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Quality assurance, shelf life, stability studies of ASU herbal, medicinal plants-*Syzygium aromaticum* (Linn.) Merr LM Perry and *W. fruticosa* (Linn.) Kurz

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Abstract
Introduction: QA, Shelf life, Stability Studies of ASU. herbal products remains a challenging task. The Coarse powder of SA and WF are specially designed for oral consumption and contains herbal ingredients known for their specific medicinal benefits. Storage conditions can significantly affect the shelf life of ASU. herbal Coarse powders, therefore, it is essential to assess the stability of these Coarse powders. According to ICH / WHO guidelines, which is used to treat various human ailments. This study aims to evaluate the QA, SL, SS investigated, analyzed parameters of coarse powders of flowers buds and flowers parts of the plant drugs SA and WF.
Methods: The QA, SL, SS investigated studies with the accelerated stability studies at 40 °C and a relative humidity (RH) of 75% ±5 over a period of 6 months, with assessments conducted at the 0, 2nd, 4th, and 6th months. Various parameters, including Organoleptic characteristics, Pharmacognosy, HPTLC. identification, physico-chemical properties, Toxicological studies having investigated HM, AT, PR and MB load, were monitored during these intervals of SA and WF were carried out and performed using standard methods. The accelerated testing conditions are at least 10 °C Temp. higher than the long–term study conditions and are intended to increase the rate at which degradation reactions take place thus revealing quality changes at an early stage globally climatic zones are divided into max. 6 months intervals time period for shelf life, stability studies and the storage conditions.
Results: The results of these studies were taken into consideration when estimating the QA, SL, SS of SA and WF Course powder drugs. The extended shelf life estimate was determined by applying an accelerated deterioration rate of 10% for physico-chemical parameters.
Conclusions: The QA, SL, SS findings were revealed that the test drugs batches were stability is confirmed, no max. significance changes occurred in tested samples and shown stable potent of undeteriorate condition. As a result, it was established that the SA and WF course powder have an estimated shelf life Max. 1 years and eight months and 2 Year. The Studies revealed data's can be provide referential supports and essential in the future for QA, Product Acceptability, Pharmaco-vigilance aspects.

Keywords: QA, shelf life, stability studies, organoleptic, pharmacognosy, HPTLC. identification, Physico-chemical, toxicological studies, SA and WF course powder.

Introduction
World Health Organization (WHO) has emphasized the need to ensure quality control of medicinal plant products by using modern techniques and by applying suitable parameters and standards. In order to overcome certain inevitable shortcomings of the pharmacopoeial monograph, other quality control measures must also be explored (Ahmed *et al*., 2017, Anonymous, a2011) [20, 35] The quality assurance and quality control of ASU. Herbal crude drugs and formulated products are important in justifying their acceptability in modern system of medicine. Hence it is required to conduct the research on drugs standardization and product validation to provide effective, curable and safe drugs to the needy mass suffering from various ailments (Sagar *et al*., c2024, 2023, a2020, b2020) [4, 10, 13, 14].
When assessing the quality of herbal products over time, stability testing is crucial as it considers diverse environmental factors, such as humidity, sunlight, air, and climate. This testing is instrumental in establishing guidelines for shelf life, Stability and storage. The ASU. (Ayurvedic) healing approach involves diverse dosage forms, adding complexity to standard quality control. Herbal tablet forms, known for their rigid structure in round, oval, or square shapes, include additives like disintegrates, lubricants, glidants, and binders to preserve tablet integrity and potency.

Ayurvedic tablets, created for oral use, often feature beneficial medicinal herbal components. The term "Stability" denotes a product's ability to stay within defined limits under specific storage conditions. Essential for determining shelf life, stability studies, including accelerated and real-time analyses, are prevalent in the pharmaceutical sector. Accelerated stability testing is particularly valuable for insights into the shelf life of herbal medicines. The concentration and presence of active phytochemical components have a direct impact on the quality, effectiveness, and shelf life of herbal products. It is crucial that variations in bioactive components do not exceed ±5% of the initial concentration. Storage conditions significantly influence the shelf life of Triphala tablets, and assessments help ascertain the duration for which the tablets can uphold their intended quality and therapeutic properties. This ensures they remain secure and efficacious for consumers over time (Irudaya *et al*., 2024) [1].

The quality assurance and quality control of herbal crude drugs and formulated products are important in justifying their acceptability in modern system of medicine. Hence it is required to conduct the research on drugs standardization and product validation to provide effective, curable and safe drugs to the needy mass suffering from various ailments (Sagar *et al*., a, b.c, d, e, f, g2024, 2023, 2022, a, b2020, 2017, 2015, b2013) [2-11, 13, 14, 18, 29, 33].

Pharmacological Activities and Active Phytochemacal Constituents of SA and WF

Syzygium aromaticum Linn

Medicinal plant drug Laung (Clove) *Syzygium aromaticum* Linn used pharmacological activities as a Toothache or Muscular pain (Waj-ul-Asnam), Weakness of the Stomach (Zof-e-Meda), Hepatitis or Weakness of Liver (Zof-e-Kabid), Dyspepsia (Sue-Hazm), Flatulence in the stomach and Colic (Nafkh-e-Shikam Qulanj) problems. As per Ayurvedic System of Medicine, it is used for respiratory disorder (Svasa), vomiting (Chardi), bloating or gaseous distension of abdomen (Adhmana), wheezing, breathing difficulty (Hikka), cough, cold (Kasa), chronic respiratory disorder (Ksaya or Kshaya), excessive thirst (Trsna orTrushna), indigestion or acidity (Amlapitta), bleeding disorder (Pittasran ashana), asthma (Shwasa) and improving digestion strength and taste. ntibacterial, antifungal, antioxidant, antistress activity, anti-inflammatory, anticancerous, antiviral, analgesics activity, dental care activity, Mosquito repellent, insecticidal activities and Neuroprotective activity (Sagar *et al*., a2017) [18].

