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A Newsletter By: ASSOCIATION OF MANUFACTURERS OF AYURVEDIC MEDICINES

President's Message

Dear Readers,

Ayurveda is not only a treatment way rather it is a universal way to keep the entire universe healthy and pleasant. There is a need to educate people about Ayurveda, its principles and its practical applications, seasonal ailments, changing life style and associated disease, diet etc. Ayurveda educates people to maintain and follow the healthy way to remain free from diseases. In the era of evidence based research, documentation of clinical experiences, observations, case studies and procedures from AYUSH systems is mandatory so that sufficient evidence for practice of AYUSH systems is established. Scholars should be trained in Information technology tools as also modern diagnostic techniques to validate research on modern parameters. Need of the day are new scientific evidences for traditional practices is and awareness among the younger generation about concepts of Ayurveda. At this critical juncture, both veterans and youngsters must play complementary roles. And then, the valuable knowledge of Ayurveda will reach global heights.

Wishing a readers a Happy Deepawali

Best Wishes!!

Vaidya Devender Triguna

Honoured with Padma Shri and Padma Bhushan

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From the Editor's desk

Dear Readers,

It is pleasure to present to our readers the second issue of InfoAyurveda. In this issue, we have compiled information from diverse perspectives for the benefit to our readers.

The ASU sector has see from good developments. Union Ministry of AYUSH is in the process of drafting a new National Policy on AYUSH -2016. The ministry's initiative in this regard is significant as the earlier 'National Policy on Indian Systems of Medicine and Homoeopathy' was framed way back in 2002 and since then the country has witnessed a number of new developments in the field of Indian Systems of Medicine and Homoeopathy. The Union Cabinet chaired by the Prime Minister Shri Narendra Modi has approved signing of a Memorandum of Understanding (MoU) between India and Tanzania in the field of Traditional Systems of Medicine and Homeopathy. The MoU will provide structured frame work for the cooperation between the two countries for the promotion and propagation of Indian Traditional Systems of Medicine & Homeopathy in Tanzania. The newly added Appendix I B in Schedule Y, describes data to be submitted along with the application to conduct clinical trial or import or manufacture of a Phytopharmaceutical drug in the country. G.S.R. 918(E) & S.O.1352(E) have been reproduced.

We invite suggestions and feedback from our readers, as also some articles they wish to contribute. We also call for manufacturers of ASU Drugs and allied herbal industry to join our association and make it stronger, as in unity we stand and in unity we shall succeed.

Wishing our readers happiness & prosperity!!

Warm Regards,
Dr. J.L.N. Sastry
On behalf of Editorial Board.

A Publication of:

Association of Manufacturers of Ayurvedic Medicines

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Members of AMAM'S Executive Committee

Editorial Board

Annual General Meeting of AMAM 2015-2016
Minutes of the Meeting

The Annual General Meeting of AMAM was held at India Habitat Centre to inform members about achievements of AMAM in the year 2015 – 2016 and to discuss on the Industry issues to be pursued/ taken up by the Association in the upcoming year and decide on the way forward. The event was graced by the presence of Shri Ajit Mohan Sharan, Secretary, Ministry of AYUSH, the Chief Guest and Prof. V.K. Joshi, Chairman, Ayurvedic Pharmacopoeia Commission, the Guest of Honour of the occasion, along with dignitaries and representatives of the various Government bodies and the Industry. Main highlights of the event were an interactive session between the AYUSH Industry & APC Chairman, Prof. VK Joshi. Dr. J.L.N Sastry, Joint Secretary AMAM briefed about the issues related to API & AFI from Industry perspective.

Dr. Vedula Sasibhushan presided over the meeting and welcomed the Guests and the Executive Committee Members.

Padmashri Vaidya Devender Triguna Ji, President AMAM, emphasized the need for raising the quality of AYUSH herbomineral medicines and the need for enhancing the standards of research & education in Ayurveda. He emphasized that promotion of AYUSH premium mark by industry will facilitate the issue. He also raised the concern regarding substances like Kasturi and Praval which are used as raw material in ASU formulations but are however not being used due biodiversity concerns.

Shri Ajit Mohan Saran, Secretary AYUSH and Chief Guest of the session said that ASU Industry is at crossroads where there is a natural shift of preferences towards ASU drugs. In such scenario, any doubts in the public regarding the credibility of ASU medicines should be removed. He informed about some pipeline initiatives like provisions for a centralized licensing regimen, coherent/ uniform yard stick for new drugs and guidelines for ASU clinical trials, aligning of AYUSH premium mark with COPP requirements, addressing issues of quality of raw materials and emphasis on pharmacopoeial work with support and cooperation from industry for credibility of Indian products abroad in terms to facilitate the same.

Dr. JLN Sastry, Jt. Secretary AMAM took the distinguished gathering through the theme of the event that Industry iterates to provide quality and standard AYUSH medicines to the public. He said that AMAM, since its inception in the year 2003, has been in the forefront in pursuing industry issues and science based Ayurveda is the core objective of AMAM. He said that standardization of AYUSH medicines is utmost priority and emphasized on the need for setting up Centralized Drugs Testing Laboratory for AYUSH medicines alike modern medicine to facilitate this. He added that Industrial manufacturing practices should also be recognized and brought forward in ways acceptable to all like pharmacopoeial standards as these differ from documented traditional manufacturing practices. In this regards, he informed that pharmacopoeial standards of various herbs being used in industry would be made available to the APC. Dr. Sastry said that standard/ authentic raw material like standardized/certified alpine species should be made available. He emphasized that training of Drug Inspectors should be a critical to standards of drugs. He further added that a central licensing system will give the desired benefit to the ASU Industry. Dr Sastry also emphasized on the need for microbial testing of the drugs and guidelines on synthetic molecules uses.

Prof. V.K. Joshi, Chairman APC presented an interface on APC and its activities and how industry can participate towards APC activities. He said that the current interaction

was a much awaited beginning. The AYUSH practitioners were well versed with maintaining the quality standards and quality and presently when traditional medicines are becoming the healthcare needs of all strata of people, providing quality standards of drugs is the need of the hour for AYUSH Industry. He emphasized that the need for addressing substitutes needs to be explored. He also informed about proposed harmonization of Ayurvedic and Unani pharmacopoeias and discussed upon the clinical data requirements for P&P medicine. He informed that Pharmacopoeial standards of veterinary products are also being prepared.

The session was followed by open forum wherein Prof V.K. Joshi interacted with various industry members.

- Shri Vijendra Prakash, Vice President AMAM informed about impact of regulations on legal meterology department and raised concerns regarding labeling issues and requirements in Ayurvedic medicines. He also iterated the issues of Advertisement requirements for Ayurvedic Drugs as per draft notification received. He further said that limiting sites for conducting clinical trials would not be feasible for states where a large number of Ayurvedic drug manufacturers are present.
- Shri Santosh Kumar Tiwari (Hamdard Ltd.) raised issues regarding harmonization of Ayurvedic and Unani Pharmacopoeias.
- Shri Rajendra Dobriyal (Hindustan Unilever Ltd.) enquired what constituted New Drugs in Ayurveda and the clinical trial requirements for them and suggested that as science cannot be stagnant, new standards should be made considering the richness of minerals and contamination by silica contents etc of raw materials. He also raised concern about clinical trial requirements for P&P medicine.
- Shri Pradeep Multani emphasized on the need for timelines for approval of drugs and conduction of clinical trials/ fee requirements and place of conduct should be listed.
- Dr. Rajiva K Rai (Dabur India Ltd.) enquired regarding data supplied to state licensing authorities' and its validation by the state licensing authorities.
- Shri Ravikant (Ayurvet) enquired about licensing requirements for Ayurvedic veterinary products.
- Shri Gaurav Sharma (Rekitt Benckiser) opined that regulations for ASU Drug industry should be prospective and not retrospective.

Shri Pradeep Multani, Hon. Gen secretary AMAM, informed the members about the achievement of the Association and the issues pursued by the Association in the year 2015 – 2016. He lauded the supported given to ASU industry concerns by the Ministry of AYUSH, especially the signing of WTO agreement for global propagation of AYUSH. Shri Multani said that since ASU Drugs are included in the lowest of VAT and excise slabs as of now, similar provisions should be requested in GST also and GST rates may kindly be in the lowest slab of essential goods so that no additional burden is levied on the ASU industry. Shri Multani also drew the attention of Secretary AYUSH about modifications required in the draft notification on approval system for advertisements of AYUSH products and medicines.

