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Review Article

AN OVERVIEW ON VEGETABLE ORIGIN DRUGS USED IN AYURVEDA, INCLUDED IN THE SCHEDULE (E1) OF THE DRUGS AND COSMETICS RULES, 1945

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ABSTRACT

The Drugs and Cosmetics Rules, 1945 are the rules which Government of India framed under the Drugs and Cosmetics Act, 1940. The objective of the act is to regulate the quality, safety and efficacy of the drugs and cosmetics sold in India. Schedule (E1) of the rules enlist the poisonous substances under the Ayurvedic (including Siddha) and Unani Systems of Medicine. The present work is an overview on the vegetable origin poisonous drugs used in Ayurvedic system of medicine. **Methods**: 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**: Schedule (E1) is related to Rule 161(2) of The Drugs and Cosmetics Rules, 1945; which instructs that if an ASU medicine contain any one of the Schedule (E1) drug as an ingredient, its label must contain a caution note, warning the user that it should be taken only under medical supervision. 14 vegetable origin drugs are categorized under the list of poisonous substances in Ayurvedic system. All these drugs have promising therapeutic utility which was also proved by various researches. Even though included in *Visha-Upavisha varga* (group of poisonous substances), these drugs are not toxic as Ayurveda advocates the unique processing method of *Shodhana* (purification) before using them therapeutically. Effect of *Shodhana* (purification) was also proved by various researches. **Conclusion**: Ayurvedic medicine, containing Schedule (E1) drug as an ingredient should be sold and used only under valid prescription of a registered physician. They are to be manufactured only after proper *Shodhana* (purification) of the poisonous ingredient. Caution label should be there on the medicine bottle. Physicians must ensure judicious usage of these medicines by giving proper patient education regarding the dosage and duration of administration.

INTRODUCTION

AYUSH System of Medicine is the traditional and non-conventional systems of healthcare and healing which include Ayurveda Yoga, Naturopathy, Unani, Sidha, Sowa-Rigpa & Homoeopathy etc.[1] Government of India has taken several steps to ensure the optimal development and propagation of these systems of medicine. Quality, safety and efficacy of drugs used in healthcare is always a matter of concern both for the public and authorities. Several Acts and Rules are enacted by the Government of India to regulate the manufacture, sale, export, research etc. of these drugs. Drugs and Cosmetics Act, 1940, Drugs and Cosmetics Rules,1945, Drugs and Magic Remedies Act,1954, Narcotic Drugs and Psychotropic Substances Act,1985 etc. are few among them.

The Drugs and Cosmetics Act, 1940 (23 of 1940) is an act to regulate the import, manufacture, distribution and sale of drugs and cosmetics in India.[2] Ayurveda, Sidha and Unani (ASU) drugs were included under the purview of the act in 1964 by amendment (Act 13 0f 1964, wef 01-02-1969),[3] to regulate their manufacturing and sale. Chapter IV-A of D&C Act, 1940 describes the provisions relating to Ayurveda, Sidha and Unani drugs.[3] The Drugs and Cosmetics Rules, 1945 are the rules which the Govt. of India framed under the Drugs and Cosmetics Act, 1940. There are several schedules to these rules. Among them Schedule

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(E1) describes the list of poisonous substances under the Ayurvedic (including Siddha) and Unani Systems of Medicine.[4] The present work is an overview on the vegetable origin poisonous drugs used in Ayurveda, mentioned in the Schedule (E1).

Thorough 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, Nighantus, API, AFI, various books of Dravyaguna Vigyan etc. and also published research papers in online databases.

