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Review Article

Vegetable Origin Drugs

A Critical Review on Safe Handling of Vegetable Origin Drugs used in Ayurveda from Schedule (E1) of the Drugs and Cosmetics Rules, 1945

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Introduction: The Drugs and Cosmetics Rules, 1945 were established by the Government of India under the authority of the Drugs and Cosmetics Act, 1940. This Act is designed to ensure that drugs and cosmetics sold in India meet standards for quality, safety, and effectiveness. Schedule (E1) of these rules identifies poisonous substances of plant origin that are used in the Ayurvedic, Siddha and Unani systems of medicine. The focus of the present work is on the safe handling and use of plant origin poisonous drugs used in Ayurvedic system of medicine.

Methodology: A thorough evaluation of literature was done, including the relevant portions of the Drugs and Cosmetics Rules, 1945, authoritative text books of Ayurveda, published research papers in reputed journals.

Results: The Drugs and Cosmetics Rules, 1945, which mandates that ASU drugs in which the Ayurvedic system classifies fourteen medications with vegetable origins under the category of poisonous substances. Despite being part of the Visha-Upavisha which is a category of poisonous substances, these medications are not hazardous because Ayurveda recommends a special method of cleansing called Shodhana before utilizing them for therapeutic purposes. Schedule E (1) of the Drugs and Cosmetics Rules, 1945, is associated with Rule 161(2).

Conclusion: Ayurvedic drug manufacturers, dealers, Vaidya and physicians must be aware and focus on the safe manufacturing practices of medicines, rational prescription and safe dosage of medicines and sale of such medicines should be done only under the valid prescription. By ensuring appropriate information to patients regarding the dosage and administration.

Keywords: Visha-Upavisha Varga, Poisonous drugs, Schedule (E1), Drugs and Cosmetic Rules 1945

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Introduction

The AYUSH system encompasses traditional and alternative healthcare practices such as Ayurveda, Yoga, Naturopathy, Unani, Siddha, *Sowa-Rigpa,* and Homeopathy.[1] To foster the growth and integration of these systems, the Government of India has launched various initiatives. A primary focus has been ensuring the quality, safety, and efficacy of AYUSH medicines. To regulate the production, distribution, export, and research of these medicines, the government has enacted several laws and regulations, including the Drugs and Cosmetics Act of 1940 and the Drugs and Cosmetics Rules of 1945.[2] These legal frameworks establish standards for manufacturing practices, quality control, and licensing requirements for AYUSH products. Additionally, the Ministry of AYUSH has implemented Good Manufacturing Practices (GMP) guidelines under Schedule T of the Drugs and Cosmetics Act to ensure hygienic conditions and quality assurance in the production of Ayurvedic, Siddha, and Unani medicines.[3] In addition, monitoring and the safety of AYUSH medicines post-marketing, a pharmacovigilance program was launched to collect and analyse data on adverse drug reactions, thereby enhancing patient safety**.** Drugs and Cosmetics Act, 1940, Drugs and Cosmetics Rules, 1945. There are several schedules to these rules among of them schedule (E1) describes the list of poisonous substances under the ASU medicine.

Schedule E1, as delineated in Rule 161(2) of the Drugs and Cosmetics Rules, 1945, is a critical component of India's regulatory framework governing the use of certain potent substances in traditional medicine systems. This schedule enumerates specific drugs of plant, animal, and mineral origin utilized in Ayurvedic, Siddha, and Unani (ASU) practices, which are classified as poisonous and thus necessitate stringent controls to ensure public safety.

Materials and Methods

Through literature searches about relevant portions of the Drugs and Cosmetics Act, 1940 and Drugs and Cosmetics Rules, 1945, and published research papers related to the topic that are available online in databases like PubMed, Google Scholar etc were collected and reviewed.

Details regarding the plant origin drugs mentioned in the Schedule (E1) were reviewed from the authoritative text books of Ayurveda like Samhitas, API, AFI, various books of Dravyaguna Vigyan etc.