Shri Tejinder Singh, Treasurer AMAM, presented details of the Audited & Unaudited Accounts of AMAM for the financial Year ending 31st March 2016. Shri Pradeep Multani briefed about the changes in the AMAM Executive Committee. With a general consensus, Dr. Arun Gupta (Head, Medical Affairs & Clinical Research, Dabur India Limited) was introduced as Joint Secretary, AMAM. Dr. Vedula Sasibhushan from Dabur India Limited was introduced as Executive Committee Member. The need for expansion of membership, to consider available options for strengthening and revitalization of the Association and garnering support on issues pertaining to industry from Govt. bodies was iterated by all the members. The AGM ended with Vote of Thanks proposed by Dr. Arun Gupta (Joint Secretary, AMAM).

Representations made by AMAM to the Government Bodies

1. Representation for continuation of the existing concessional treatment on all Ayurveda products under the proposed Goods and Services Tax ('GST')


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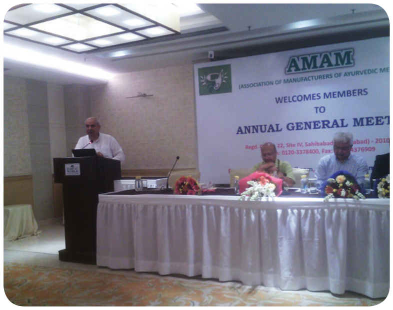
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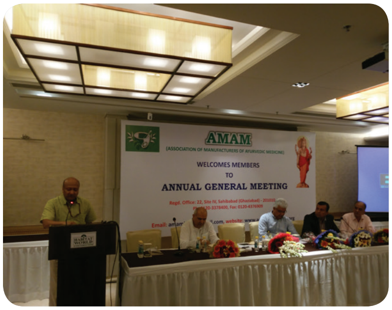
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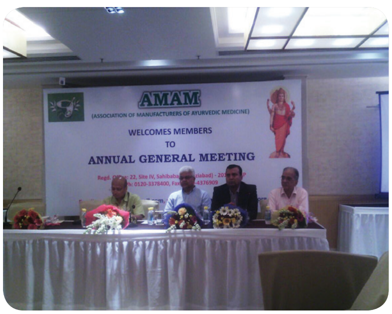
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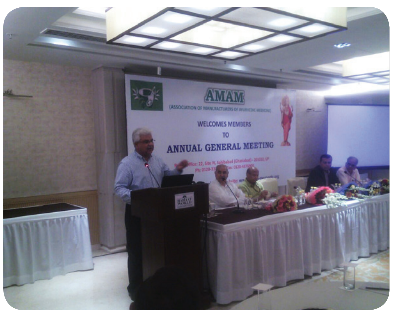
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regime.

2. Representation to Shri Ajit M. Sharan, IAS Secretary, Ministry of AYUSH, Govt of India:- CoPP documents issuance concerns

3. Representation to Shri Ajit M. Sharan, IAS Secretary, Ministry of AYUSH, Govt of India:- Regarding A Preferred Policy Option For Pack Aged Honey Under The Proposed Goods And Services Tax('GST') Regime

4. Representation to Shri Ajit M. Sharan, Secretary, Ministry of AYUSH, Govt of India, on Shelf life draft notification suggestions

5. Representation to Shi Sripada Yesso Naik and Prof. Ram Gopal Yadav Chairman, Parliamentary Standing Committee of Health & Family Welfare, Rajya Sabha :- Parliamentary Standing Committee on Health & Family Welfare Observations–Industry Point-wise submission to the same.

6. Representation to the Under Secretary to the Govt. of India, Ministry of AYUSH, AYUSH Bhawan, New Delhi-110 023, (2) Sh. Shripad Yesso Naik, AYUSH -Independent Charge Hon'ble State Minister of Health & Family Welfare; (3) ShriAjit M Sharan, Secretary,Deptt.of AYUSH, Govt. of India:- Comments/ Consolidate opinion/ views on the notification No.104/Nutraceuticals/ FSSAI/2013issued by Ministry of Health & F/W reg.

7. Representation to Shri Ajit M Sharan, Secretary, Ministry of AYUSH, Govt of India, AYUSH Bhawan:- Mainstreaming AYUSH–Arogya Bhava

8. Representation to Shri Ajit M.Sharan,IAS Secretary,Ministry.ofAYUSH, Govt.of India, AYUSH Bhawan:-Meeting to discussWHO-COPP of Ayurvedic,Siddha and Unani Drugs–reg.

AMAM

9. Representation to Shri A.K. Ganeriwala, Joint Secretary Deptt. of AYUSH, Govt. of India:- Formulation of Holistic National Policy on AYUSH –2016.

10. Representation to Ministry of Health & F/W, Bangladesh:- on Request for Intervention through Bangladesh Embassy on issues related to the manufacturing of Ayurvedic products in Bangladesh.

11. Representation to Shri Ajit M Sharan, Secretary, Ministry of AYUSH, Govt. of India on issues of Regulatory requirements and clinical trials of ASUdrugs;

12. Representation to Shri Ajit M Sharan, Secretary, Ministry of AYUSH, Govt of India & Prof. S.S. Handa on comments on the provisions particularly the list of A.S.U. ingredients in various schedules of the FSSAI notification on food, safety & standards.

13. Representation to Joint Secretary-cum-Director General (Labour Welfare) Government of India, Ministry of Labour & Employment:- Objection to Notification dated 30 March 2016 regarding Wages payable to Workmen by Contractor and our Suggestion:- Contradiction with Minimum Wages Act applicable in all States of India. Serious probability of IR issues in very Factory.

14. Comments/ suggestions on draft notification on approval system for advertisements on AYUSH products/medicines-Regarding.REF: Draft Notification of G.S.R.396(E)

रजिस्ट्री सं० डी० एल०-33004/99 REGD. NO. D. L.-33004/99

भारत का राजपत्र
The Gazette of India

असाधारण
EXTRAORDINARY
भाग II—खण्ड 3—उप-खण्ड (ii)
PART II—Section 3—Sub-section (ii)
प्राधिकार से प्रकाशित
PUBLISHED BY AUTHORITY

सं. 858] नई दिल्ली, बृहस्पतिवार, अप्रैल 7, 2016/चैत्र 18, 1938
No. 858] NEW DELHI, THURSDAY, APRIL 7, 2016/CHAITRA 18, 1938

MINISTRY OF AYURVEDA, YOGA AND NATUROPATHY, UNANI, SIDDHA AND HOMOEOPATHY (AYUSH)

NOTIFICATION

New Delhi, the 12th August, 2016

G.S.R. 789(E).—Whereas the draft of certain rules further to amend the Drugs and Cosmetics Rules, 1945 was published as required by sub-section (1) of section 33N of the Drugs and Cosmetics Act, 1940 (23 of 1940) in Part II, Section 3, Sub-section (i) of the Gazette of India, Extraordinary, vide number G.S.R 897(E), dated the 24th November, 2015 inviting objections and suggestions from persons likely to be affected thereby before the expiry of a period of forty five days from the date on which copies of the Official Gazette containing the said notification were made available to the public;

And whereas, the said Gazette was made available to the public on the 24th November, 2015;

And whereas, objections or suggestions received from the public on the said draft rules have been considered by the Central Government;

Now, therefore, in exercise of the powers conferred by sub-section (1) of section 33-N read with clause (e) of sub-section (2) of the said section of the Drugs and Cosmetics Act, 1940 (23 of 1940), the Central Government, after consultation with the Ayurvedic, Siddha and Unani Drugs Technical Advisory Board, hereby makes the following rules further to amend the Drugs and Cosmetics Rules, 1945, namely:-

RULES

1. (1) These Rules may be called the Drugs and Cosmetics (5th Amendment) Rules, 2016.

(2) They shall come into force on the date of their publication in the Official Gazette.