Syzygium aromaticum Linn, oil was reported to contain bio-active phytochemical constituents of nearly 36 components with a highconcentration of eugenol (88.58%), eugenol acetate (5.62%), β-caryophyllene(1.39%), less concentration of 2-heptaanone (0.93%), ethylhexanoate (0.66%), humuleno (0.27%), α-humulenol (0.19%), calacorene (0.11%) and calamenene(0.10%) (Pulikottil and Nath, 2015, Chaieb *et al*., 2007). Eugenol (4-allyl-1-hydroxy-2-methoxybenzene), a phenolic non-nutrient compound, is one of themajor components with a molecular weight of 164.20 and β-caryophyllene, the other major constituent of clove oil which has a molecule weight of 204.35. (Lee *et al*., 2002, Sagar *et al*., a2017). The Siddha Pharmacopeia of India reported the presence of active constituents such as Caryophyllene oxide, caryphylla-3(12), 6-dien-4-ol, caryophylla-3(12), 7(13)-dien-6 α-al, eugenol (77.1% of volatile oil), acetophenone, 2-hydroxy, 4, 6, di-methoxy-5-methylaceto phenone, β-caryophyllene, eugeno lacetate, derivative of β-caryophyllene, α-humulene and its expoxide, benzylsalicylate, α-cardinol, γ-decalacetate, fenchone, hexanol, 2-hexanone, methylpalmitate, α-murolene, palustrol, propyl benzoate, α-thujene, β-selinene and eugenine. (Sagar *et al*., a2017) [18].

Woodfordia fruticosa (Linn.) Kurz

Reported effective therapeutics uses of multipurpose medicinal potent plant Dhataki / Dhaiphool / Gul-e-Dhawa (*Woodfordia fruticosa* (Linn.) Kurz), pharmacological activities foundas Anti-hyperglycemic activity, Anti-depressant activity, Anti-inflammatory activity, Anti-cancer activity, Wound healing activity, Hepatoprotective activity, Anti-bacterial activity, Antioxidant activity, Anti-enteroviral activity, Gastroprotective activity, Antifertility activity, Prebiotic activity, Analgesic activity, Antipsoriatic activity, Immunostimulatory activity, Anti-asthmatic activity, successfully investigated in *in vitro* or in vivo studies of research. (Sagar *et al*., a, c, f 2024, Sajwan *et al*., d2024, Giri *et al*., 2023) [2, 4, 5, 7, 9].

Woodfordia fruticosa (Linn.) Kurz was reported to contain bio-active phytochemical constituents phenolic, non-phenolic, flavonoids, essential oil, compounds like 1, 2, 3, 6-tetra-O-galloyl-β-d-glucose, 1, 2, 3, 4, 6-penta-O-galloyl-β-d-glucose, tellimagrandin, gemin D, hetero phylliin A, woodfordins A, B, C and oenothein B. (Sagar *et al*. a, c, f 2024, Sajwan *et al*., d2024, Giri *et al*., 2023) [2, 4, 5, 7, 9].

Materials and Methods

Test Product Details

Data from formal shelf life, stability studies should be provided on at least three primary batches of the drugs substance. The batches should be prepared to a minimum of pilot scale in coarse powder form by the same synthetic route as, and using a method of preparation and procedure that simulates the final process to be used for, prepared batches. The overall quality of the batches of drug substance placed on formal stability studies should be representative of the quality of the material to be made on a production scale.

Sample Size quantity and packing: The weight of each batches of studies drugs samples typically ranges from 400gm and there are kept in to 400ml food grade air tight plastic Containers.

Storage conditions in the stability chamber

Initially Real time Shelf life Stability Study have planned for 0, 2, 4, 6 Months, Gap period at Climatic Stability Chamber, maintained Specific temperature and Humidity % at a Control Room Temp (CRT), ambient condition. Stored at Stable temperature range 30 °C (Max.) ±2 °C and Humidity range 60% (Max) ± 2% RH, Fixed Temp. and humidity Condition, As same for Accelerated Shelf life Stability Study have been planned and carried out for 0, 2, 4, 6 Months Gap period at Climatic Stability Chamber maintained specific temperature and Humidity % at an Control Room Temp. (C.R.T.) ambient condition at Stable temperature range 40°C(Max.) ±2°C and Humidity range 70% (Max) ± 5%RH (Fixed Temp. and humidity Condition Stored in to 2 Stability Chambers of every Examined 3 ASU Herbal Single batches or Compound formulated Drugs samples taken for start and initiated the studies, according to the acceptable limits proposed by AYUSH or Regularity authorities and ICH guidelines basis (Sagar *et al*., 2017, 2016, 2013) [19, 24, 32].

Finally, we have decided and applied study of the accelerated stability. The study was carried out in a 2 stability chambers

(Remi Elektrotechnik Ltd, Model: SC-35 PLUS) following the ICH guidelines Q1A (R2). Samples were stored at a temperature of 40 °C±2 °C, with a relative humidity of 70%±5%, and this condition was maintained for a period of 6 months. (Irudaya *et al*., 2024) [1].

Frequency of withdrawal

The impact of the intervention was evaluated at study intervals of 0, 2, 4, and 6 months over a 6-month period. In the accelerated stability study, a degradation level of 10% was established as the acceptable threshold. (Irudaya *et al*., 2024) [1].

Parameters Analysed and Investigated

Shelf life, Stability and Quality Assurance Studies of ASU/ TAM Herbal crude / single drugs, Herbal formulated Drugs: Accounting to WHO it is the process involving the physicochemical evaluation of crude drug covering the aspects, as selection and handling of crude material, safety, efficacy and stability assessment of Single drugs and finished product, documentation of safety and risk based on experience, provision of product information to consumer and product promotion (Sagar *et al*. c2024, 2017, 2016, 2013, Ritch *et al*., 2000, Wani *et al*., 2021) [4, 19, 24, 32].

Macro and Microscopic, Organoleptic Examination

For Identification of right variety and search of adulterants

1. **Foreign Organic Matter:** Remove of matter other than source plant to get the drug in pure form.
2. **Ash Values:** It is criteria to judge the identity and purity of crude drug-total ash, sulfated ash, water soluble ash and acid insoluble ash etc.
3. **Moisture Content:** To check moisture content helps prevent degradation of product.
4. **Extractive Values:** These are indicating the approximate measure of chemical constituents of crude drug.
5. **Crude Fiber:** To determine excessive woody material Criteria for judging purity.
6. **Qualitative Chemical Evaluation:** It covers identification and characterization of crude drug with respect to phytochemicals Constituent.
7. **Chromatographic Examination:** Include identification of crude drug based on use of major chemical constituent as marker.
8. **Qualitative Chemical Evaluation:** Criteria to estimate amount the major class of constituents.
9. **Toxicological Studies:** Pesticide residue, potentially toxic elements, and Microbial count approach to minimize their effect in final product.