Composition of Schedule E1 in Ayurveda[4,5]

According to the notification (G.O.I. Notification No. 1-23/67-D dated 2-2-1970), the Ayurvedic system includes:

- **Plant-Origin Substances (15):** *Ahipena (Papaver somniferum), Arka (Calotropis gigantea), Bhallataka (Semecarpus anacardium), Bhanga (Cannabis sativa), Danti (Baliospermum montanum), Dhattura (Datura metel), Gunja (Abrus precatorius), Jaipala (Croton tiglium), Karaveera (Nerium indicum), Langali (Gloriosa superba), Parasika Yavani (Hyoscyamus niger), Snuhi (Euphorbia nerifolia), Vatsanabha (Aconitum ferox), Vishamushti (Strychnos nux-vomica),* and *Shringivisha (Aconitum chasmanthum).*
- **Animal-Origin Substance (1)**: *Sarpa Visha* (Snake venom).
- **Mineral-Origin Substances (9)**: *Hartala* (Arsenic trisulfide), *Gauripashana* (Arsenic), *Parada* (Mercury), *Manahshila* (Arsenic disulfide), *Tuttha* (Copper sulfate), *Rasa Karpura* (Mercurous chloride), *Sindura* (Red oxide of lead), *Hingula* (Cinnabar), and *Girisindura* (Red oxide of mercury).

Over time, the Indian government has updated the list of potentially toxic substances used in Ayurvedic medicine, known as Schedule E1 under the Drugs and Cosmetics Rules, 1945. These changes aim to enhance patient safety by refining which parts of certain plants are considered harmful. Schedule (E1) pertains to the 1945 Drugs and Cosmetics Rules, Rule 161(2).

This Schedule lists the poisonous substances employed in ASU systems, together with information about their scientific name, specific toxic component, and source (vegetable, animal, or mineral).

Prior to 1982, the Schedule was referred to as Schedule (E), which was removed. In 2010, it was replaced by Schedule (E1) with new modifications (G.S.R. 683 (E) dated 19-08-2010).[6] The following are the changes made to the Ayurvedic medical system's list of toxic substances.

For instance, *Snuhi* (*Euphorbia nerifolia*) was removed from the list, indicating it's no longer classified as a poisonous plant in this context. Additionally, the seeds of *Ahipena* (Papaver somniferum) and *Bhanga* (Cannabis sativa) were exempted, suggesting that these parts are deemed less risky. Conversely, for *Gunja* (*Abrus precatorius*) and *Jaipala* (*Croton tiglium*), only the seeds were included in the list, highlighting that these specific parts are particularly toxic.**[7]** These revisions aim at establishing a balance between patient safety and the therapeutic advantages of Ayurvedic medications, reflecting an increasing awareness of the toxic effects of various plant parts.

Table 1: List of poisonous substances in Vegetable origin under Ayurvedic Systems of Medicine included in Schedule (E1)

I. Drugs of vegetable origin[6]	
1. Ahipena (Except seeds)	Papaver somniferum Linn
2. Arka	Calotropis procera (Ait.) R. Br.
3. Bhallataka	Semecarpus anacardium Linn.f.
4. Bhanga (Except seeds)	Cannabis sativa Linn. (Except seeds)
5. Danti	Baliospermum montanum Mull. Arg.
6. Dhattura	Datura metel Linn
7. Gunja (seed)	Abrus precatorius Linn. (seed)
8. Jayapala (seed)	Croton tiglium Linn.
9. Karaveera	Nerium indicum Mill.
10. Langali	Gloriosa superba Linn.
11. Parasika yavani	Hyoscyamus niger Linn.
12. Vatsanabha	Acontium chasmanthum Stapf ex Holmes.
13. Vishamushti	Strychnos nux-vomica Linn.
14. Shringivisha	Acontium chasmanthum Stapf ex Holmes
II. Drugs of Animal Origin	
15. Sarpa Visha	Snake poison
III. Drugs of Mineral Origin	
16. Gauripaashana	Arsenic
17. Haritala	Arseno sulphide
18. Manashila	Arseno sulphide
19. Parada	Mercury
20. Rasa Karpura	Hydrargyri subchloridum
21. Tuttha	Copper sulphate
22. Hingula	Cinnabar

Substances listed under Schedule E1 of the Drugs and Cosmetics Rules, 1945, must comply with specific safety regulations to ensure they are used properly and safely. These medicines must carry a clear warning label that states: "Caution: To be taken under medical supervision," in both English and Hindi, as required by Rule 161(2).**[8]**

They should only be used under the supervision of a qualified healthcare professional, as the ingredients in Schedule E1 can be very potent and may lead to harmful effects if misused. In Ayurvedic practice, such substances are first purified through a traditional process called *Shodhana*. This purification reduces their toxicity and enhances their healing properties, with different methods used depending on the specific substance.**[9]**

By ensuring correct labeling, professional supervision, and proper purification, these potent ingredients can be used safely and effectively in traditional medicine.