2. In the Drugs and Cosmetics Rules, 1945, for rule 161-B the following rule shall be substituted, namely:-

"161-B. Shelf life or date of expiry of medicines.—(1) The date of expiry of Ayurvedic, Siddha or Unani medicines shall be conspicuously displayed on the label of container or package of Ayurvedic, Siddha or Unani medicine, as the case may be, and after the said date of expiry, no medicine shall be marketed, sold, distributed or consumable;

Provided that this rule shall apply to Ayurvedic, Siddha and Unani medicines seeking licence or renewal of licence for manufacturing after the date of notification of the rules.

Provided also that this rule shall not be applicable to the Ayurvedic, Siddha or Unani medicines manufactured and marketed

prior to the date of this notification.

(2) Every person applying for licence or renewal of licence for the manufacturing of Ayurveda, Siddha or Unani medicines defined under clause (h) of section 3 of the Act shall submit to the State Licensing Authority scientific data based shelf life or date of expiry of the medicine based on the Real time stability studies of medicines in accordance with the guidelines prescribed in the Ayurvedic Pharmacopoeia of India.

Provided that this sub-rule shall be applicable after three years from the date of notification of the rules. (3) The guidelines regarding stability studies as prescribed in the Ayurvedic Pharmacopoeia of India, Part-I, Volume-VIII shall be applicable to all the medicines of Ayurvedic, Siddha and Unani.

(4) The State Licensing Authority shall, before granting license or renewal of license for an Ayurvedic, Siddha or Unani medicine, ensure validity of the data submitted by the manufacturer in support of the claimed shelf-life of that medicine.

(5) The State Licensing Authority may at any time direct the manufacturer to provide the samples of the medicine and any other related information; and may share it with the Pharmacopoeial Laboratory for Indian Medicine, Ghaziabad for analysis or independent validation.

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(6) Where the manufacturer fails to comply with direction of the State Licensing Authority under subrule (5), the license for the manufacturing of the medicine shall be liable for suspension after giving a reasonable opportunity of being heard.

(7) Any person aggrieved by an order passed by the State Licensing Authority under sub-rule (6), may within sixty days of such order, appeal to the Central Government, and the Central Government may, after such enquiry into the matter as is considered necessary, pass such order in relation thereto as it deems fit. The decision of the Central Government shall be final and binding.

(8) The shelf life or date of expiry of an Ayurveda, Siddha or Unani medicine defined under clause (a) of section 3 of the Act shall, unless otherwise determined on the basis of scientific data, be as follows:-10 years

S. No.	**Dosage form**	**Shelf life or date of expiry with effect from the date of manufacture**
(1)	**(2)**	**(3)**
(i)	Anjana	
	a) Anjana made from Kasthaushadhi	1 year
	b) Anjana made from Kasthaushadhi along with Rasa/Uprasa/Bhasma	2 years
	c) Anjana made only from Rasa/Uprasa/Bhasma	3 years
(ii)	Arka	1 year
(iii)	Asava Arista	10 years
(iv)	Avaleha, Khanda, Paka, Guda	3 years
(v)	Churna, Kwatha Churna, Lepa Churna, Danta Manjan (Churna)	2 years
(vi)	Dhoopan	2 years
(vii)	Dravaka, Lavana, Kshara	5 years
(viii)	Ghrita	2 years
(ix)	Guggulu	5 years
(x)	Gutika/Vati	
	(I) Gutika or Vati containing Kasthaushadhi along with Rasa / Uprasa/ Bhasma/ Guggulu (including Lepa Gutika and GhanVati)	5 years
	(II) Gutika or Vati containing only Kasthaushadhi (including Lepa Gutika and Ghan Vati)	3 years
	(III) Gutika / Vati containing only Ras / Uprasa / Bhasma except Naga, Vanga and Tamra Bhasma	10 years
(xi)	Karna/ Nasabindu	2 years

(xii)	Kupipakva Rasayana	10 years
(xiii)	Malahar	3 years
(xiv)	Mandura-Lauha	10 years
(xv)	Naga Bhasma, Vanga Bhasma and Tamra Bhasma	5 years
(xvi)	Netrabindu	1 year
(xvii)	Parpati	10 years
(xviii)	Pishti and Bhasma except Naga, Vanga and Tamra Bhasma	10 years
(xix)	PravahiKwatha	3 years
(xx)	Rasayoga	
	(I) Rasayoga Containing only Rasa / Uprasa / Bhasma except Naga, Vanga and Tamra Bhasma	10 years
	(II) Rasayoga Containing Rasa / Uprasa/ Bhasma along with Kasthaushadhi/Guggulu	5 years
(xxi)	Sattva (derived from medicinal plant)	2 years
(xxii)	Sharkar / Panak/Sharbat	3 years
(xxiii)	Shveta parpati	2 years
(xxiv)	Taila	3 years
(xxv)	Varti	2 years

(Siddha medicines)

S. No.	Dosage form	Shelf life or date of expiry with effect from the date of manufacture
(1)	**(2)**	**(3)**
(i)	**Curanam**	
	Kutinir Curanam/Adai Curanam/Kanchi Curanam/Utkali Curanam/Pittu Curanam/ Podithimirthal Curanam/ Podi/ Pattru Curanam/ Pottanam or Kizhi Curanam/ Ottratam Curanam/ Vethu Curanam/ Pugai Curanam/Kali Curanam / Thuvalai Curanam	2 years
(ii)	Mattirai/Vatakam	
	(I) Containing only Mooligai ingredients (including Kudineer Curanam Mattirai) (eg. Nilavembu kutinir Mattirai)	2 years
	(II) Containing Mooligai ingredients along with Thathu Porutkal/ Jeeva Porutkal /Parpam/Centuram /Cunnam. (including kutinir Curanam Mattirai)	5 years
	(III) Containing only Thathu Porutkal /Parpam/Centuram/Cunnam/ Kattu/ Kalanku.	10 years
(iii)	Rasa-Paadana Marunthugal (All Mercurial Preparation)	
	(I) Containing Mooligai ingredients along with Thathu Porutkal/Parpam/ Centuram/Cunnam /Kattu/Kalanku	
	(II) Containing only Thathu Porutkal / Parpam/Centuram/Cunnam Kattu/ Kalanku	
(iv)	Parpam / Centuram	
	(I) Containing only Mooligai ingredients (eg. KungiliyaParpam)	
	(II) Containing Mooligai ingredients with Thathu Porutkal / Parpam/ Centuram/ Cunnam/ Kattu/Kalanku (eg. Aya Centuram)	10 years
	(III) Containing Mooligai ingredients with Jeeva Porutkal (e.g. Sangu Parpam)	10 years

(v)	Karuppu	
	(I) Containing only Mooligai ingredients (eg. Vasambu Sutta Kari)	2 years
	(II) Containing Mooligai ingredients with Thathu Porutkal (e.g. Sivanar Amirtham, Thalaga Karuppu)	5 years
	(III) Containing Mooligai ingredients with Jeeva Porutkal (e.g. Kasthuri Karuppu, Pattu Karuppu)	5 years
(vi)	Patankam	
	(I) Mooligai based Patankam (eg. Sambirani Patankam)	
	(II) Rasa based Patankam (eg. Rasa Centuram)	
(vii)	Kulampu	
	Based on process-	
	(I) Araippu Kulampu (eg. Agathiyar Kulampu)	5 years
	(II) Erippu Kulampu (eg. Kumatti Kulampu)	3 years
(viii)	Meluku	
	Based on process-	
	(I) Araippu Meluku (eg. Linga Meluku)	5 years
	(II) Idippu Meluku (eg. Rasa Gandhi Meluku / Idi Vallthi Meluku)	3 years
	Based on raw materials-	
	(III) Mooligai Meluku (eg. Malaikudara Meluku)	3 years
(ix)	Karpam	
	Based on raw materials-	
	(I) Mooligai Karpam (eg. Karisalai Karpam , Thiripala Karpam)	2 years
	Based on raw materials-	
	(II) Mooligai Thathu Karpam (eg. Aya Bringaraja Karpam)	5 years
	Based on process-	
	(III) Araippu Karpam (eg. Irunelli Karpam)	3 years
(x)	Satthu	
	(I) Satthu derived from Mooligai (eg. Seenthil Satthu)	
	(II) Satthu derived from Thathu Porutkal (eg. Aya Satthu,Thurusu Satthu)	10 years
	(III) Satthu derived from Jeeva Porutkal (eg. Sembu Satthu derived from Poonagam, Mayiliragu)	5 years
(xi)	Ilakam / Legiyam/ Iracayanaam	3 years
(xii)	Kallikkam/ Mai/ Kalimbu/ Neer/ Venney	1 year
(xiii)	Karam (Karanool)	2 years
(xiv)	Kattu (Medicated bandage cloth)/Seelai/Varthy/ Thiri	1 year
(xv)	Kattu / Kalanku/ Cunnam	10 years
(xvi)	Kutinir / Kiyazham(with preservatives)	3 years
(xvii)	Manappaku/ Panagam	3 years
(xviii)	Nasiyathuli/Kanthuli /Sevithuli	1 year
(xix)	Ney / Ghirutham/Kadugu	2 years
(xx)	Oothal/Nasigaparanam/ Thoopasarakku	1 year
(xxi)	Pakkuvam , Thennoral	1 year
(xxii)	Panda Vaippu	10 years