(Sagar *et al*., a, b, c, d, e, f, g2024, 2023, 2022, a, b2020, 2017, 2015, 2016, 2013, Ritch *et al*., 2000, Wani *et al*., 2021) [2-8, 10, 11, 13, 14, 18, 19, 29, 24, 32, 33]. Details description please may see in Graphical Abstract, Figure-1 respectively.

Details Graphical Illustration / Graphical Abstract and Shelf life, Stability Studies research data's of *S. aromaticum* Linn and *W. fruticosa* (Linn) Kurz clearly Shown as follows in Fig.-1, Fig.-2, 3, 4, 5 and Table-4, 5, 6, 7 and 8 respectively: [1-5, 7, 9, 18, 19, 24, 32].

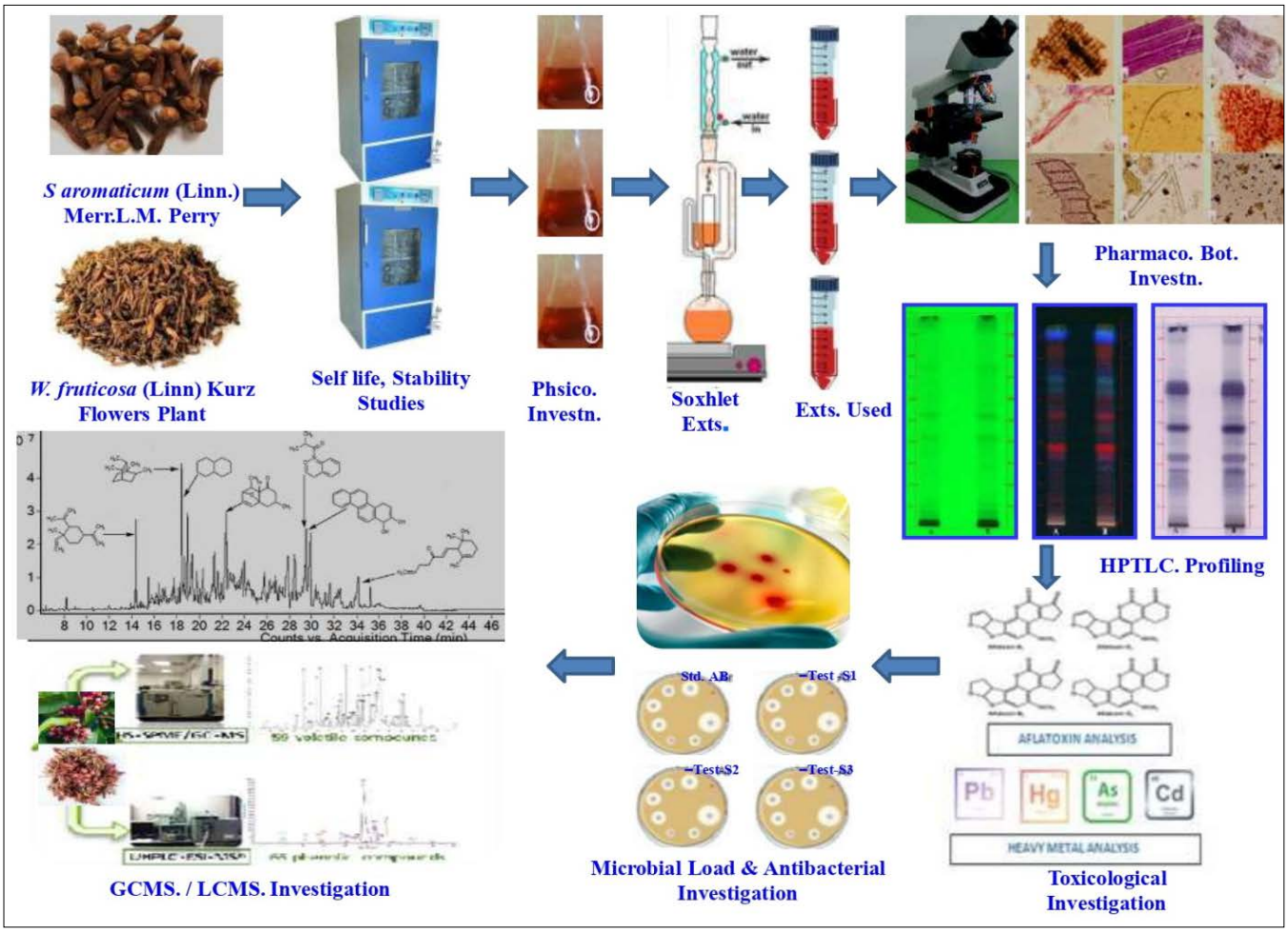

Fig 1: Graphical Illustration

Guideline for Stability testing and Shelf life: determination of ASU medicine Stability studies is carried out to demonstrate that the medicine will remain suitable for consumption during shelf period when stored under the condition(s) mentioned on the packaging. On the product label, if there is no mention about any specific storage condition, then it is assumed that the product can be stored at room temperature (below 30 °C), Studies Single drugs in Course powder form used as complete Accelerated Shelf life, Stability studies planed and their various ASU formulations prepared Shown in Table-2, 3, 4 respectively. (Azahar *et al*., 2019, Anonymous.a2016. The Gazette of India, Ananomous, c2016, The Drugs and Cosmetics Act and Rules, Ananomous, d2016, Ananymous, WHO, 2009, Anonymous, ICH Guidelines, 2003, Ananymous, WHO, 2001, Ananumous, 1973) [15, 25, 27, 28, 40, 43, 44, 47].

Table 1: Shelf Life of ASU Medicine [15, 25, 27, 28, 40, 43, 44, 47].