Toxicity profile of plant origin Ayurvedic formulations listed under Schedule (E1).

Ayurvedic literature classifies poisonous drugs into two categories: *Visha* and *Upavisha,* based on their potency and lethality.**[10]** *Visha* substances are highly toxic and potentially lethal, whereas *Upavisha* substances are less toxic but still capable of causing harmful effects. Among the plant-based drugs listed under Schedule (E1) in Ayurveda, *Vatsanabha* and *Shringivisha* are classified as *Visha* due to their high toxicity. In contrast, *Ahiphena, Arka, Bhallataka,* Bhanga, *Dhattura, Gunja, Jayapala, Karaveera, Langali* and *Vishamushti* fall under the *Upavisha* category, as they are less potent but still produce toxic symptoms. The *Visha* (poisonous) character of *Danti* and *Parasika Yavani* is not mentioned in Ayurvedic texts. However, *Danti* is one of the *Moolini Dravyas* (useful medicines of which roots are beneficial) and has *Tikshna, Ushna, Vikashi*, and *Aasukari* qualities**[11]** that are comparable to those of *Visha* (poison).**[12]**

Additionally, before using *Danti* in formulations, its *Samskara* (processing) is specified in order to eliminate its *Vikashi* virtue.**[11]** Tropane alkaloids make *Parasika Yavani* toxic, and excessive levels of it can have major adverse impacts.**[13]**

Pharmacological activities of plant origin Ayurvedic drugs in Schedule (E1)

- All the vegetable origin drugs mentioned in Schedule (E1) are extensively used in therapeutics by Ayurvedic system of medicine.**[14]** While looking into the pharmacological properties, all the drugs have *Tikshna-Ushna Guna, Katu Rasa* and very few have shown *Prabhava* (special effect).

- Being grouped under *Visha-Upavisha* category, all are fast acting (*Asukari*), as *Sukshma* and *Yogavahi*, which in turn helps to exhibit the therapeutic action in very small doses.
- Screening of formulations which commonly practised by Ayurvedic practitioners reveal the extensive use of *Visha* and *Upavisha*
- Nearly 160 formulations are mentioned in the Ayurveda formulary of India and about 430 formulations in *Bhaishajya Ratnavali.* **[15]**

Table 2: Method of *Shodhana* (Purification), Dosage & Important formulations of plant origin Ayurvedic drugs in Schedule (E1)