Rule 161, in the Part XVII of the Drugs and Cosmetics Rules, 1945 is about the labeling, packing and limit of alcohol in Ayurvedic (including Siddha) or Unani drugs. In that, 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'.[5] So if an ASU medicine contain any one of the Schedule (E1) drug as an ingredient, the label of that medicine should have a warning that, it should be consumed only under medical supervision. Ministry of AYUSH issued a public notice on 01-02-2016, that the public is advised to purchase and consume ASU medicines, containing drugs mentioned in Schedule (E1) as an ingredient, only on prescription from a registered medical practitioner and avoid purchasing them online and using them without medical consultation.[6] Also Central Consumer Protection Authority issued an advisory dated 14th July 2022, concerning the sale of ASU drugs containing ingredients listed in Schedule (E1) of D&C Rules, 1945 on e-commerce platforms.[7] According to the advisory, sale of such drugs must be done only after a valid prescription of registered medical practitioner is uploaded by the user or patient on the e-platform.

Schedule (E1) of the Drugs and Cosmetics Rules, 1945[8]

Schedule (E1) is related to Rule 161(2) of the Drugs and Cosmetics Rules, 1945. The poisonous drugs used in ASU systems are mentioned in this Schedule along with their source (vegetable, animal or mineral), specific poisonous part and scientific identity. Earlier the Schedule was known as Schedule (E), which was omitted in 1982. It was substituted by Schedule (E1), with new amendments in 2010 (G.S.R. 683 (E) dated 19-08-2010) [8]. The amendments related to the list of poisonous substances under Ayurvedic system of medicine are as follows. The plant origin drugs *Snuhi*, seeds of *Ahiphena* and *Bhanga;* mineral origin drugs *Sindhura* and *Girisindhura* were removed from the list of poisons. Source plants of *Vatsanabha* and *Shringi visha* are mentioned as same. Regarding *Gunja* and *Jayapala,* only seeds are considered as poisonous. [9]

Table 1: List of poisonous substances under Ayurvedic Systems of Medicine included in Schedule (E1) [8]

I. Drugs of vegetable origin		
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

Vegetable origin drugs of Ayurvedic System of Medicine included in Schedule (E1) [8]

14 vegetable origin drugs are categorized under the list of poisonous substances in Ayurvedic system. There are some notable features on observing the list in the schedule. The drug *Vishamushti* is not numbered. There is only 13 vegetable origin drugs are numbered in the schedule. Also the botanical sources of *Vatsanabha* and *Shringi visha* are the same and the source plant of *Karaveera* is shown as *Rerium indicum* Mill. Details regarding the plant origin drugs are as follows:

Table 2: Details of vegetable poisonous substances under the Ayurvedic Systems of Medicine included in Schedule E (1)

Sl No	Sanskrit name	Botanical name	Vernacular names	Habit	Useful parts
1.	*Ahipena*	*Papaver somniferum* Linn.	English- Opium Poppy Hindi- Aphim Malayalam- Karuppu	Erect annual robust herb	Latex of fruit, seed, seed oils, unripe capsules, flower
2.	*Arka*	*Calotropis procera* (Ait.) R. Br.	English- Apple of Sodom, Madar tree Hindi- Madar Malayalam-Erikku	Erect shrub	Root, stem bark, latex, flower, leaf
3.	*Bhallataka*	*Semecarpus anacardium* Linn.f.	English- Marking nut Hindi- Bhilawa Malayalam- Cheru	Medium sized deciduous tree	Fruit, gum, oil
4.	*Bhanga*	*Cannabis sativa* Linn.	English- Indian Hemp Hindi- Bhaang Malayalam- Kanchavu	Erect annual herb	Leaf, Flowering/ fruiting tops, resin,
5.	*Danti*	*Baliospermum montanum* Mull. Arg.	English- Wild Croton Hindi- Danti Malayalam- Naga danti	Stout undershrub	Root, seed, leaf
6.	*Dhattura*	*Datura metel* Linn.	English- White Thorn apple Hindi- Dathura Malayalam- Ummam	Annual herb or shrub	Whole plant
7.	*Gunja*	*Abrus precatorius* Linn.	English- Jequirity Hindi- Ratti Malayalam- Kunni	Slender perennial climber	Seed, root, leaf
8.	*Jayapala*	*Croton tiglium* Linn.	English- Croton Hindi- Jamalgota Malayalam- Neervalam	Small evergreen tree	Seed, seed oil
9.	*Karaveera*	*Nerium indicum* Mill.	English- Indian oleander Hindi- Kaner Malayalam- Arali	Large evergreen woody shrub/ small tree	Root, root bark
10.	*Langali*	*Gloriosa superba* Linn.	English- Glory Lily Hindi- Kalihari Malayalam- Menthonni	Climber with leaf tendril	Tuberous root