Shelf life or date of expiry 2 years-	
Ayurvedic Formulation	Anjana made from kasthaushadi along with Rasa/Uprasa/Bhasma, Churna, Kwatha Churna, Lepta Churna, Danta Manjan (Churna), Dhoopan, Ghrita, Karna/Nasabindu, Sattva (derived from medicinal plant), Shveta parpati, Varti
Siddha Formulation	Araippu Karpam (e.g. Irunelli Karpam), Karam (Karanool), Karuppu containing only Mooligai ingredients (e.g. Vasambu Sutta Kari), Kutinir Curanam/Adai Curanam/Kanchi Curanma/Utkali Curanam/Pittu Curanam/ Podithimirthal Curanam/ Podi/ Pattru Curanam/Pottanam or Kizhi Curanam/Ottratam Curanam/ Vethu Curanam/Pugai Curanam/Kali Curanam/ Thuvalai Curanam, Mattirai/Vatakam containing only Mooligai ingredients (including Kudineer Curanam Mattirai) (e.g. Nilavembu kutinir Mattirai), Mooligai Karpam (e.g. Karisalai Karpam, Thiripala Karpam), Ney/Ghiruthan/Kadugu, Parpam/Centuram containing only Mooligai ingredients (e.g. Kungiliya Parpam), Peechu, Rasa-Paadana Marunthugal (All Mercurial Preparation) containing Mooligai ingredients along with Thathu, Porutkal/Parpam/Centuram/Cunnam/Kattu/Kalanku, Satthu derived from Mooligai (e.g. Seenthi Satthu), Sutigai, Tiravakam (derived from ThathuPorutkal)
Unani Formulation	Ayarij/Joshanda/Sunoon/Zuroor/Ghazah, Marham/Zimad/Qairooti, Shiyaf, Sufoof (Without Salt)

Table 2: ASU Medicinal Plants Drugs ASU Classical Formulations, (Anonymous, 2007, Anonymous.1986) [42, 46].

Syzygium aromaticum Linn	Lavangadi Vati, Lavangadi Curna, Habb-e-Ambar, Habb-e-Ambar Momyaee, Habb-e-tursh Mushtahi, Qurs-e-Tutiya-e-Kabir, Kohal-e-Roshnai, Itrifal Ghudadi, Jawarish-e-Jalinoos, Jawarish-e-Narmushk, Jawarish Zarooni sada, Jawarish-e-Bisbasa, Majoon-e-Kundur, Jawarish-e-Oad Tursh, Jawarish-e-Utraj, Khamira-e-Abresham Arshadwala, Mojoon-e-Dabeedul Ward, Majoon-e-Fanjosh, Majoon-e-Khadar, Majoon-e-lana, Majoon-e-Muluki, Majoon-e-Seer Alwi Khani, Majoon-e-Suparipak, Raughan-e-Qaranful, Raughan-e-Surkh, Araq-e-Ambar, Araq-e-Chobchini, Sunoon-e-Mujalli, Majoon-e-Jalali, Majoon-e-Kalkalanaj, Habb-e-Munaish.
Woodfordia fruticosa (Linn.) Kurz	Brhat Gangadhara Curna and Used in preparation of various ASU Formulations in Ashava's and Arishta's, Ayurvedic classical Formulations preparations.

Table 3: Recommended storage conditions for ASU medicines [15, 25, 27, 28, 40, 43, 44, 47].

S. No.	Study	Storage condition	Minimum time
1.	Accelerated	40º C ± 2º C 75% RH ± 5% RH	6 months
2.	Real time / Long Term	30º C ± 2º C 60% RH ± 5% RH	12 months

Determination of Shelf Life: The evaluation of shelf life involved considering various parameters, including pH, water-soluble extract, alcohol soluble extract, moisture, ash, and the active phytochemical ingredients. Data from three batches, collected at the 0^{th}, 2^{nd}, 4^{th}, and 6^{th} months, were compiled, and the average values for these parameters were calculated. To assess shelf life, separate data graphs were plotted for each parameter, depicting the four-time points, to analyze the slope and intercept of the trends. Shelf life was determined by calculating the time it takes for a 5% degradation in these parameters to occur, employing a specific formula. Shown in Table-5, 6, 7 and 8 respectively in every studies batches of SA and WF Coarse Powders Sinle ASU Drugs. (Irudaya *et al*., 2024, Azahar *et al*., 2019, Anonymous. A 2016. The Gazette of India, Ananomous, c2016, The Drugs and Cosmetics Act and Rules, Ananomous, d2016, Patgiri *et al*., 2014, Ananymous, WHO, 2009, Anonymous, ICH Guidelines, 2003, Anonymous, WHO, 2001, Anonymous, 1973) [1, 15, 25, 27, 28, 30, 40, 43, 44, 47].
Month When 10% degradation occurs = [0 Month Assay value – {(0 Month Assay Value X 10) / 1000}]-Intercept).

Slope: Applying this formula, the shelf life of each individual parameter was calculated. Subsequently, the average shelf life of the product was determined by considering all these parameters collectively. To estimate the overall shelf life of the Triphala tablets in accelerated studies, an extrapolation was performed using a real-time aging factor of 3.3. This factor is specifically applicable to climate zones III and IV countries, such as India, and is employed (Irudaya *et al*., 2024, Anonymous.a2016, WHO Stability testing Guidelines, 2009, The Gazette of India, Anonymous, c2016, Anonymous, ICH Guidelines, 2003, Anonymous, WHO, 2001) [1, 25, 27, 40, 43, 44].

Result and Discussion: [1, 15, 16, 17, 25, 27, 28, 30, 40, 41, 43, 44, 47].
In reviled results contrast, within the pharmaceutical and Indian System of Medicine system for investigation of ASU Single & compound formulated medicinal products, the term "shelf life" refers to the duration during which an Active Pharmaceutical Ingredient (API) or Finished Pharmaceutical Product (FPP) is expected to retain its quality and efficacy within approved stability specifications. Despite numerous quality assessments of ASU medicinal products being published, there is insufficient evidence to support shelf-life research. The unexpected longevity of the shelf life, surpassing traditional expectations of ASU Medicinal plants,