(xxiii)	Peechu	2 years
(xxiv)	Sutigai	2 years
(xxv)	Tailam / Ennai/ Poochu	3 years
(xxvi)	Tinir	1 year
(xxvii)	Tiravakam (derived from ThathuPorutkal)	2 years

(Unani medicines)

S. No.	Dosage form	Shelf life or date of expiry with effect from the date of manufacture
(1)	(2)	(3)
(i)	Arq (except Arq-e-Ajeeb)	
(ii)	Arq -e-Ajeeb	5 years
(iii)	Ayarij / Sunoon/ Zuroor/Ghazah	2 years
(iv)	Burood	1 year
(v)	Shiyaf	2 years
(vi)	Surma / Kohal	3 years
(vii)	Habb	3 years
(viii)	Halwa	3 years
(ix)	Itrifal	3 years
(x)	Jauhar/ Jawahir	5 years
(xi)	Jawarish	4 years
(xii)	Khamira	3 years
(xiii)	Kushta	10 years
(xiv)	Laboob	3 years
(xv)	Laooq	3 years
(xvi)	Majoon / Dawa	3 years
(xvii)	Marham / Zimad / Qairooti	2 years
(xviii)	Mufarreh	3 years
(xix)	Murabba	1 year
(xx)	Nabeez	10 years
(xxi)	Qurs	3 years
(xxii)	Qutoor	1 year
(xxiii)	Raughaniyat/ Tila	3 years
(xxiv)	Sharbat/ Sikajabeen	3 years
(xxv)	(I) Sufoof (Without Salt)	2 years
	(II) Sufoof (Containing salt)	1 year
(xxvi)	Tiryaq	3 years

[F. No. K. 11024/5/2013-DCC (AYUSH)]

ANIL KUMAR GANERIWALA, Jt. Secy.

Note : The principal rules were published in the Gazette of India vide notification No. F. 28-10/45H(I), dated 21st December, 1945 and were last amended vide notification G.S.R 640(E) dated 29.06.2016.

रजिस्ट्री सं० डी० एल०-33004/99 REGD. NO. D. L.-33004/99

भारत का राजपत्र
The Gazette of India

असाधारण
EXTRAORDINARY
भाग II—खण्ड 3—उप-खण्ड (i)
PART II—Section 3—Sub-section (i)
प्राधिकार से प्रकाशित
PUBLISHED BY AUTHORITY

सं. 245] नई दिल्ली, सोमवार, अप्रैल 4, 2016/चैत्र 15, 1938
No. 245] NEW DELHI, MONDAY, APRIL 4, 2016/ CHAITRA 15 , 1938

MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health and Family Welfare)

NOTIFICATION

New Delhi, the 30th November, 2015

G.S.R. 918(E).— Whereas a draft of the rules further to amend the Drugs and Cosmetics Rules, 1945, was published, as required by section 12 and section 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940), vide notification of the Government of India in the Ministry of Health and Family Welfare (Department of Health and Family Welfare), number G.S.R. 702(E), dated the 24th October, 2013, in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i), dated the 24th October, 2013, inviting objections and suggestions from all persons likely to be affected thereby before the expiry of a period of forty-five days from the date on which the copies of the Official Gazette of the said notification were made available to the public;

And whereas copies of the Gazette were made available to the public on the 29th October, 2013;

And whereas, the objections and suggestions received from the public on the said draft rules have been considered by the Central Government.

Now, therefore, in exercise of the powers conferred by section 12 and section 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940), the Central Government, after consultation with the Drugs Technical Advisory Board, hereby makes the following rules further to amend the Drugs and Cosmetics Rules, 1945, namely:-

1. (1) These rules may be called the Drugs and Cosmetics (Eighth Amendment) Rules, 2015.

   (2) They shall come into force on the date of their publication in the Official Gazette.

2. In rule 2 of the Drugs and Cosmetics Rules, 1945 (hereinafter referred to as the said rules), after clause (ea) the following clause shall be inserted, namely:—

   '(eb). "Phytopharmaceutical drug" includes purified and standardised fraction with defined minimum four bio-active or phyto-chemical compounds (qualitatively and quantitatively assessed) of an extract of a medicinal plant or its part, for internal or external use of human beings or animals for diagnosis, treatment, mitigation or prevention of any disease or disorder but does not include administration by parenteral route'.

3. In rule 122-A of the said rules,-

   (i) in sub-rule (1), in clause (b), in the second proviso, for the words, figures and letter "Appendix I or Appendix IA", the words, figures and letters, "Appendix I or

Appendix IA or Appendix IB", shall be substituted;

(ii) in sub-rule (2), for the words, figures and letter "Appendix I or Appendix IA", the words, figures and letters, "Appendix I or Appendix IA or Appendix IB", shall be substituted.

4. In rule 122-B of the said rules,-

(i) in sub-rule (1), in clause (b), in the second proviso, for the words, figures and letter "Appendix I or Appendix I A", the words, figures and letters, "Appendix I or Appendix IA or Appendix I B", shall be substituted;

(ii) in sub-rule (2), for the words, figures and letter "Appendix I or Appendix IA", the words, figures and letters, "Appendix I or Appendix IA or Appendix IB", shall be substituted.

5. In rule 122-E of the said rules, in clause (a), after the words "bulk drugs substance," the words "or phytopharmaceutical drug" shall be inserted.

6. In Schedule Y of the said rules, after APPENDIX IA, the following Appendix shall be inserted, namely:-

"APPENDIX I B

DATA TO BE SUBMITTED ALONG WITH APPLICATION TO CONDUCT CLINICAL TRIAL OR

IMPORT OR MANUFACTURE OF A PHYTOPHARMACEUTICAL DRUG IN THE COUNTRY

PART - I

1. Data to be submitted by the applicant:

1.1. A brief description or summary of the phytopharmaceutical drug giving the botanical name of the plant (including vernacular or scriptural name, wherever applicable), formulation and route of administration, dosages, therapeutic class for which it is indicated and the claims to be made for the phytopharmaceutical product.

1.2. Published literature including information on plant or product or phytopharmaceutical drug, as a traditional medicine or as an ethno medicine and provide reference to books and other documents, regarding composition, process prescribed, dose or method of usage, proportion of the active ingredients in such traditional preparations per dose or per day's consumption and uses.

1.3. Information on any contraindications, side effects mentioned in traditional medicine or ethno medicine literature or reports on current usage of the formulation.

1.4. Published scientific reports in respect of safety and pharmacological studies relevant for the phytopharmaceutical drug intended to be marketed,-

(a) where the process and usages are similar or same to the product known in traditional medicine or ethno medicine; and

(b) where process or usage is different from that known in traditional medicine or ethno medicine.

1.5. Information on any contraindications, side effects mentioned or reported in any of the studies, information on side effects and adverse reactions reported during current usage of the phytopharmaceutical in the last three years, wherever applicable.

1.6. Present usage of the phytopharmaceutical drug, – to establish history of usages, provide details of the product, manufacturer, quantum sold, extent of exposure on human population and number of years for which the product is being sold.

2. Human or clinical pharmacology information:

2.1. Published scientific reports in respect of pharmacological studies including human studies or clinical studies or epidemiological studies, relevant for the phytopharmaceutical drug intended to be marketed,-

(a) where the process and usages are similar or same to the product known in traditional medicine or ethno medicine; and

(b) where process or usage is different from that known in traditional medicine or ethno medicine.