11.	*Parasika yavani*	*Hyoscyamus niger* Linn.	English- Henbane Hindi- Khurasanee ajvayan Malayalam- Khurasaanee	Annual or biennial herb	Seed
12.	*Vatsanabha*	*Acontium chasmanthum* Stapf ex Holmes.	English- Aconite Hindi- Meethabisha Malayalam- Vatsanabhi	Erect perennial herb	Root
13.	*Vishamushti*	*Strychnos nux-vomica* Linn.	English- Poison nut tree Hindi- Kuchala Malayalam- Kanjiram	Medium sized deciduous tree	Seed, Bark, Leaf
14.	*Shringivisha*	*Acontium chasmanthum* Stapf ex Holmes.	English- Aconite Hindi- Meethabisha Malayalam- Vatsanabhi	Erect perennial herb	Root

Table 3: Chemical constituents, *Rasapanchaka* & Indications of plant origin Ayurvedic drugs included in Schedule (E1)

Sl No	Sanskrit name	Major chemical constituents[10,11,12,13]	*Rasapanchaka*[10,12]	Indications[10, 12]
1.	*Ahiphena*	Opium alkaloids are isoquinoline alkaloids-morphine, codeine, narcotine, papaverine, heroin	***Rasa**: Tikta, Kashaya* ***Guna**: Laghu, Ruksha, Sukshma, Vyavayi, Vikashi* ***Virya**: Ushna* ***Vipaka**: Katu* ***Prabhava**: Madaka* ***Karma**: Kapha hara, Grahi, Vedanaasthapana, Nidrajanana, Akshepahara, Shothahara*	*Anidra, Atisara, Kasa, Soola*
2.	*Arka*	Glycosides - Calotropin(more toxic than Strychnine), calotoxin	***Rasa**: Tikta, Katu* with *lavana anurasa* ***Guna**: Snigdha, Laghu* ***Virya**: Ushna* ***Vipaka**: Katu* ***Karma**: Kapha vata samana, Bhedana Vamaka*	*Kushta, Switra, Gulma, Udara, Krimidanta, Khalitya, Arsas*
3.	*Bhallataka*	Tarry oil containing anacardic acid, non-volatile alcohol (cardol), bhilawanol, anacardoside	***Rasa**: Katu, Tikta, Madhura, Kashaya* ***Guna**: Laghu, Snigdha, Tikshna* ***Virya**: Ushna* ***Vipaka**: Madhura* ***Karma**: Kaphavata samana, Dipana, Pachana, Chedi, Bhedi, Medhya*	*Arsas, Anaha, Grahani, Gulma, Krimi, Kushta, Udara*
4.	*Bhanga*	Major active euphoric principle is tetrahydrocannabinol (THC), cannabinoids, volatile terpenes and sesquiterpenes	***Rasa**: Tikta* ***Guna**: Laghu, Tikshna* ***Virya**: Ushna* ***Vipaka**: Katu* ***Prabhava**: Madaka* ***Karma**: Vatakapha samana, Dipana, Grahi, Pachana, Vakvardhana*	*Agnimandya, Anidra, Atisara, Klaibya, Grahani*
5.	*Danti*	Triterpenoids, resinous glycosides, phorbol esters, steroids, saponins, alkaloids, flavonoids	***Rasa**: Katu* ***Guna**: Guru, Sara, Tikshna, Vikashi, Aasukari* ***Virya**: Ushna* ***Vipaka**: Katu* ***Prabhava**: Virechana*	*Arsas, Asmari, Kushta, Udara,Udavarta Twak dosha, Gulma, Kamala, Pliha, Vrana*