is attributed to the integration of advanced packaging technology. This technological innovation plays a pivotal role in effectively controlling and regulating various aspects of the manufacturing process, thereby minimizing or eliminating potential drawbacks that could compromise the stability of the product (Irudaya *et al*., 2024) [1]. This expectation is contingent on the product being stored under recommended conditions and products Quality assurance and acceptability from customer end. The shelf life for course churna form churna (powders) and tablets, as stipulated in rules 161-B and 1945 of the Drug and Cosmetic Act 1940 and 1945, respectively, is set at 2 and 3 years. These regulations are documented in GSR 763(E) dated 15.10.2009, with amendments up to 31.12.2016. Nevertheless, the guidelines for stability studies, outlined in the Ayurvedic Pharmacopoeia of India, Part-I, Volume-VIII, are pertinent to all Ayurvedic medicines (Irudaya *et al*., 2024, Anonymous. API, 2008) [1, 41]. These guidelines are designed to establish scientific, data-driven shelf-life determinations through real time and accelerated studies. Discovered that three different brands of Triphala churna shared similar parameter values, except for a noticeable distinction in the flow properties of the powder. This underscores the importance of conducting analytical evaluations for each batch to optimize the final product and establish quality control and assurance limits. (Irudaya *et al*., 2024, Agarwal *et al*., 2018) [1, 16]. In other studies, reported that the HPTLC chromatographic fingerprint of Triphala Tablets remained consistent throughout their study, which focused on the stability control strategy of a Triphala solution. They identified an equilibrium point based on the balance between physical and chemical stabilities. (Irudaya *et al*., 2024, Huang *et al*., 2018) [1, 17]. In a separate study examined the physical parameters, such as description and loss on drying, finding them to be in accordance with ICH guidelines. No degradation was observed, supporting the safety and efficacy of the product. (Irudaya *et al*., 2024, Shivakumar *et al*. 2016) [1, 23]. It's noteworthy that the course powder drug samples of SA and WF are prepared using the grinding, hammer machine process, a manufacturing approach that not only meets but complies with Organoleptic, morphological, appearance, Pharmacognosy and HPTLC identification, hence slightly significant changes were evaluated and shown in physicochemical parameters, alcohol soluble extractive matter %, Water soluble extractive matter %, volatile oil%, pH at (10% Solution) for 6th Months stored at accelerated conditions in Stability Chambers. Therefore, our investigation of ASU Medicinal plants, products commenced to assess the stability and shelf-life of Coarse form Powders of SA and WF. In this accelerated stability study, ASU Medicinal plants-based product batches were investigated at intervals of 0th, 2nd, 4th, and 6th months. Figure-1, 2 and 3, Graphical Illustration, Fresh and Dried form of investigated Coarse form Powders of SA and WF Drugs. Illustrates the changes in Applied Course powder drug samples of SA and WF, colour and appearance up to the sixth month, indicating minimal alterations in organoleptic qualities, including appearance, colour, taste, odour, and smell (Table 5 and Table-7). Table 6 demonstrates insignificant changes in the physico-chemical profile at different intervals. The proximate quality assurance, shelf life, stability studies investigated and analysis results for Course powder drug samples of SA and WF, as presented in Table 8, indicate compliance with expected standards or specifications. Crucially, In Table 6 and 8 confirms Toxicological Studies that the Course powder drug samples of SA and WF were devoid of Aflatoxins and microbial contamination form 0 and 6 month shelf life stability studies.

Table 4: Evaluation of Organoleptic identifications, properties for SA Coarse Powder

Parameters	Batches	Month 0th	Month 2nd	Month 4th	Month 6th	Criteria	Result
Appearance	B-1	Coarse Powder Form	Coarse Powder Form	Coarse Powder Form	Coarse Powder Form	Anonymous, API/UPI: 1986, 2007, 2009, 2011, 2022 [46, 42, 35, 36, 38-40]	No significant change
	B-2	Coarse Powder Form	Coarse Powder Form	Coarse Powder Form	Coarse Powder Form	Anonymous, API/UPI: 1986, 2007, 2009, 2011, 2022 [46, 42, 35, 36, 38-40]	No significant change
	B-3	Coarse Powder Form	Coarse Powder Form	Coarse Powder Form	Coarse Powder Form	Anonymous, API/UPI: 1986, 2007, 2009, 2011, 2022 [46, 42, 35, 36, 38-40]	No significant change
Colour	B-1	Light brown	Light brown	Light brown	Light brown	Anonymous, API/UPI: 1986, 2007, 2009, 2011, 2022 [46, 42, 35, 36, 38-40]	No significant change
	B-2	Light brown	Light brown	Light brown	Light brown	Anonymous, API/UPI: 1986, 2007, 2009, 2011, 2022 [46, 42, 35, 36, 38-40]	No significant change
	B-3	Light brown	Light brown	Light brown	Light brown	Anonymous, API/UPI: 1986, 2007, 2009, 2011, 2022 [46, 42, 35, 36, 38-40]	No significant change
Taste	B-1	Astringent sensation	Astringent sensation	Astringent sensation	Astringent sensation	Anonymous, API/UPI: 1986, 2007, 2009, 2011, 2022 [46, 42, 35, 36, 38-40]	No significant change
	B-2	Astringent sensation	Astringent sensation	Astringent sensation	Astringent sensation	Anonymous, API/UPI: 1986, 2007, 2009, 2011, 2022 [46, 42, 35, 36, 38-40]	No significant change
	B-3	Astringent sensation	Astringent sensation	Astringent sensation	Astringent sensation	Anonymous, API/UPI: 1986, 2007, 2009, 2011, 2022 [46, 42, 35, 36, 38-40]	No significant change
Odour	B-1	Spicy aromatic	Spicy aromatic	Spicy aromatic	Spicy aromatic	Anonymous, API/UPI: 1986, 2007, 2009, 2011, 2022 [46, 42, 35, 36, 38-40]	No significant change
	B-2	Spicy aromatic	Spicy aromatic	Spicy aromatic	Spicy aromatic	Anonymous, API/UPI: 1986, 2007, 2009, 2011, 2022 [46, 42, 35, 36, 38-40]	No significant change
	B-3	Spicy aromatic	Spicy aromatic	Spicy aromatic	Spicy aromatic	Anonymous, API/UPI: 1986, 2007, 2009, 2011, 2022 [46, 42, 35, 36, 38-40]	No significant change
Smell	B-1	Agreeable	Agreeable	Agreeable	Agreeable	Anonymous, API/UPI: 1986, 2007, 2009, 2011, 2022 [46, 42, 35, 36, 38-40]	No significant change
	B-2	Agreeable	Agreeable	Agreeable	Agreeable	Anonymous, API/UPI: 1986, 2007, 2009, 2011, 2022 [46, 42, 35, 36, 38-40]	No significant change
	B-3	Agreeable	Agreeable	Agreeable	Agreeable	Anonymous, API/UPI: 1986, 2007, 2009, 2011, 2022 [46, 42, 35, 36, 38-40]	No significant change

Table 5: Pharmacognosy, HPTLC, fingerprinting, physicochemical toxicological shelf life, stability studies of SA Coarse Powder

