particulars: Labels must prominently display essential particulars such as the drug's name, net content, manufacturer details, license number, batch

number, date of manufacture, and indications for external use.

- **Exemptions:** Certain coverings used solely for packing, transport, or delivery are exempt from labelling requirements.

Rule 161A: Export Provisions:

- Adaptation to Destination Laws: It allows for the adaptation of labels and packages for export to meet the specific requirements of destination country laws. Despite adaptations, essential particulars such as drug name, manufacturer details, batch/lot number, date of manufacture, and main ingredients must be prominently displayed on the container.
- **Code Number Provision:** In cases where consignees request no manufacturer details for non-classified drugs, a code number approved by the Licensing Authority is required on labels, ensuring traceability and compliance with regulatory standards.

Rule 161B: **Expiry and Shelf Life Standards**:

- Date of Expiry: Rule 161B mandates the prominent display of the date of expiry on labels, ensuring the safe use of medicines.

Name of the group of medicine	Shelf life
Habb (Pills)	3 years
Qurs (Tablets)	3 years
Majoon/Dawa	3 years
Khamira	3 years
Itrifal	3 years
Tiryaq	3 years
Laooq	2 years
Laboob	2 years
Halwa	2 years
Mufarreh/Yaqooti	2 years
Burood/Surma/Kohal	3 years
Kushta	5 years
Raughaniyat	3 years
Marham/Zimad/Qairooti	3 years
Ayarij/Sufoof	2 years
Safoof (Namak wala/containing salt)	1 year
Sharbat/Sikanjabeen	3 years
Jawarish	3 years
Capsule	3 years
Arq	1 year
Qutoor	1 year
Nabeez	5 years
Murabba	1 year
Tila	2 years

PART XVIII
GOVERNMENT ANALYSTS AND INSPECTORS FOR ASU DRUGS

Rule 162 delineates the duties of inspectors involved in regulating the manufacturing of ASU drugs.

- Inspection Responsibilities: Inspectors are required to conduct biannual inspections of licensed premises to ensure compliance with licensing conditions, statutory provisions, and rules under the Drug and Cosmetics Act.
- Reporting Obligations: Following each inspection, inspectors must submit detailed reports to the controlling authority, outlining observations regarding adherence to regulatory requirements.
- Sample Collection and Analysis: Inspectors have the authority to collect drug samples during inspections for subsequent testing and analysis, aiming to verify product quality, potency, and safety.
- Prosecution Authority: Inspectors are empowered to initiate legal proceedings in cases of violations of the Drug and Cosmetics Act and associated rules, reinforcing the importance of regulatory compliance.

Rule 162A outlines the qualifications required for individuals serving as State Drug Licensing Authorities responsible for licensing Ayurvedic, Siddha, and Unani drugs.

- **Educational Qualifications:** The individual must possess Ayurvedic/Siddha/Unani qualifications as per Schedule II of the Indian Medicine Central Council Act, 1970, or a B Pharma (Ayurveda) degree from a recognized university.
- **Experience Requirement:** A minimum of five years' experience in Ayurvedic, Siddha, or Unani drug manufacturing, testing, or enforcement of relevant provisions of the Drug and Cosmetics Act, 1940, and associated rules. Alternatively, teaching/research experience in clinical practice of Ayurveda, Siddha, or Unani systems is acceptable.

Rule 163 outlines the procedural requirements for dispatching samples to government analysts for testing or analysis.

- **Method of Dispatch:** Samples for testing or analysis must be sent to the Government Analyst by registered post or by hand in a sealed package, accompanied by a memorandum in Form 18-A enclosed in an outer cover addressed to the Government Analyst.
- Both the package and outer cover must be marked with a distinguishing number to facilitate identification and tracking.
- A copy of the memorandum and a specimen impression of the seal used to seal the package must be sent separately to the Government Analyst by registered post or by hand.
- **Receipt and Inspection:** Upon receipt of the package, the Government Analyst or an authorized officer must open it, record the condition of the seals, and proceed with the analysis.
- **Reporting of Results:** Once the test or analysis is completed, the Government Analyst must provide one copy of the results in Form 13-A to the sender and simultaneously send another copy to the Controlling Authority and the Drugs Controller, India.