			***Karma**: Kaphapithahara, Tikshna virechaka, Rakta dosha hara*	
6.	*Dhattura*	Tropane alkaloids – Hyoscine (Scopolamine) is the major constituent, while atropine and l-hyoscyamine is very less in quantity	***Rasa**: Tikta, Katu* ***Guna**: Guru, Tikshna* ***Virya**: Ushna* ***Vipaka**: Katu* ***Prabhava**: Madaka* ***Karma**: Kaphavaatahara, Visha hara, Sula prasamana, Varnya*	*Swasa, Jwara, Visha, Indralupta*
7.	*Gunja*	Abrin, hypaphorine, precatorine, glycyrrhizin, choline	***Rasa**: Tikta, Kashaya* ***Guna**: Lagu, Ruksha, Tikshna* ***Virya**: Ushna* ***Vipaka**: Katu* ***Karma**: Kaphavatahara, Vedanasthapana, Kesya*	*Kushta, Vrana, Vatavyadhi, Indralupta*
8.	*Jayapala*	Crotonoside (isoguanosine), Crotonoleic acid, Glyceryl crotonate, Phorbol esters	***Rasa**: Katu* ***Guna**: Guru, Ruksha* ***Virya**: Ushna* ***Vipaka**: Katu* ***Karma**: Kaphavatahara, Tikshna virechaka*	*Jwara, Jalodara, Vibandha, Sopha, Krimi*
9.	*Karaveera*	Cardiac Glycosides-Oleandrin, oleandrigenin	***Rasa**: Katu, Tikta, Kashaya* ***Guna**:Laghu, Ruksha, Tikshna* ***Virya**: Ushna* ***Vipaka**: Katu* ***Karma**: Kaphavatahara, Sirovirechana, Hridya, Chakshushya*	*Vrana, Upadamsa, Kushta, Jalodara, Kandu, Jwara, Swasa, Krimi, Sopha*
10	*Langali*	Amino alkaloids (Proto-alkaloids) – Colchicine	***Rasa**: Katu, Tikta, Kashaya* ***Guna**:Laghu, Sara, Tikshna* ***Virya**: Ushna* ***Vipaka**: Katu* ***Prabhava**: Garbha patana* ***Karma**: Kaphavatahara, Garbhasaya sankochaka*	*Kushta, Arsas, Vrana, Sula, Garbha salya, Sopha*
11.	*Parasika yavani*	Tropane alkaloids- l-hyoscyamine is the major constituent, while atropine and hyoscine is very less in quantity	***Rasa**: Katu, Tikta* ***Guna**: Guru, Ruksha* ***Virya**: Ushna* ***Vipaka**: Katu* ***Karma**: Kaphavatahara, Grahi, Rochana, Pachana, Vedanasthapana, Madaka*	*Anaha, Asmari, Sula, Swasa, Anidra, Unmada, Gulma, Raja krichra*
12.	*Vatsanabha*	Alkaloids- Aconitine, Indaconitine, Chasmaconitine, Chasmathinine, bikhaconitine	***Rasa**: Madhura* ***Guna**: all the 10 gunas of visha* ***Virya**: Ushna* ***Vipaka**: Madhura* ***Karma**: Tridoshahara, Rasayana, Sweda janana, Deepana, Pachana, Hridaya uthejaka,*	*Vata roga, Vatakaphaja Jwara, Jwaratisara*
13.	*Vishamushti*	Bitter indole alkaloids - Strychnine, Brucine Glycoside (Loganin),	***Rasa**: Katu, Tikta* ***Guna**: Laghu, Ruksha, Tikshna* ***Virya**: Ushna*	*Arsas, Kandu, Vrana, Kushta, Vata roga, Ardita*