2.2. Pharmacodynamic information (if available).

2.3. Monographs, if any, published on the plant or product or extract or phytopharmaceutical. (Copies of all publications, along with english translation to be attached.)

PART – II

Data generated by applicant

3. Identification, authentication and source of plant used for extraction and fractionation:

3.1. Taxonomical identity of the plant used as a source of the phytopharmaceutical drug giving botanical name of genus, species and family, followed by the authority citation (taxonomist's name who named the species), the variety or the cultivar (if any) needs to be mentioned.

3.2 Morphological and anatomical description giving diagnostic features and a photograph of the plant or plant part for further confirmation of identity and authenticity. (Furnish certificate of confirmation of botanical identity by a qualified taxonomist).

3.3 Natural habitat and geographical distribution of the plant and also mention whether the part of the plant used is renewable or destructive and the source whether cultivated or wild.

3.4 Season or time of collection.

3.5 Source of the plant including its geographical location and season or time of collection.

3.6 A statement indicating whether the species is any of the following, namely:-

(a) determined to be endangered or threatened under the Endangered Species Act or the Convention on International Trade in Endangered species (CITES) of wild Fauna and Flora;

(b) entitled to special protection under the Biological Diversity Act, 2002 (18 of 2003);

(c) any known genotypic, chemotypic and ecotypic variability of species.

3.7. A list of grower or supplier (including names and addresses) and information on the following items for each grower or supplier, if available or identified already, including information of primary processing, namely:-

(a) harvest location;

(b) growth conditions;

(c) stage of plant growth at harvest;

(d) harvesting time;

(e) collection, washing, drying and storage conditions;

(f) handling, garbling and transportation;

(g) grinding, pulverising of the plant material; and

(h) sieving for getting uniform particle size of powdered plant material.

3.8. Quality specifications, namely:-

(a) foreign matter;

(b) total ash;

(c) acid insoluble ash;

(d) pesticide residue;

(e) heavy metal contamination;

(f) microbial load;

(g) chromatographic finger print profile with phytochemical reference marker;

(h) assay for bio-active or phytochemical compounds; and

(i) chromatographic fingerprint of a sample as per test method given under quality control of the phytopharmaceutical drug (photo documentation).

3.9 . An undertaking to supply specimen sample of plant duly labeled and photocopy of the certificate of identity confirmation issued by a qualified taxonomist along with drawings or photographs of the diagnostic morphological and histological features of the botanical raw material used for the confirmation of authenticity.

4. Process for extraction and subsequent fractionation and purification:

4.1. Quality specifications and test methods for starting material.

4.2. Steps involved in processing.

(a) details of solvent used, extractive values, solvent residue tests or limits, physico-chemical tests, microbial loads, heavy metal contaminants, chromatographic finger print profile with phytochemical reference markers, assay for active constituents or characteristic markers, if active constituents are not known;

(b) characterisation of final purified fraction;

(c) data on bio-active constituent of final purified fraction;

(d) information on any excipients or diluents or stabiliser or preservative used, if any.

4.3. Details of packaging of the purified and characterised final product, storage conditions and labeling.

5. Formulation of phytopharmaceutical drug applied for:

5.1. Details of the composition, proportion of the final purified fraction with defined markers of phytopharmaceutical drug per unit dose, name and proportions of all excipients, stabilisers and any other agent used and packaging materials.

5.2. Test for identification for the phytopharmaceutical drug.

5.3. Quality specifications for active and inactive phytopharmaceutical chromatographic finger print profile with phytochemical reference marker and assay of active constituent or characteristic chemical marker.

6. Manufacturing process of formulation:

6.1. The outline of the method of manufacture of the dosage form, along with environmental controls, in-process quality control tests and limits for acceptance.

6.2. Details of all packaging materials used, packing steps and description of the final packs.

6.3. Finished product's quality specifications, including tests specific for the dosage form, quality and chromatographic finger print profile with phytochemical reference marker and assay for active constituent or characteristic marker, if active constituents are not known.

7. Stability data:

7.1. Stability data of the phytopharmaceutical drug described at 4 above, stored at room temperature at 40 +/- 2 deg. C and humidity at 75%RH +/- 5%RH for 0, 1, 2, 3 and 6 months.

7.2 Stability data of the phytopharmaceutical drug in dosage form or formulation stored at room temperature at 40 +/- 2 deg. C and humidity at 75%RH +/- 5%RH for 0, 1, 2, 3 and 6 months, in the pack intended for marketing.

8. Safety and pharmacological information:

8.1. Data on safety and pharmacological studies to be provided.

8.2. Animal toxicity and safety data:

(a) 28 to 90 days repeat dose oral toxicity on two species of animals;

(b) In-vitro genotoxicity data (Ame's test and Chromosomal aberration test as per Schedule Y);

(c) dermal toxicity tests for topical use products;

(d) teratogenicity study (only if phytopharmaceutical drug is intended for use during pregnancy).

9. Human studies:

9.1. Clinical trials for phytopharmaceutical drugs to be conducted as per applicable rules and guidelines for new drugs.

9.2. For all phytopharmaceutical drugs data from phase I (to determine maximum tolerated dose and associated toxicities) and the protocols shall be submitted prior to performing the studies.

9.3. Data of results of dose finding studies performed and the protocols shall be submitted prior to performing the studies:

Provided that in the case of phytopharmaceutical drug already marketed for more than five years or where there is adequate published evidence regarding the safety of the phytopharmaceutical drug, the studies may be abbreviated, modified or relaxed.

10. Confirmatory clinical trials:

10.1. Submit protocols for approval for any specific or special safety and efficacy study proposed specific to the phytopharmaceutical drug.

10.2. Submit proposed protocol for approval for human clinical studies appropriate to generate or validate safety and efficacy data for the phytopharmaceutical dosage form or product as per applicable rules and guidelines.

10.3. Submit information on how the quality of the formulation would be maintained during the above studies.

11. Regulatory status:

11.1. Status of the phytopharmaceutical drug marketed in any country under any category like functional food or dietary supplement or as traditional medicine or as an approved drug.

12. Marketing information:

12.1. Details of package insert or patient information sheet of the phytopharmaceutical drug to be marketed.

12.2. Draft of the text for label and carton.

13. Post marketing surveillance (PMS):

13.1. The applicant shall furnish periodic safety update reports every six months for the first two years after approval the drug is granted.

13.2. For subsequent two years the periodic safety update reports need to be submitted annually.

14. Any other relevant information:

Any other relevant information which the applicant considers that it will help in scientific evaluation of the application.".

[F. No. X. 11014/2/2012-DFQC]

K. L. SHARMA, Jt. Secy.

Note: The principal rules were published in the Gazette of India vide notification No. F.28-10/45-H (1) dated the 21st December, 1945 and was last amended vide notification number GSR 826 (E), dated the 30th October, 2015.

रजिस्ट्री सं० डी० एल०-33004/99 REGD. NO. D. L.-33004/99

भारत का राजपत्र
The Gazette of India

असाधारण
EXTRAORDINARY
भाग II—खण्ड 3—उप-खण्ड (ii)
PART II—Section 3—Sub-section (ii)
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सं. 858] नई दिल्ली, बृहस्पतिवार, अप्रैल 7, 2016/चैत्र 18, 1938
No. 858] NEW DELHI, THURSDAY, APRIL 7, 2016/CHAITRA 18, 1938

MINISTRY OF ENVIRONMENT, FOREST AND CLIMATE CHANGE

NOTIFICATION

New Delhi, the 7th April, 2016

S.O. 1352(E).—In exercise of the powers conferred by section 40 of the Biological Diversity Act, 2002 (18 of 2003) and in supersession of the notification number S.O.2726(E), dated the 26th October 2009, the Central Government, in consultation with the National Biodiversity Authority, hereby declares that the provisions of this Act shall not apply to the biological resources specified in column (3) of the Table below, having the illustrative trade or common name as mentioned in column (4) of the said Table, with plant part as specified in column (5) of the aforesaid Table and having the Source as mentioned in column (6) of the aforesaid Table, provided the said biological resources are normally traded as commodities subject to the terms enumerated in the Notes given below the said Table, namely:-

for details refer to : http://ismenvis.nic.in/Database/MoEF_6514.aspx

Public Notice : Ministry of AYUSH

K.11025/01/2015-DCC (AYUSH)-part

Government of India

Ministry of Ayurveda,Yoga & Naturopathy,Unani,Siddha and Homeopathy (AYUSH) AYUSH Bhawan,'B' -Block,GPO Complex, INA,New Oefh-110023

PUBLI C NOTICE

Consumers of Ayurvedic, Siddha and Unani drugs including the concerned stakeholders and public at large are hereby informed that the manufacturing of these drugs is regulated under the provisions of the Drugs and Cosmetics Act, 1940 and Rules thereunder. Such Ayurvedic, Siddha and Unani drugs containing any of the potentially hazardous ingredients of plant, animal or mineral origin as specified in the Schedule E(1), Rule 161(2) of the Drugs and Cosmetics Rules, 1945, are required to be taken under medical supervision. As per the legal provisions, caution in this regard is to be printed on the label of the container of such medicines. Accordingly, the public is advised to purchase and consume such Ayurvedic, Siddha and Unani drugs only on prescription from a qualified registered practitioner of the respective system and avoid purchasing them online and using them without medical consultation.