PHARMACOPOEIAL LABORATORY FOR INDIAN MEDICINES TO FUNCTION AS CENTRAL DRUGS LABORATORY FOR THE PURPOSE OF TESTING OR ANALYSIS OF ASU DRUGS

Rule 163A outlines the functions of the Pharmacopoeial Laboratory for Indian Medicine :

- Developing pharmacopoeial standards and drafting monographs.
- Serving as the Central Appellate Drug Laboratory.
- Conducting analysis of drug samples under relevant regulations.

- **Reference Facilities:** Maintaining a reference museum and herbarium.
- Training Center: Operating a training center for quality control methods.
- Carrying out tasks assigned by the Government of India.

Rule 163B states that:

- The Central Drug Laboratory's responsibilities for ASU drugs are managed at the Pharmacopoeial Laboratory for Ayurvedic, Siddha, and Unani Medicine in Ghaziabad, Uttar Pradesh.
- The Director of the Pharmacopoeial Laboratory oversees the functions related to these drugs, serving as the authoritative figure for their regulation and oversight.

Rule 163C governs the dispatch of samples for testing or analysis:

- Samples for testing ASU drugs must be sent by registered post in sealed packets, enclosed with a memorandum in Form 1A specified in Schedule A, to the Director of the Pharmacopoeial Laboratory for Indian Medicine.
- Both the packet and the outer cover should be marked with a distinct number to facilitate identification.
- Additionally, a copy of the memorandum in Form 1A and a specimen impression of the seal used to seal the packet must be sent separately by registered post to the Director of the Pharmacopoeial Laboratory for Indian Medicine.

Rule 163D: Upon receipt of the sample packet, an authorized officer at the Pharmacopoeial Laboratory for Indian Medicine is required to open it and record the condition of the seal on the packet.

Rule 163E: After the completion of the test or analysis, the results, along with full test protocols, must be promptly provided to the sender in the specified format in form 2A

Rule 163F: This section outlines the fees for conducting tests and analyses, as specified in Schedule B-1 of the Drug and Cosmetics Rules.

Rule 163G: Certificates issued by the Pharmacopoeial Laboratory for Indian Medicine must be signed by the Director or an authorized officer designated by the Central Government.

Rule 164 delineates the method of test or analysis to be employed concerning ASU drugs:

- The method of test or analysis must adhere to specifications outlined in the Ayurvedic, Siddha, or Unani Pharmacopoeia.
- If no specific tests are specified in the pharmacopoeias, the Government Analyst may employ scientifically established tests to determine whether the drug contains the ingredients as stated on the label.

Rule 165 delineates the qualifications required for a Government Analyst:

- The Government Analyst must possess qualifications prescribed in Rule 44 or hold a degree in ASU System conferred by a recognized University, State Government, or Statutory Faculties, Councils, and Boards of Indian Systems of Medicine recognized by the Central or State Government.
- Additionally, the Government Analyst must have a minimum of three years' postgraduate experience in drug analysis in a laboratory under the control of a Government Analyst appointed under the Act, a Chemical Examiner to Government, or the Head of an institution approved for this purpose.

Rule 166 outlines the duties of a Government Analyst :

- The Government Analyst is responsible for analyzing or testing drug samples sent by Inspectors or other authorized entities under the Act.
- They must furnish reports of the test or analysis results in accordance with the rules.
- Government Analysts appointed under