		Vomicine	***Vipaka**: Katu* ***Karma**: Kaphavatahara, Grahi, Madakaraka, Vedanahara*	
14.	*Shringivisha*	Alkaloids- Aconitine, Indaconitine, Chasmaconitine, Chasmathinine, bikhaconitine	***Rasa**: Madhura* ***Guna**:* All the 10 *Gunas* of *Visha* ***Virya**: Ushna* ***Vipaka**: Madhura* ***Karma**: Tridoshahara, Rasayana, Sweda janana, Deepana, Pachana, Hridaya uthejaka,*	

Table 4: Method of *Shodhana*(Purification), Dosage & Important formulations of plant origin Ayurvedic drugs in Schedule (E1)

Sl No	Sanskrit name	Method of *Shodhana* (Purification) [14]	Dosage[10]	Formulations[10] [12]
1.	*Ahiphena*	21 times *Bhavana* in *Shringavera (Ardraka) swarasa*	30-125mg	*Ahiphenasav, Ashtakshari gutika, Akarakarabhadi vati, Nidrodaya rasa*
2.	*Arka*	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*. [15] *Arka Ksheera* is Sudha(pure) by itself. Also same Shodhana vidhi (Purification method) as that of *Snuhi ksheera* (*Euphorbia neriifolia* Linn.) can be applied. [16]	Root for decoction- 1-3 gm Leaf *churna* – 250-750 mg Stem bark *churna*- 0.5-1 gm *Kshira*[17] - ¼ - ¾ gm	*Arka lavana, Arka ksheeradi lepa*
3.	*Bhallataka*	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*	*Vijaya* put in a muslin bag and wash in water till free from turbdity and then dry.	*Churna*- 125-250mg	*Jatiphaladi churna, Madanaananda modaka Trailokya vijaya vati*
5.	*Danti*	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.* [18]	*Churna*- 1-3 gm	*Abhayarishta, Dantyarishta, Kankayana gutika, Dantiharitaki, Kaisora guggulu, Punarnava mandura*

6.	*Dhattura*	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*	*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*	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*	*Dola yantra swedana* with *Godugdha* for 2 hours.	*Churna*- 30-125mg	*Brihanmarichadya taila, Karaviradya taila*
10	*Langali*	Soak small pieces of *Langali mula* in *Gomutra* for 24 hours, then wash and dry.	125-250mg	*Nirgundi taila, Mahavishagarbha taila, Kalakuta rasa, Kasisadi taila*
11.	*Parasika yavani*	-	125-500mg	*Sarpagandhaghna vati*
12.	*Vatsanabha*	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*	*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*	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*

Toxicological profile of plant origin Ayurvedic drugs in Schedule (E1)

Ayurvedic literature classified poisonous drugs into *Visha* and *Upavisha* based on their potency and lethality.[19] Upavishas are less toxic in nature and not so lethal but produce toxic symptoms. Among the vegetable drugs in Ayurvedic system, mentioned under Schedule (E1), *Vatsanabha* and *Shringivisha* belong to the category of *Visha* while *Ahiphena, Arka, Bhallataka, Bhanga, Dhattura, Gunja, Jayapala, Karaveera, Langali* and *Vishamushti* belong to the group of Upavishas. There is no reference about the *Visha* (poisonous) nature of *Danti* and *Parasika yavani*. But *Danti* possess *Tikshna, Ushna, Vikashi, Aasukari* properties[18] which is similar to the properties of *Visha* (poison) and it is mentioned as one among the *Moolini dravyas* (best drugs of which roots are beneficial).[20] Also *Samskara* (processing) of *Danti* is mentioned before using in formulations in order to remove its *Vikashi* property.[18] Toxicity of *Parasika yavani* is due to the presence of tropane alkaloids and its overdose causes serious adverse reactions.[21]