Sr. No.	Analyzed Parameters /Studies	Batches	0th Months	2nd Months	4rd Months	6th Months	API/UPI/WHO Standard Parameters	Reference API/UPI
Pharmacognosy Identification								
1.	Organoleptic-Colour, odour, test, smell	B1	Light brown, Spicy aromatic Astringent, Agreeable	Light brown, Spicy aromatic Astringent, Agreeable	Light brown, Spicy aromatic Astringent, Agreeable	Light brown, Spicy aromatic Astringent, Agreeable	Should be Complies	Anonymous, API/UPI: 1986, 2007, 2009, 2011, 2022 [46, 42, 35, 36, 38-40]
		B2	As above	As above	As above	As above		
		B3						
2.	Macro and Microscopic identification:	B1	Complies	Complies	Complies	Complies	Should be Complies	Anonymous, API/UPI: 1986, 2007, 2009, 2011, 2022 [46, 42, 35, 36, 38-40]
		B2	Complies	Complies	Complies	Complies		
		B3	Complies	Complies	Complies	Complies		
HPTLC. Fingerprinting Identification								
3.	HPTLC	B1	Complies	Complies	Complies	Complies	Should be Complies	Anonymous, API/UPI: 1986, 2007, 2008, 2009, 2016, [46, 42, 41, 38-40, 25-27]
		B2	Complies	Complies	Complies	Complies		
		B3	Complies	Complies	Complies	Complies		
Physicochemical Analysis								
4.	Foreign Organic Matter, w/w, %	B1	0.10%	0.13%	0.18%	0.28%	NMT-2.0%	Anonymous, API/UPI, 1986, Appendix 2.2.2 [46].
		B2	0.10%	0.12%	0.16%	0.32%		
		B3	0.12%	0.14%	0.19%	0.36%		
5.	Total Ash, w/w, %	B1	6.38%	6.41%	6.04%	5.98%	NMT-7.0%	Anonymous, API/UPI, 1986, 2022, Appendix 2.2.3 [46].
		B2	6.36%	6.39%	6.06%	5.99%		
		B3	6.39%	6.44%	6.01%	5.99%		
6.	Acid-insoluble Ash, w/w.%	B1	0.833%	0.824%	0.680%	0.590%	NMT-1.0%	Anonymous, API/UPI, 1986, 2022, Appendix 2.2.4 [46].
		B2	0.834%	0.842%	0.620%	0.590%		
		B3	0.836%	0.833%	0.650%	0.550%		
7.	Alcohol-soluble extractive, w/v, %	B1	9.54%	9.52%	9.04%	8.52%	NLT-3.0%	Anonymous, API/UPI, 1986, 2022, Appendix 2.2.6 [46].
		B2	9.52%	9.54%	9.02%	8.61%		
		B3	9.56%	9.54%	9.08%	8.69%		
8.	Water-soluble extractive, w/v, %	B1	27.52%	27.72%	27.25%	26.35%	NLT-9.0%	Anonymous, API/UPI, 1986, 2022, Appendix 2.2.7 [46].
		B2	27.50%	27.68%	27.16%	26.55%		
		B3	27.54%	27.66%	27.32%	26.42%		
9.	Volatile oil, %	B1	13.84%	13.80%	13.52%	12.85%	NLT-15%	Anonymous, API/UPI, 1986, 2022, Appendix 2.2.10 [46].
		B2	13.84%	13.82%	13.42%	12.86%		
		B3	13.86%	13.84%	13.41%	12.81%		
10.	Loss in wt on drying, w/w, %, at 105^{O}C	B1	5.032%	5.038%	4.980%	4.620%	NMT-8.0%	IH.
		B2	5.034%	5.036%	4.060%	4.780%		
		B3	5.036%	5.038%	4.880%	4.750%		
11.	pH (10 %, Solution)	B1	4.8	4.9	5.0	5.2	4.0-5.5	IH.
		B2	4.8	4.7	4.9	5.2		
		B3	4.7	4.9	5.1	5.4		
Toxicological Studies								
12.	Heavy Metals-Lead (Pb), Arsenic (As, Cadmium (Cd), Mercurry (Hg) in ppm.	B1	Complies	Complies	Complies	Complies	Should be under permissible limit / Complies	Anonymous, API/UPI: 1986, 2007, 2008, 2009, 2011, 2022 [46, 42, 41, 38-40, 35, 36]
		B2	Complies	Complies	Complies	Complies		
		B3	Complies	Complies	Complies	Complies		
13.	Aflatoxins, B1, G1 and B2 G2 in ppm	B1	Complies	Complies	Complies	Complies	Should be under permissible limit / Complies	Anonymous, API/UPI: 1986, 2007, 2008, 2009, 2011, 2022 [46, 42, 41, 38-40, 35, 36]
		B2	Complies	Complies	Complies	Complies		
		B3	Complies	Complies	Complies	Complies		
14.	Pesticide residues-Organo chlorine, pesticides, Organo phosphorus pesticides, Pyrethroids etc., potentially toxic elements in ppm or ppb levels	B1	Complies	Complies	Complies	Complies	Should be under permissible limit / Complies	Anonymous, API/UPI: 1986, 2007, 2008, 2009, 2011, 2022 [46, 42, 41, 38-40, 35, 36]
		B2	Complies	Complies	Complies	Complies		
		B3	Complies	Complies	Complies	Complies		
15.	Microbial load contaminations-TBC/TFC detect in cfu/gm.	B1	Complies	Complies	Complies	Complies	Should be under permissible limit / Complies	Anonymous, API/UPI: 1986, 2007, 2008, 2009, 2011, 2022 [46, 42, 41, 38-40, 35, 36]
		B2	Complies	Complies	Complies	Complies		
		B3	Complies	Complies	Complies	Complies		
16.	Microbial load contaminations-*Escherichia coli, Salmonella typhai Spp. Staphylococcus aurous* author pathogenic contamination	B1	Complies	Complies	Complies	Complies	Should be Absent / Nil.	Anonymous, API/UPI: 1986, 2007, 2008, 2009, 2011, 2022 [46, 42, 41, 38-40, 35, 36]
		B2	Complies	Complies	Complies	Complies		
		B3	Complies	Complies	Complies	Complies		

Table 6: Evaluation of Organoleptic identifications, properties for WF Coarse Powder