FORMS	PURPOSE
FORM 1 (Rule 163C)	Memorandum to the Pharmacopoeial Laboratory for Indian Medicine (PLIM)
FORM 2A (Rule 163E)	Certificate of test or analysis from the Pharmacopoeial Laboratory for Indian Medicine or Government Analyst
FORM 13A (Rule 163-5)	Certificates of tests or analysis by Government Analyst under section 33H of the Drugs and Cosmetics Act, 1940
FORM 18A (Rule 163-1)	Memorandum to Government Analyst
FORM 24D (Rule 153)	Application for the grant/renewal of a licence to manufacture for sale of Ayurvedic/ Siddha or Unani drugs
FORM 24E (Rule 154A)	Application for grant or renewal of a loan licence to manufacture for sale Ayurvedic (including Siddha) or Unani Drugs
FORM 25D (Rule 154)	Licence to manufacture for sale of Ayurvedic (including Siddha) or Unani drugs
FORM 25E (Rule 154A)	Loan Licence to manufacture for sale Ayurvedic (including Siddha) or Unani Drugs
FORM 26D (Rule 155)	Certificate of renewal of licence to manufacture for sale of Ayurvedic / Siddha or Unani drugs
FORM 26E (Rule 155A)	Certificate of renewal of loan licence to manufacture for sale of Ayurvedic / Siddha or Unani Drugs
FORM 26E-I (Rule 157B)	Certificate of Good Manufacturing Practices (GMP) to manufacture of Ayurveda, Siddha or Unani drugs
FORM 26E2-I (Rule 158C)	State Drug Controller or Licensing Authority for Ayurveda, Siddha and Unani Medicines
FORM 26E2-II (Rule 158C) Free Sale Certificate	State Drug Controller or Licensing Authority for Ayurveda, Siddha and Unani Medicines
FORM 26 E3 (Rule 158C) Non-Conviction Certificate	State Drug Controller or Licensing Authority for Ayurveda, Siddha and Unani Medicines
FORM 35 (Rules 158 and 158A)	Form in which the Inspection Book shall be maintained
FORM 47 (Rule 160 A)	Application for grant or renewal of approval for carrying out tests on Ayurvedic, Siddha and Unani drugs or raw materials used in the manufacture thereof on behalf of licensees for manufacture for sale of Ayurvedic, Siddha and Unani drugs
FORM 48 (Rule 160 B)	Approval for carrying out tests or analysis on Ayurvedic, Siddha and Unani drugs or raw materials used in the manufacture thereof on behalf of licensees for manufacture for sale of Ayurvedic, Siddha and Unani drugs
FORM 49 (Rule 160- I)	Certificate of renewal for carrying out tests or analysis on Ayurvedic, Siddha or Unani drugs or raw materials used in the manufacture thereof on behalf of licensees for manufacture for sale of Ayurvedic, Siddha or Unani drugs

FORMS	PURPOSE
FORM 50 (Rule 160 D(f)	Report of test or analysis by approved Laboratory
SCHEDULE B(1) (Rule 163F)	FEES FOR THE TEST OR ANALYSIS BY THE PHARMACOPOEIAL LABORATORY FOR INDIAN MEDICINE (PLIM) OR THE GOVERNMENT ANALYST
SCHEDULE TA (Rule 157 A)	FORM FOR RECORD OF UTILIZATION OF RAW MATERIAL BY AYURVEDA OR SIDDHA OR UNANI LICENSED MANUFACTURING UNITS DURING THE FINANCIAL YEAR

section 33F are required to periodically forward reports of their analytical work and research to the Government for potential publication.

Rule 167 details the qualifications necessary for an Inspector:

- The individual must meet the requirements outlined in Rule 49 and have received practical training in manufacturing ASU drugs.
- Alternatively, they may hold a degree in ASU System, or a degree in Ayurveda Pharmacy from a recognized institution.
- A diploma in ASU Systems from a recognized State Government or institution is also acceptable.

PART XIX
STANDARDS OF AYURVEDIC, SIDDHA AND UNANI DRUGS

Rule 169 delineates the permissible excipients for ASU drugs, in accordance with established standards such as the Indian Pharmacopoeia, Prevention of Food Adulteration Act, and Bureau of Indian Standard Act.

- Excipients, including additives, preservatives, antioxidants, and flavoring agents, must adhere to specified limits and quality specifications as outlined in relevant regulations.
- Only natural coloring agents permitted by the Prevention of Food Adulteration Rules and colors approved under the Drugs and Cosmetics Rules are allowed.
- Clear labeling requirements for preservatives and coloring agents are mandated.
- Manufacturers must disclose additives used in formulations and ensure their rationality, safety, and appropriate quantities.
- Artificial sweeteners are permitted in proprietary ASU products, subject to statutory warnings and adherence to specified acceptable daily intake levels as recommended by the US FDA:
  - Sucralose: 5 mg/kg body weight
  - Aspartame: 40 mg/kg body weight
  - Saccharin: 5 mg/kg body weight
  - Acesulfame K: 15 mg/kg body weight
- Any prior notifications from the Department of AYUSH regarding excipients, additives, or preservatives are superseded by these regulations.

REFERENCE

Drugs and Cosmetics Act, 1940, Rules, 1945; Government of India