Details of toxicity of the poisonous drugs are mentioned below:[22,23]

***Papaver somniferum* Linn.**

Latex from unripe fruit capsule of the plant has opium alkaloids. They are somniferous poisons (narcotics) which belong to the class of Cerebral neurotoxins. Natural derivatives of opium are called opiates. Among them the alkaloids morphine, codeine and thebaine have sedative and analgesic properties, while papaverine and narcotine have anti-tussive and smooth muscle relaxant property. Opiates produce major toxic effects upon the central nervous system, cardiovascular system and gastrointestinal tract.

Fatal dose: Crude opium- 200 to 900mg is fatal, in a non-addicted adult. Morphine- 180 to 480mg

Fatal period: 45 minutes - 9 to 12 hours minimum and 2 to 3 days' maximum.

***Calotropis procera* (Ait.) R. Br**

Calotropis is an irritant organic poison. Major principles are uscharin, calotoxin, calotropin and gigantin. Fatal dose: Uncertain.

Fatal period: 12 hours.

***Semecarpus anacardium* Linn.f.**

Irritant poison, especially the seeds whose active principles are Semicarpol and Bhilawanol.

Fatal dose: Uncertain. Fatal period: 12 to 24 hours.

Cannabis sativa* Linn. *(Except seeds)

The plant is a deliriant cerebral neurotoxic poison. It is considered as the most widely used drug for substance abuse. Active principle is present in its resin. Principal constituent is cannabinol, which has no action, but on exposure to heat, it is partly converted into very active THC. All parts of the plant have active principle except stem, root and seeds. In India Cannabis is used in three forms- *Ganja* (composed of small leaves and flowering tops of female plants), *Charas/Hashish* (dried resinous exudate from flower tops), *Bhang* (decoction of dried mature leaves and flower stems). Routes of absorption can be through both gastrointestinal and respiratory tracts.

Fatal dose: 2000mg of Charas, 8000mg of *Ganja*, 10000mg/kg body weight of *Bhang*.

Fatal period: 12 hours to several days.

***Datura metel* Linn**

It is a deliriant cerebral poison. All parts of the plant are toxic, especially the seeds and fruit. Poisoning occurs only if seeds are masticated and swallowed.

Fatal dose: 100-125 seeds (0.6-1gm). Fatal period: 3-4 hours to 24 hours.

***Abrus precatorius* Linn. (seed)**

Organic irritant poison. Seeds of the plant contain a toxalbumen, abrin, which is similar to viperine snake venom. Toxalbumen (phytotoxin) is a toxic protein that causes agglutination of red cells and causes haemolysis. Abrin also inhibits protein synthesis and causes cell death.

Fatal dose: 60 to 120mg of abrin (1-2 crushed seeds) Fatal period: 3-5 days.

***Croton tiglium* Linn.**

Organic irritant poison. Seed and seed oil extracted from the seeds contain extremely toxic principle Crotin which is a toxalbumen and Crotonoside, a glycoside which is less poisonous.

Fatal dose: 1 to 2ml of oil or 4-6 crushed seeds. Fatal period: 4 to 6 hours to 3-6 days.

***Nerium indicum* Mill**

All parts of the plant, especially fruit with kernels or seeds, including nectar are poisonous. It belongs to the class of cardiac poison and contains several cardiac glycosides, like nerin, neriodorin, oleandrin, oleandrigenin etc. Poison is absorbed easily via skin and gastrointestinal route.

Fatal dose: 15 to 20gm of the root; 5 to 15 leaves. Fatal period: 24 to 36 hours.

***Gloriosa superba* Linn**

All parts of the plant are poisonous especially tubers and contain the toxic alkaloid colchicine. It has anti-mitotic activity that arrests mitosis in metaphase

Fatal dose: about 6mg/Kg body weight.

Fatal period: 12–72 hrs.