Manufacturers of Ayurvedic, Siddha and Unani drugs shall ensure to imprint **'Caution: to be taken under medical supervision'** both in English and Hindi on the labels of all such Ayurvedic, Siddha and Unani drugs which contain potentially hazardous ingredients of plant, animal or mineral origin as specified in the Schedule E(l) of the Drugs and Cosmetics Rules, 1945. Cases of contravention of these provisions, as and when found, shall be immediately brought to the notice of the concerned State Licensing

Authority for appropriate action.

Dated: 1st February, 2016

(Jasmine James)

Under Secretary to the Govt. of India

(Note: Drugs & Cosmetics Rule 161 {2) and Schedule E (1} is uploaded in the MinistryJs website www.indianmedicine.nic. in under Acts, Rules and Notifications)

AYUSH Ministry Drafting New National Policy on AYUSH

After about 14 years since its last policy, the Union Mministry of AYUSH is in the process of drafting a new National Policy on AYUSH -2016.

The ministry's initiative in this regard is significant as the earlier 'National Policy on Indian Systems of Medicine and Homoeopathy' was framed way back in 2002 and since then the country has witnessed a number of new developments in the field of Indian Systems of Medicine and Homoeopathy.

These developments include launching of National AYUSH Mission, bringing out MSR on Ayurveda, amendments in various Acts concerning AYUSH, enhancing quality of education through regulatory bodies, provision of infrastructural facilities for drug industry to ensure safety and efficacy of AYUSH drugs, the organization of World Ayurveda Congress in November, 2014, and the historic celebration of the first International Day of Yoga on June 21, 2015. Besides, global exposure to AYUSH has also taken place in a big way since then.

The ministry is drafting a new national policy on AYUSH as there is renewed and focused thrust on the development of AYUSH systems and their integration in the healthcare delivery system of the country, as has been emphasized on many occasions by Prime Minister Narendra Modi.

The Indian Systems of Medicine & Homoeopathy continue to be widely used in the country due to their accessibility, and sometimes, because they offer the only kind of medicine within the physical and financial reach of the patient. The Indian medicine system is also embedded in the beliefs of a wide section of the public and continues to be an integral and important part of their lives and for some, it is also a way of life.

Complementary and Alternative Medicine or Traditional Medicine is rapidly growing worldwide. In India also, there is resurgence of interest in Indian Systems of Medicine. People are becoming concerned about the adverse effects of chemical based drugs and the escalating costs of conventional health care. Longer life expectancy and life style related problems have brought with them an increased risk of developing chronic, debilitating diseases such as heart disease, cancer, diabetes and mental disorders. Although new treatments and technologies for dealing with them are plentiful, nonetheless more and more patients are now looking for simpler, gentler therapies for improving the quality of life and avoiding iatrogenic problems.

Courtesy: Pharmabiz

सत्यमेव जयते
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आयुर्वेद, योग व प्राकृतिक चिकित्सा
यूनानी, सिद्ध एवं होम्योपैथी (आयुष) मंत्रालय
भारत सरकार
आयुष भवन, 'बी' ब्लाक, जी.पी.ओ. कॉम्पलेक्स,
आई.एन.ए., नई दिल्ली-110023

Ministry of Ayurveda, Yoga & Naturopathy
Unani, Siddha and Homoeopathy (AYUSH)
Government of India
Ayush Bhawan, 'B' Block, GPO Complex
INA, New Delhi-110023

D.O No Z. 18017/01/2016-DCC (AYUSH)
Dated: 8th June, 2016

Subject: Formulation of New National AYUSH Pollcy-2016.

Dear President/Secretary of AYUSH Drugs Manufacturers Association,

Ministry of A YUSH is considering to update the provisions of National Policy of Indian Systems of Medicine and Homoeopathy- 2002 for focused strategic actions in the times to come. In this regard, suggestions and viewpoints from concerned stakeholders are important for the Ministry to take a considered view for finalizing the objectives and strategies to be outlined for development of AYUSH. May I urge the AYUSH drugs industry to kindly send suggestions from the policy perspective of imbibing safety, efficacy and quality assurance of drugs manufactured in the country. These inputs will be consolidated with consultative process in evolving the new AYUSH Policy document. Shall be grateful, if your valuable response is received at the earliest not later than 20th June 2016 by e-mail at dckaloch@rediffmail.com or Speed Post.

(Dr. D.C. Katoch)

Head, Drugs Control Cell

Thanking you and regards.

Cabinet approves agreement between AYUSH and WHO for traditional medicine

The Union Cabinet on Wednesday, Feb. 17, 2016, gave its approval to an agreement between the Ministry of Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homoeopathy (AYUSH) and the World Health Organisation (WHO) in the field of traditional medicine, a move aimed at improving acceptability and branding AYUSH systems internationally.

According to a government statement, the Cabinet meeting chaired by Prime Minister Narendra Modi approved the pact, which will also help in long-term collaboration with the WHO in facilitating and generating awareness about AYUSH systems of medicine through education, skill development, workshops and exchange programmes between the Ministry of AYUSH and the WHO for building capacity. It will also facilitate advocacy and dissemination of information on AYUSH systems amongst member states while collaborating with third parties to create synergy in implementing the WHO "Traditional Medicine Strategy: 2014-2023", particularly in the context of AYUSH systems.

As a first step in long-term collaboration, India will assign to the WHO activities for development of its technical documents and publications, like benchmarks for training in Yoga, and practice in Ayurveda, Unani Medicine and Panchakarma. The agreement is expected to benefit the practitioners of AYUSH systems.

Under the pact, AYUSH and WHO will subsequently take up other mutually agreed activities and initiatives that could encompass multilateral collaboration for promotion of Traditional and Complementary Medicine (T&CM) systems. This will include development of the WHO publication on the basic terminologies for T&CM, establishment of a database for global T&CM practitioners and a network of international regulatory cooperation for T&CM practices.

The expenditure for carrying out collaborative activities will be met from the allocated budget under the existing plan schemes of Ministry of AYUSH.

During a presentation by the AYUSH Ministry on July 3, 2014, Prime Minister Narendra Modi had asked it to seize opportunities so as to take the lead at a time when holistic health care has gained currency. It was also emphasised that a road map be prepared to establish India's credentials in holistic healthcare, including preparation of authoritative and credible literature.

Source: http://www.ibtimes.co.in/cabinet-approves-areement-between-ayush-who-traditional-medicine-667353

Cabinet approves MoU between India and Tanzania in the field of Traditional Systems of Medicine

The Union Cabinet chaired by the Prime Minister Shri Narendra Modi has approved signing of a Memorandum of Understanding (MoU) between India and Tanzania in the field of Traditional Systems of Medicine and Homeopathy.

The MoU will provide structured frame work for the cooperation between the two countries for the promotion and propagation of Indian Traditional Systems of Medicine & Homeopathy in Tanzania.

There are no additional financial implications involved. The financial resources necessary to conduct research, training courses, conferences / meetings will be met from the existing allocated budget and existing plan schemes of Ministry of AYUSH.