SN	Drugs of Vegetable Origin and chemical composition [16-19]	Method of Sodhana (Purification)[20]	Therapeutic Dose[21]	Formulations[16,18]
1.	Ahipena (Except seeds) **Chemical Composition:** Opium alkaloids are isoquinoline alkaloids- morphine, codeine, narcotine, papaverine, heroin	21 times Bhavana in Shringavera (Ardraka) Swarasa	30-125mg	Ahiphenasav, Ashtakshari Gutika, Akarakarabhadi Vati, Nidrodaya Rasa
2.	Arka **Chemical Composition:** Glycosides – Calotropin (more toxic than Strychnine), calotoxin	To purify Arka Ksheera, Tila (Sesamum indicum Linn.) is fried and put into it. Either 2 or 3 among the following combination of Ela, Maricha, Nagahwa & Pippali is fried and put into Arka Ksheera. Arka Ksheera is Sudha (pure) by itself. Also, same Shodhana Vidhi (Purification method) as that of Snuhi Ksheera (Euphorbia neriifolia Linn.) can be applied.	Root for decoction 1-3gm Leaf Churna- 250-750 mg Stem bark Churna- 0.5-1 gm Kshira[17] - ¼ - ¾ gm	Arka Lavana, Arka Ksheeradi Lepa
3.	Bhallataka **Chemical Composition:** Anacardic acid, nonvolatile alcohol (cardol), bhilawanol, anacardoside	Take Bhallātaka, remove the attached thalamus and soak in Gomūtra for 7 days. Replace Gomūtra every 24 h with fresh Gomūtra. After 7 days, rinse the Bhallātaka twice with water, to wash off the Gomūtra. Soak Bhallātaka in Godugdha for 7 days, replacing Godugdha every 24 h with fresh Godugdha. After 7 days, rinse the Bhallātaka 2 or 3 times with water to wash off the Godugdha. Put the Bhallātaka in a thick jute bag containing coarse brick powder and rub carefully, with a view to reduce the oil content in Bhallātaka. Wash the processed seed with water and dry.	1.2gm of drug in Kshirapaka form Oil- 10-20 drops	Amrita Bhallataka Leha, Bhallataka Rasayana, Sanjivani Vati, Guggulutiktaka Ghrita
4.	Bhanga (Except seeds) **Chemical Composition:** Major active euphoric principle is tetrahydrocannabinol (THC), cannabinoids, volatile terpenes and sesquiterpenes	Vijaya put in a muslin bag and wash in water till free from turbidity and then dry.	Churna- 125- 250mg	Jatiphaladi Churna, Madanaananda Modaka Trailokya Vijaya Vati
5.	Danti **Chemical Composition:** Triterpenoids, resinous glycosides, phorbol esters, steroids, saponins, alkaloids, flavonoids	Roots of Danti are smeared with the paste of Pippali (Piper longum Linn.) and Madhu (honey); and wrapped with the leaves of Kusha (Desmostachya bipinnata Stapf.) and then coated with mud and Putapaka Swedana is done. After that roots are separated and dried under sunlight. This process reduces the Vikashi property of Danti.	Churna- 1-3 gm	Abhayarishta, Dantyarishta, Kankayana Gutika, Dantiharitaki, Kaisora Guggulu, Punarnava Mandura
6.	Dhattura **Chemical Composition:** Tropane alkaloids Hyoscine (Scopolamine) is the major constituent, while atropine and l hyoscyamine is very less in quantity.	Seeds are soaked in Gomutra for 12 hours. Wash with water and then subject to Dola Yantra Swedana with Godugdha for one Yama (3 hours). Then remove the testa and can be used.	100-200mg	Kanakasava, Ekangavira Rasa, Tribhuvanakirti Rasa, Laghu Vishagarbha Taila
7.	Gunja (Seeds) **Chemical Composition:** Abrin, hypaphorine, precatorine, glycyrrhizin, choline	Dola Yantra Swedana with Kanjika for one Yama (3 hours). Remove the outer cover, wash and dry.	Churna- 60- 180mg	Mritasanjivani Gutika, Gunjabhadra Rasa

8.	Jayapala (Seeds) **Chemical Composition:** Crotonoside (isoguanosine), Crotonoleic acid, Glyceryl crotonate, Phorbol esters	Remove testa of Jayapala seeds and subject to Dola Yantra Swedana with Godugdha for 3 hours. Then remove the embryo of the seed, dry the cotyledons and powder. Next Bhavana is to be done with Nimbu Swarasa for 3 days. After that dry in sun.	Churna- 6-12mg	Ichabhedi Rasa, Jalodarari Rasa, Mahajwarankusa Rasa, Sukhavirechana Vati
9.	Karaveera **Chemical Composition:** Cardiac Glycosides- Oleandrin, oleandrigenin	Dola Yantra Swedana with Godugdha for 2 hours.	Churna- 30- 125mg	Brihanmarichadya Taila, Karaviradya Taila
10.	Langali **Chemical Composition:** Amino alkaloids (Proto-alkaloids) Colchicine	Soak small pieces of Langali Mula in Gomutra for 24 hours, then wash and dry.	125-250mg	Nirgundi Taila, Mahavishagarbha Taila, Kalakuta Rasa, Kasisadi Tail
11.	Parasika Yavani **Chemical Composition:** tropane alkaloids- hyoscyamine is the major constituent, while atropine and hyoscine are very less in quantity	--	125-500mg	Sarpagandhaghna Vati
12.	Vatsanabha **Chemical Composition:** Alkaloids- Aconitine, Indaconitine, Chasmaconitine,Chasmathinine, bikhaconitine	Small pieces of Vatsanabha are bundled in clean muslin cloth, soak in Gomutra for three days and kept under sunlight, replacing the latter every day. Then wash and dry.	Churna- 15-30mg	Tribhuvanakirti Rasa, Anandabhairava Rasa, Sutasekhara Rasa, Hinguleswara Rasa, Mrityunjaya Rasa, Mahavatavidhwamsa Rasa
13.	Vishamushti **Chemical Composition:** Bitter indole alkaloids Strychnine, Brucine Glycoside (Loganin), Vomicine	Vishamushti (Kupilu) is kept in Gomutra for 7 days. Fresh Gomutra is to be replaced every day. Thereafter it is removed and washed with water. Then Swedana in Godugdha with Dola Yantra for 3 hours is done. The testa and embryo are removed, the cotyledon is roasted in ghee and powdered well.	Churna- 60- 125mg	Lakshmivilasa Rasa, Ekangavira Rasa, Karaskara Ghrita
14.	Shringivisha **Chemical Composition:** Alkaloids- Aconitine, Indaconitine, Chasmaconitin, Chasmathinine, bikhaconitine	Small pieces of root are bundled in clean muslin cloth, and soak in Gomūtra for three days, replacing the latter every day. Then wash and dry.	Churna- 15-30mg	Tribhuvanakirti Rasa, Anandabhairava Rasa, Sutasekhara Rasa, Hinguleswara Rasa, Mahavatavidhwamsa Rasa