***Hyoscyamus niger* Linn**

Its toxicity is due to the presence of the tropic alkaloids, i.e., hyoscyamine, atropine and especially scopolamine, and the whole plant is toxic. [24,25]

***Acontium chasmanthum* Stapf ex Holmes**

It belongs to the class of cardiac poison. Whole plant, especially roots are poisonous. Aconitine, pseudo-aconitine, bikhaconitine etc are the active principles. Routes of absorption are through skin and oral route.

Fatal dose: 1gm of root; 250mg of root extract, 3 to 5mg of alkaloid Aconitine.

Fatal period: 3 to 24 hours' maximum (average 6 hours).

***Strychnos nux-vomica* Linn**

It is a spinal poison. Seeds are the toxic part of the plant which contains alkaloids like strychnine and brucine. Seeds also contain a glucoside, loganin. Bark, wood and leaves contain brucine but no strychnine.

Fatal dose: 50 to 100mg; one crushed seed. Fatal period: 1 to 2 hours

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.[26] 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 *Upavishas* drugs. Nearly 160 formulations are mentioned in the Ayurveda formulary of India and about 430 formulations in Bhaishajya Ratnavali. [27] Specific pharmacological properties of all these drugs are also proven by various research works.

How *Visha* (poison) become *Oushadha* (medicine)?

Drugs having toxicity is effectively used as a medicine. This demonstrates the peculiarity of Ayurveda. According to Acharya Charaka, even a potent poison can act as best medicine if administered properly.[28] In Charaka samhitha Vimana sthana 8th chapter, in the context of *Bheshaja pariksha, 'Prasamskarana'* (processing) of *Oushadha* (medicine) is mentioned as one among the quality control parameters of raw drugs. [29] Also Acharya Charaka mentioned the importance of '*Samskara'* (processing) in the preparation of both *Ahara* (food) and *Oushadha* (medicine). The word *Samskara* (processing) means potentiating a drug by adding new qualities or by lowering the bad effect. *Toya-agni sannikarsha* (contact or processing with water and fire), *Bhavana* (trituration), *Soucha/Shodhana* (purification) etc are the methods described for *Samskara* (processing).[30] *Shodhana* (purification) is the *Samskara* (processing) of a toxic drug which convert it into non-toxic, which renders its therapeutic use. Aim of *Shodhana* (purification) procedure is to optimize the safety and efficacy of the raw drug before using it therapeutically.

Even though Acharya Charaka introduced the concept of *Samskara* (processing) of raw drugs, the specific methods of *Shodhana* (purification) of *Visha dravyas* (poisonous drugs) is explained in the books related to *Rasasastra*. Processing of drugs along with different media having variable PH with or without the presence of heat for a specified period of time will make the drug non-toxic or less toxic with minimum side effects. The media used in the process of *Shodhana* (purification) has very important role in either breaking down or destroying the chemical constituents that are not required. Studies have shown that the toxic constituents are transferred into media rendering the drug nontoxic.[31] Detoxification is done without losing the *Virya* (potency) of the drug which is essential for its therapeutic action. Effect of *Shodhana* (purification) in reducing the toxicity of plant drugs were also proved by various researches.[32-46] After *Shodhana* (purification), these drugs can be used in treating different therapeutic conditions including cancer. [47]