Background: India is blessed with well-developed systems of traditional medicine including medicinal plants, which hold tremendous potential in the global health scenario. Traditional Medicine is an important element of life of Tanzanian people and Traditional medicines are used as first aid or stop-gap measure before the patient is referred to modern health facilities.

Tanzania is an important East African country with historical ties with India and with substantial population of around 70 thousand Indian diaspora. Tanzania and India have traditionally enjoyed close, friendly and co-operative relations. In recent years, the relationship of the two countries has been marked by close contacts at the highest political level including cooperation in the field of Health and medicine.

The Ministry of AYUSH as a part of its mandate to propagate Indian systems of Medicine globally had signed MoUs with several other countries which include China, Malaysia, Hungary, Bangladesh, Nepal, etc.

Source:http://pib.nic.in/newsite/PrintRelease.aspx?relid=146798

File No.A.11019/05/2016 (HPC)

Ministry of AYUSH

Government of India

AYUSH Bhavan,

B Block, GPO Complex

New Delhi-110023

Dated 23rd September. 2016

MEETING NOTICE

Subject: Celebration of National Ayurveda Day Reg.

The Ministry of AYUSH Govt. of India has decided to celebrate National Ayurveda Day every year on Dhanvantri Jyanti (Dhan Teras). This year it will be celebrated on 28th October, 2016. The theme for this year is "Ayurveda for prevention and control of Diabetes mellitus". The main function will be organize at Delhi in the form of one day seminar on the subject. All the state governments, all Ayurveda educational institutes, Ayurveda hospitals, Ayurveda Pharma industry, Ayurveda Doctors associations and other stakeholders will be requested to celebrate the National Ayurveda Day falling on 28th October, this year.

A meeting under Chairmanship of Secretary has been called on 29th September 2016 at 3.00 p.m. at the Gr. Fl conference hall of Ministry of AYUSH to discuss about the various activities and responsibilities of various stakeholders in organizing the event.

You are requested to make it convenient to attend the meeting.

Dr. Manoj Nesari

Adviser (Ay.)

Ministry of AYUSH

Govt. Of India

AYSUH Bhavan, GPO Complex, INA

New Delhi 110 028

(O) +91 11 24651972

To

Mr. Pradeep Multani

General Secretary Association of Manufacturers of Ayurvedic Medicine(AMAM)

Sub: "Ayurveda Expo 2016" at Kandy City Centre, the World Heritage City, Kandy, Sri Lanka during 07 – 09 October, 2016.

We are happy to inform you that with the support of Govt. of India, ASSOCHAM is mounting a delegation of Ayurveda companies to participate at Ayurveda Expo 2016 at Kandy City Centre, the World Heritage City, Kandy, Sri Lanka during 07 – 09 October, 2016. This prestigious event is jointly being organized by the Government of Sri Lanka, Provincial Department of Ayurveda and the Central Provincial Council in Sri Lanka.

The theme of this event is "Traditional System of Medicine for Current Health Challenges". The event represents perfect platform for Buyer-Seller Meet between overseas countries and Indian Exhibitors. This is a focused event in which more than 20 overseas countries are expected to participate with more than one lakh footfall of visitors. The event is entitled the both B2B and retail.

The proposed biennial event has become very popular of Ayurvedic products, Medicinal Plants & Spices, organic food & beverages, wellness products, personal health care & skin care items, health tonic & supplements, essential oil, equipments and natural healing etc-offering huge business opportunities as well as excellent networking for Indian participating companies for accelerating the promotion of Indian ayurvedic products.

The cost of 9 sqm (3x3) furnished stall ready to occupy is Rs.30,000/- (Rupees Thirty thousand only) inclusive of all taxes.

The stalls are allotted on first come, first served basis. As we have limited stalls which are heavily subsidized by the Government, please confirm your booking at the earliest. Payments are accepted by Bank Transfer/Cash/Demand Draft in favour of ASSOCHAM, New Delhi. Registration Form is enclosed herewith.

For stall booking, please contact Mr Abhishek Sivan, Mob: 9871894065, E-mail : abhishek.sivan@assocham.com

Should you need any further clarification/additional information, please don't hesitate to contact the undersigned. Assuring you my best co-operation always.

Thanking you & Regards,

Yours sincerely,

(S.S. Chawla)

Senior Director & CEO-Herbal Division

Mob: 9810050681

THE ASSOCIATED CHAMBERS OF COMMERCE AND INDUSTRY OF INDIA

DSRAWAT

Sub. : "14th Middle East Natural & Organic Products Expo (MENOPE) 2016" to be held at Dubai International Convention & Exhibition Centre, Dubai, UAE during 29th to 1st December, 2016

Greetings from ASSOCHAM!!

I am happy to inform you that ASSOCHAM is mounting a delegation for participation in **14th Middle East Natural & Organic Products Expo - MENOPE. This is a 828 mega event annually being held in Dubai (UAE) over the past 13 years.** The event is supported by the Ministry of Commerce & Industry, Department of Commerce.

MENOPE 2016 is the only Niche Exhibition for **Organic, Ayurvedic, Herbal, Food & Beverages, Natural and Eco-Friendly products** in the entire Middle East & North Africa. This event is most sought -after which is business oriented, covering the following sectors:

- Herbal, Ayurvedic & Herbs products
- Natural Living & Therapy
- Natural Cosmetics & Skin care products
- Natural Health care & Nutrition products
- Natura/Beauty & Wei/ness
- Food & Cereal products
- Medicinal Plants
- Wei/ness products
- Healthcare supplements
- Agro including Organic and Natural products
- Spices, Tea & Coffee

There is a huge demand of the **organic and natural products in UAE**. Rising interest in natural wellness and ayurvedic products has enormously increased the overall demand in the organic sector in the region. According to the latest study undertaken, the organic farming in the GCC region is expected to be over US$15 billion by the year 2018 which reflects the changing habits of consumers looking for healthy, chemical and toxin free food products.

In the previous year, more than 130 exhibitors from 28 countries participated like, Germany, Philippines, Bulgaria, Ghana, France, Kuwait, Saudi Arabia, Japan, UK, Turkey, USA, Switzerland, Spain, Canada, Singapore, Malaysia, Russian, CIS, Iran including UAE etc. The products displayed were Organic products, Herbs & Spices, Natural Cosmetics, Cereal products, Supplements, Natural Remedies, Traditional remedies, etc. The key buyers were from leading wholesalers, distributors, importers and exporters, supermarkets, hotel & restaurants, catering contractors, online retailers.

The three days exhibition will also have concurrently **conference on ayurvedic, natural organic, agriculture & sustainable products.** Learned speakers, professionals and experts will address the conference. The organizer will also offer the facility for match-making, buyer-seller meet.

MENOPE 2016 in Dubai provides huge business opportunities for manufacturers, distributors, traders and retailers to come under one roof to generate substantial leads and gain more contacts to increase exports and build new and strong business relationships.

Cost of Stalls:-

The built-up furnished stall ready to occupy of 9 Sqmtr. (3X3) heavily subsidized is Rs. 1,00,000/- (inclusive all taxes). **We request you for the participation of your esteemed association to set-up a suitable stall and for circulation of the above information amongst your esteemed members for their possible participation.**

Interested parties may please send the amount through **NEFT OR Demand Draft drawn in favour of ASSOCHAM, Delhi. Registration Form is enclosed.** Corner stalls will be allotted on first come first served basis.

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D. S. Rawat

Efficacy and Safety of Pudin Hara Pearls in Indigestion

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ABSTRACT

Quest for safer alternative has lead to herbal product research that can effectively relieve the symptoms of indigestion without any untoward effect. Pudin Hara Pearls comprise extracts of Mentha sp. which are used traditionally to provide relief in symptoms of indigestion. Objective of the current study was to evaluate the efficacy and safety of Pudin Hara Pearls in management of indigestion. 43 patients with functional dyspepsia were administered Pudin Hara Pearls (1cap/tid) after meals for 5 days or resolution of symptoms, whichever was earlier. Efficacy was assessed from baseline basis improvement in symptoms of indigestion such as acid regurgitation, heart burn, stomach pain, upper abdominal bloating and nausea; and the Investigator's and the patient's global evaluation of therapeutic response. Safety was assessed on basis of development of adverse events and changes in hematological and biochemical profiles. Pudin Hara Pearls produced significant improvement in symptoms of indigestion such as acid regurgitation, upper abdominal bloating and nausea. No adverse events were reported. It could be concluded Pudin Hara Pearls are effective in the management of symptoms functional dyspepsia and can be used safely.