Parameters	Batches	Month 0th	Month 2nd	Month 4th	Month 6th	Criteria	Result
Appearance	B-1	Coarse Powder Form	Coarse Powder Form	Coarse Powder Form	Coarse Powder Form	Anonymous, API/UPI: 1986, 2007, 2009, 2011, 2022 [46, 42, 35, 36, 38-40]	No significant change
	B-2	Coarse Powder Form	Coarse Powder Form	Coarse Powder Form	Coarse Powder Form	Anonymous, API/UPI: 1986, 2007, 2009, 2011, 2022 [46, 42, 35, 36, 38-40]	No significant change
	B-3	Coarse Powder Form	Coarse Powder Form	Coarse Powder Form	Coarse Powder Form	Anonymous, API/UPI: 1986, 2007, 2009, 2011, 2022 [46, 42, 35, 36, 38-40]	No significant change
Colour	B-1	Light bright golden yellow	Light bright golden yellow	Light bright golden yellow	Light bright golden yellow	Anonymous, API/UPI: 1986, 2007, 2009, 2011, 2022 [46, 42, 35, 36, 38-40]	No significant change
	B-2	Light bright golden yellow	Light bright golden yellow	Light bright golden yellow	Light bright golden yellow	Anonymous, API/UPI: 1986, 2007, 2009, 2011, 2022 [46, 42, 35, 36, 38-40]	No significant change
	B-3	Light bright golden yellow	Light bright golden yellow	Light bright golden yellow	Light bright golden yellow	Anonymous, API/UPI: 1986, 2007, 2009, 2011, 2022 [46, 42, 35, 36, 38-40]	No significant change
Taste	B-1	Slightly Bitter	Slightly Bitter	Slightly Bitter	Slightly Bitter	Anonymous, API/UPI: 1986, 2007, 2009, 2011, 2022 [46, 42, 35, 36, 38-40]	No significant change
	B-2	Slightly Bitter	Slightly Bitter	Slightly Bitter	Slightly Bitter	Anonymous, API/UPI: 1986, 2007, 2009, 2011, 2022 [46, 42, 35, 36, 38-40]	No significant change
	B-3	Slightly Bitter	Slightly Bitter	Slightly Bitter	Slightly Bitter	Anonymous, API/UPI: 1986, 2007, 2009, 2011, 2022 [46, 42, 35, 36, 38-40]	No significant change
Odour	B-1	Indistinct	Indistinct	Indistinct	Indistinct	Anonymous, API/UPI: 1986, 2007, 2009, 2011, 2022 [46, 42, 35, 36, 38-40]	No significant change
	B-2	Indistinct	Indistinct	Indistinct	Indistinct	Anonymous, API/UPI: 1986, 2007, 2009, 2011, 2022 [46, 42, 35, 36, 38-40]	No significant change
	B-3	Indistinct	Indistinct	Indistinct	Indistinct	Anonymous, API/UPI: 1986, 2007, 2009, 2011, 2022 [46, 42, 35, 36, 38-40]	No significant change
Smell	B-1	Agreeable	Agreeable	Agreeable	Agreeable	Anonymous, API/UPI: 1986, 2007, 2009, 2011, 2022 [46, 42, 35, 36, 38-40]	No significant change
	B-2	Agreeable	Agreeable	Agreeable	Agreeable	Anonymous, API/UPI: 1986, 2007, 2009, 2011, 2022 [46, 42, 35, 36, 38-40]	No significant change
	B-3	Agreeable	Agreeable	Agreeable	Agreeable	Anonymous, API/UPI: 1986, 2007, 2009, 2011, 2022 [46, 42, 35, 36, 38-40]	No significant change

Table 7: Pharmacognosy, HPTLC, fingerprinting, physicochemical toxicological shelf life, stability studies of WF Coarse Powder

Sr. No.	Analyzed Parameters /Studies	Batches	0th Months	2nd Months	4rd Months	6th Months	API/UPI/WHO Standard Parameters	Reference API/UPI
Pharmacognosy Identification								
1.	Organoleptic-Colour, odour, test, smell	B1	Light bright Golden yellow, Indistinct, Slightly Bitter, Agreeable	Light bright golden yellow, Indistinct, Slightly Bitter, Agreeable	Light bright golden yellow, Indistinct, Slightly Bitter, Agreeable	Light bright golden yellow, Indistinct, Slightly Bitter, Agreeable	Should be Complies	Anonymous, API/UPI: 1986, 2007, 2009, 2011, 2022 [46, 42, 35, 36, 38-40]
		B2	As above	As above	As above	As above		
		B3						
2.	Macro and Microscopic identification:	B1	Complies	Complies	Complies	Complies	Should be Complies	Anonymous, API/UPI: 1986, 2007, 2009, 2011, 2022 [46, 42, 35, 36, 38-40]
		B2	Complies	Complies	Complies	Complies		
		B3	Complies	Complies	Complies	Complies		
HPTLC. Fingerprinting Identification								
3.	HPTLC	B1	Complies	Complies	Complies	Complies	Should be Complies	Anonymous, API/UPI: 1986, 2007, 2008, 2009, 2016, [46, 42, 41, 38-40, 25-27]
		B2	Complies	Complies	Complies	Complies		
		B3	Complies	Complies	Complies	Complies		
Physicochemical Analysis								
4.	Foreign Organic Matter, w/w, %	B1	0.08%	0.08%	0.07%	0.08%	NMT-2.0%	Anonymous, API/UPI, 1986, Appendix 2.2.2 [46].
		B2	0.09%	0.07%	0.09%	0.08%		
		B3	0.09%	0.07%	0.08%	0.08%		
5.	Total Ash, w/w, %	B1	6.12%	6.20%	5.92%	5.60%	NMT-10%	Anonymous, API/UPI, 1986, Appendix 2.2.3 [46].
		B2	6.00%	6.11%	5.90%	5.68%		
		B3	6.14%	6.24%	5.93%	5.54%		
6.	Acid-insoluble Ash, w/w.%	B1	0.776%	0.774%	0.600%	0.590%	NMT-1.0%	Anonymous, API/UPI, 1986, Appendix 2.2.4 [46].
		B2	0.778%	0.776%	0.610%	0.590%		
		B3	0.776%	0.774%	0.650%	0.550%		
7.	Alcohol-soluble extractive, w/v, %	B1	12.58%	12.56%	12.14%	11.98%	NLT-7.0%	Anonymous, /UPI, 1986, Appendix 2.2.6 [46].
		B2	12.58%	12.54%	12.08%	11.92%		
		B3	12.56%	12.52%	12.12%	11.96%		
8.	Water-soluble extractive, w/v, %	B1	28.52%	28.42%	28.01%	27.90%	NLT-28%	Anonymous, API/UPI, 1986, Appendix 2.2.7 [46].
		B2	28.56%	28.52%	28.00%	27.88%		
		B3	28.58%	28.56%	28.04%	27.80%		
9.	Loss in wt on drying, w/w, %, at 105^{O}C	B1	6.062%	6.044%	5.980%	5.840%	NMT-8.0%	IH.
		B2	6.083%	6.066%	5.890%	5.620%		
		B3	6.062%	6.076%	5.960%	5.680%		
10.	pH (10 %, Solution)	B1	4.8	4.8	4.9	5.0	4.0-5.0	IH.
		B2	4.7	4.7	4.8	5.1		
		B3	4.8	4.8	4.9	5.2		