According to Acharya R, Ranade A, Surana M, Pawar SD, adopting scientifically validated traditional purification techniques for poisonous medicinal drugs of plant and mineral origin can ameliorate their neurotoxic effects and enhance their therapeutic efficacy.[33] Scientific studies have proved that the percentage of major toxic chemical constituents have been reduced after *shodhana* with different media. Removal of aconitine from *Vatsanabha* tuber is more when processed with cow's urine. *Shodhana* proved the reduction of toxic contents Strychnine and Brucine from *Kupeelu* seeds. Changes of the Rf value in purified *Bhallataka* in comparison to raw reveals the chemical changes, toxic urushiol into non-toxic anacardol, after *Shodhana* procedure. GC-MS studies on Datura metel and D. innoxia proved the reduction of the toxic chemical hyosciamine and scopolamine. Reduction of colchicine percentage in case of *gomutra shodhita langali* tuber and depletion of more toxic alkaloid hypaphorine and protein abrin of Abrus precatorius in HPTLC study showed the impact of *shodhana*.[32] Detoxification is also a technique to enhance the potency and efficacy of a drug in addition to the reduction of the toxic properties.[32] Recent pharmacological researches, on different animal models, have proved that the drugs like *Vatsanabha, Kupeelu, Bhallataka, Gunja, Dhatura, Langali* and *Vacha* etc. after *shodhana* are less toxic and pharmacologically more effective than the raw drugs.[32] *Shodhana* (purification) has a definite impact upon the properties of *Danti* also.[37] It is worthwhile to adopt *Shodhana* processes as per Indian system of medicine in the development of herbal formulations with application of modern technology to assess its safety and efficacy. [34]

In addition to *Shodhana* (purification), Ayurveda propose additional pharmacovigilance by emphasizing the importance of *Yukti* (logical reasoning) in treatment. Acharya Charaka says that all *Dravyas* (substances) in this universe are medicinal if used in accordance to *Yukti* (logical reasoning). [48] *Yukti* (logical reasoning) is mentioned as one among the *Paradi/Chikitsopayogi gunas* (qualities useful for treatment). [49] Poison can be modified into medicine through logic. Application of this *Yukti* (logical reasoning) can be seen while analysing different Ayurvedic formulations. All the classical Ayurvedic formulations are designed in such a way that as a whole the particular medicine has a specific therapeutic effect. While analysing a yoga some of them are main dugs, some act as supporting drugs, some are bioavailability enhancers while some are antidotes. So if a formulation contains a *Visha dravya* (poisonous drug) as an ingredient, definitely that formulation must contain its antidote or a drug which helps in reducing the *Tikshna* property of the poisonous ingredient there by reducing its side effects. For example, Ayurvedic formulation *Vettumaran gulika* contains *Vatsanabha* as an ingredient. [50] The same

formulation also contains *Tankana* (borax) as an ingredient which is the antidote of *Vatsanabha*. So even after *Shodhana* (purification), Ayurvedic formulations are logically designed to ensure extra protection. Physicians should make certain, proper *Shodhana* (purification) of poisonous ingredients before preparing medicines for their own patients and also apply *Yukti* (logical reasoning), while designing a formulation.

CONCLUSION

The Drugs and Cosmetics Act, 1940 (23 of 1940) and the Drugs and Cosmetics Rules,1945 direct the legal provisions pertaining to the quality control and standardization of drugs and cosmetics in India, which in turn helps in their safe and effective usage. Schedule (E1) of the Rules enlist the poisonous substances under ASU systems of medicine. Even though poisonous, Ayurvedic medicines are not toxic, as they are prepared only after proper *Shodhana* (purification) of the poisonous raw drugs. Effect of *Shodhana* (purification) in reducing the toxicity is also evident from the various research works. Official books like API, AFI etc. also mentioned the purification procedure of these drugs. In addition to *Shodhana* (purification), Ayurveda ensure additional pharmacovigilance by logically designing the formulations in order to nullify the toxic effect of poisonous drug. In the present scenario, Ayurvedic medicines, on the concept of 'being harmless', many people are using them as an OTC product especially herbal extracts and proprietary medicines. So Ayurvedic drug manufacturers, dealers, *Vaidyas* and physicians must be aware and focus on the safe manufacturing practices of medicines, rational prescription and safe dosage of medicines. While manufacturing, if a medicine contains a poisonous ingredient it must be used only after proper *Shodhana* (purification). Also Caution note shall be there on the label of the medicine container. 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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