Discussion

The Drugs and Cosmetics Rules, 1945, which mandates that if an ASU medication contains any Schedule (E1) drug as an ingredient, a caution remark alerting the consumer to the fact that the medication should only be taken under medical supervision. Poisonous substances in vegetable origin serves as a crucial regulatory tool to ensure that potent substances used in traditional medicine systems are handled with the necessary caution, balancing their therapeutic potential against the imperative of patient safety. Despite their classification as poisonous, Schedule E1 substances have been traditionally employed for their medicinal properties.

According to *Acharya Charaka*, even a potent poison can act as best medicine if administered properly. **[22]** *Shodhana* is the *Samskara* of a toxic drug which convert it into non-toxic, which renders its therapeutic use. The aim of *Shodhana* procedure is to optimize the safety and efficacy of the raw drug before using it therapeutically. Studies have shown that the toxic constituents are transferred into media rendering the drug nontoxic.**[23]**

In addition to *Shodhana*, Ayurveda propose additional pharmacovigilance by emphasizing the importance of *Yukti* (logical reasoning) in treatment. **[24]** Acharya Charaka says that all *Dravyas* (substances) in this universe are medicinal if used in accordance to *Yukti.*

It is mentioned as one among the *Paradi/Chikitsopayogi Gunas* (qualities useful for treatment).**[25]** Application of this *Yukti* can be seen while analysing different Ayurvedic formulations. Some recent studies have explored their potential anti-cancer activities, suggesting that, when properly processed and administered, these substances may offer therapeutic benefits in oncology.**[26]**

For ASU Medicine, rule 161(2) mentioned that 'The container of a medicine for internal use made up ready for the treatment of human ailments shall, if it is made up from a substance specified in Schedule (E1), be labelled conspicuously with the words Caution: To be taken under medical supervision both in English and Hindi language'.**[27]**

Meanwhile part XVII of the Drugs and Cosmetics Rules, 1945, Rule 161, addresses the labeling, packaging, and alcohol limit of Ayurvedic (including Siddha) or Unani medications. ASU medications that contain substances listed in Schedule (E1) as an ingredient can only be used with a prescription from a licensed healthcare professional also they should not be bought online or used without first consulting a doctor, according to Rule 161(2).**[28]**

Additionally, on July 14, 2022, the Central Consumer Protection Authority released an advisory about the sale of ASU medications on e-commerce platforms that contain substances listed in Schedule (E1) of the D&C Rules, 1945.**[29]**

Conclusion

Ayurvedic medicines are not toxic, as they are prepared only after proper *Shodhana.* Official books like API, AFI etc. also mentioned the purification procedure of Schedule E1 Drugs.

In the present scenario, Ayurvedic drug manufacturers, dealers, Vaidya and physicians must be aware and focus on the safe manufacturing practices of medicines, rational prescription and safe dosage of medicines and sale of such medicines should be done only under the valid prescription of an authorized physician, even in e-commerce platforms.

Physicians must ensure the safe usage of medicine by properly educating the patient regarding the dose and duration of administration of these medicines.

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