Toxicological Studies-								
11.	Heavy Metals-Lead (Pb), Arsenic (As, Cadmium (Cd), Mercurry (Hg) in ppm.	B1	Complies	Complies	Complies	Complies	Should be under permissible limit / Complies	Anonymous, API/UPI: 1986, 2007, 2008, 2009, 2011, 2022 [46, 42, 41, 38-40, 35, 36]
		B2	Complies	Complies	Complies	Complies		
		B3	Complies	Complies	Complies	Complies		
12.	Aflatoxins, B1, G1 and B2 G2 in ppm	B1	Complies	Complies	Complies	Complies	Should be under permissible limit / Complies	Anonymous, API/UPI: 1986, 2007, 2008, 2009, 2011, 2022 [46, 42, 41, 38-40, 35, 36]
		B2	Complies	Complies	Complies	Complies		
		B3	Complies	Complies	Complies	Complies		
13.	Pesticide residues-Organo chlorine, pesticides, Organo phosphorus pesticides, Pyrethroids etc., potentially toxic elements in ppm or ppb levels	B1	Complies	Complies	Complies	Complies	Should be under permissible limit / Complies	Anonymous, API/UPI: 1986, 2007, 2008, 2009, 2011, 2022 [46, 42, 41, 38-40, 35, 36]
		B2	Complies	Complies	Complies	Complies		
		B3	Complies	Complies	Complies	Complies		
14.	Microbial load contaminations TBC/TFC detect in cfu/gm.	B1	Complies	Complies	Complies	Complies	Should be under permissible limit / Complies	Anonymous, API/UPI: 1986, 2007, 2008, 2009, 2011, 2022 [46, 42, 41, 38-40, 35, 36]
		B2	Complies	Complies	Complies	Complies		
		B3	Complies	Complies	Complies	Complies		
15.	Microbial load contaminations-*Escherichia coli*, *Salmonella typhai Spp.* *Staphylococcus aurous* author pathogenic contamination	B1	Complies	Complies	Complies	Complies	Should be Absent / Nil.	Anonymous, API/UPI: 1986, 2007, 2008, 2009, 2011, 2022 [46, 42, 41, 38-40, 35, 36]
		B2	Complies	Complies	Complies	Complies		
		B3	Complies	Complies	Complies	Complies		

Table 8: Shelf life Stability data @ 40 °C ± 2 and 75%±5 RH for SA and WF Coarse Powder ASU Drugs

Shelf life Stability Study of SA Coarse Powder ASU Drug					
Parameters	**10% of 0th month**	**At 10% degradation**	**Intercept**	**Slope**	**Months at 10% degradation**
Foreign Matter	0.10	0.010	0.080	0.034	0.4563
Total Ash	6.33	0.633	6.402	-0.070	10.0336
Acid Insoluble Ash	0.83	0.083	0.866	-0.047	2.4274
Alco. Sol. Ext. Matter	9.54	0.954	9.723	-0.14	8.1214
Water Sol. Ext. Matter	27.52	2.752	27.77	-0.18	16.6777
LOD	5.03	0.503	5.08	-0.05	10.088
pH	4.76	0.476	4.71	-0.08	-5.325
Volatile Oil	13.84	1.384	13.99	-0.169	9.0151
		Average mean (Months)-			6.55
		Extrapolated value (Months)-			21.61
		Shelf life (Years)-			1.80
Shelf life Stability Study of WF Coarse Powder ASU Drug					
Foreign Matter	0.08	0.008	0.082	-0.00067	6.0597
Total Ash	6.08	0.608	6.19	-0.08	8.9075
Acid Insoluble Ash	0.77	0.077	0.8	-0.03	3.3586
Alco. Sol. Ext. Matter	12.57	1.257	12.37	-0.24	4.3917
Water Sol. Ext. Matter	28.55	2.855	28.615	-0.11	24.3135
LOD	6.06	0.606	6.12	-0.05	13.158
pH	4.76	0.476	4.71	0.05	-7.7454
		Average mean (Months)-			7.49
		Extrapolated value (Months)-			24.72
		Shelf life (Years)-			2.00

Fig 2: *S aromaticum* (Linn.) Merr. Perry, Leaves & flowers buds L.M.

Fig 3: *S aromaticum* (Linn.) Merr. L.M. Perry, dried flower buds

Fig 4: *W. fruticosa* (Linn.) Kurz., Leaves & flowers buds

Fig 5: *W. fruticosa* (Linn.) Kurz, dried flowers buds

Conclusion

The extensive statistical analysis conducted on reveals investigated Course powder drug samples of SA and WF a remarkable maximum shelf life of 1 years and eight months and 2 Year. This noteworthy conclusion is drawn from an in-depth examination of accelerated stability data across various batches of the ASU course powder drug samples of SA and WF. Significantly, this analysis indicates that there were no major notable changes in the values of active ingredients, physicochemical properties, proximate components, toxicological-Aflatoxins, microbiological parameters, or organoleptic characteristics over a six-month period. This duration of scrutiny involved subjecting the product to accelerated conditions, including elevated temperature (40 °C) and humidity (75%). This adherence to quality standards further substantiates the robustness and reliability of the product. The evaluation of the stability of ASU herbal drugs, botanicals, and traditional medicines is inherently a complex and meticulous process. In this concern, the regular analysis of bioactive markers emerges as an indispensable tool. This thorough evaluation reinforces the ASU herbal product's efficacy and reliability, acceptability providing valuable insights into its sustained stability over an extended shelf life.

Limitations and Future Remarks of the Study

The present study's HPTLC identifications, Physicochemical, Pharmacological parameters studies show the presence of bioactive compounds in investigated shelf life of ASU medicinal plant course powder drug samples of SA and WF. In the future, spectral data may be used to separate and confirm these substances concurred shelf life studies of ASU Medicinal plants-based drugs.

Ethical approval

As the work is purely an *in vitro* study, ethical clearance is not required.

Author contributions

Dr Pawan Kumar Sagar (Chemistry): Carried out Instrumental, Chemistry part, Work designed and Manuscript written, Analytical data analysis. Dr. Rajeev Kurele, work designed and classical ASU herbal drugs clinical and therapeutic data's analysis review. S. Kashyap (Chemistry), Analytical data analysis review.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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