KEYWORDS: Pudin Hara Pearls, Dyspepsia, Indigestion, Herbal

INTRODUCTION

The term indigestion or dyspepsia is derived from Greek words 'dys' meaning (bad) and 'pepsis' meaning (digestion), it refers to symptoms originating in the upper gastrointestinal tract like epigastric pain, burning, fullness of abdomen, discomfort, early satiety, nausea, vomiting and belching1. Gastritis is of the leading cause of dyspepsia in many countries. An organic cause like gastro-duodenal ulcer, gastro-esophageal reflux disease or gastric cancer may be found in about 40% of dyspeptics. In others, dyspepsia is considered to be idiopathic and termed as Non-ulcer Dyspepsia or Functional Dyspepsia3. Patients with dyspepsia have reduced health-related quality of life because their symptoms, particularly abdominal pain and indigestion, cause emotional distress, problems with food and drink, and impaired vitality4,5. According to the concepts of Ayurveda, indigestion occurs when Agni or the digestive fire is imbalanced. Ayurveda recognizes this condition results due to dysfunction of Jatharagni, or the Agni situated in upper part of digestive system and identifies etiological factors like indulgence of incompatible foods, irregular food habits and seasonal variations for it6,7.

Treatment of functional dyspepsia remains problematic. Various therapies like H2-receptor antagonists, gastro-prokinetics like cisapride and itopride have been used but without much success. Proton pump inhibitors have shown modest efficacy. In acid suppression group, Al, Mg and Ca are preferred. Helicobacter pylori eradication has shown but some minor benefits8.

As treatment of functional dyspepsia with conventional medication remains unsatisfactory, herbal remedies have been tried and the results have been encouraging9,10. Pudin Hara Pearls (Mfd: Dabur India Limited) comprising extract of Pudinah (Mentha sp). is an proprietary Ayurvedic formulation intended to be used in indigestion. There are references to use Pudinah as a medicinal herb for gastrointestinal upsets since ancient times11. The current study evaluated the efficacy and safety of Pudin Hara Pearls (PHP) in patients with functional dyspepsia in terms of improvement in symptoms.

MATERIAL & METHODS

Study Product : Each 180 mg soft gel of Pudin Hara Pearls comprises of Mentha oil (Mentha piperata, Aerial part, Oil.) - 0.174 ml and Spearmint Oil (Mentha spicata, Aerial part, Ol.) - 0.034 ml, along with excepients, preservatives and colors.

Study Design : The trial was a 5 days open, prospective and comparative study conducted at Dhanvantri Ayurvedic Hospital, Chandigarh, India between March – July, 2008 after approval by the Institutional ethics committee of Dhanwantry Hospital. Subjects who entered the study had voluntarily given a written informed consent.

Patient Enrollment

Patients attending the Dept. of Kayachikitsa , Dhanwantary Hospital, Chandigarh, were screened for eligibility as per the inclusion/exclusion criteria. Male and Female subjects between 12 - 60 years of age suffering from functional dyspepsia i.e. indigestion and its related signs and symptoms such as fullness, bloating, nausea, gassy discomfort, loss of appetite, spasm and pain in the chest or abdomen for at least

on two occasions in the preceding week and were having normal hepatic and renal functions (LFT & RFT) were included.

Subjects with persistent dyspepsia, vomiting, severe epigastric pain, unintentional weight loss, iron deficiency anemia, gastro-intestinal bleeding, dysphasia, odynophagia, previous gastric surgery, epigastric mass, suspicious barium meal, peptic ulcer and NSAID use, organic deformity or malignancy of the GI tract, significant systemic and psychological condition (s) which may hamper the study proceedings, conditions requiring immediate surgical intervention, known hypersensitivity to study product or its ingredient (s), concomitant medications known to adversely interact with study products or their ingredients, alcohol or drug abuse, pregnancy, lactation and females planning to conceive in near future were excluded from the study.

Study Protocol : Detailed subject history, including the intensity and frequency of symptoms, previous treatment and physical examination were recorded at baseline. Thereafter, subjects were assigned to receive Pudin Hara Pearls 1 capsule, orally three times a day after meals for 5 days or resolution of symptoms, whichever was earlier according to computer generated randomization.

End Points

Therapeutic: 5 days of intervention with study product or resolution of symptoms which ever was earlier

Clinical: Reduction in the symptom(s), if any, associated with indigestion and its related problems

PARAMETERS OF ASSESSMENT

Improvement in the following parameters was assessed from baseline to study completion:-

I. Improvement in Subjective Symptoms of dyspepsia12:

1.	Acid regurgitation
2.	Heartburn
3.	Feeling of acidity
4.	Loss of appetite
5.	Stomach pain
6.	Upper abdominal bloating
7.	Upper abdominal dull ache
8.	Stomach pain before meals
9.	Stomach pain when anxious
10.	Vomiting
11.	Nausea
12.	Belching,
13.	Fullness of stomach
14.	Flatulence
15.	Intensity of Pain

Symptoms no. 1-12 were assessed on a five point scale where, 0=absent, 1=mild, 2=moderate, 3=severe, 4=very severe Symptoms no. 13-14 were assessed over a 4 point scale: 0=Null, 1=present, does not cause trouble in work at all; 2=present, sometimes cause trouble in work, 3=Present and due the symptom unable to do work Symptom no.15 was assessed on a 0-10 point scale on VAS, where 0 = absent/ never, 10 = extremely severe constant.

II. For global evaluations, Patients' & Investigators were asked to encircle the degree of control on a scale of 0-100%, where 0 = no relief, 100 = best relief one could get III. Safety was assessed on basis of clinically significant changes in hematological & biochemical parameters (CBC, ESR, LFT, RFT and RBS)

Follow up : Evaluation of therapeutic response was carried out daily for 5 days on basis of improvement in subjective symptoms, the ADR/AE profile and the global efficacy assessments. Hematological and biochemical profiles (CBC, ESR, LFT, RFT and RBS) were assessed at baseline and day 5. For global assessment, patients were given a daily diary with instructions to fill the diary every day. It was collected from patients on day 5.

Statistical Analysis

Statistical Analysis was carried out on SAS and included both descriptive and inferential tests Intensity of pain was analyzed using repeated measures ANOVA. Pair-wise comparisons between the groups were performed only in case of statistical significance ($p<0.05$).

RESULTS & DISCUSSION

A total 43 subjects belonging to both the sexes, between the age group of 12 - 50 years completed the study. Out of these 43 subjects, 12 (27.90%) were males and 31 (72.10%) were females. The mean age of subjects was 32.97 ± 1.92 years.

Effect on subjective symptoms: PHP was effective in reducing subjective symptoms of dyspepsia. Overall, a significant improvement in symptoms was observed visit 2 onwards and subjects reported 61.96 % improvement in symptoms from baseline at study completion (Table 1).

PHP were effective from day 1 in relieving acid regurgitation and heart burn. A significant reduction in these conditions was observed from day 2 onwards. At the end of the study almost 95% subjects got improvement in heartburn. Significant relief in feeling of acidity was observed day 4 onwards. There was significant improvement in appetite in subjects

Table 1: Effect of Treatment on Subjective Symptoms of Indigestion (with % Improvement)

Treatment	Baseline	Day 1	Day 2	Day 3	Day 4	Day 5
Pudin Hara Pearl	11.41±6.45 (21.12)	11.41±6.69 (0)	9.00±5.98* (35.06)	07.41±6.06* (50.13)	05.69±5.91* (61.95)	04.34±5.08*

*= significant, $p < 0.05$

Table 2: Individual score symptom influenced by the treatment - Pudin Hara Pearls (1 cap/tid for 5 d)

Symptom	Baseline	Day 1	Day 2	Day 3	Day 4	Day 5
Acid Regurgitation	1.27±1.18	1.20±1.16 (5.51)	0.81±0.98* (36.22)	0.62±0.78* (51.18)	0.46±0.70* (63.78)	0.27±0.54* (78.74)
Heartburn	1.23±0.99	1.13±1.01 (8.13)	0.93±1.07* (24.39)	0.83±0.97* (32.52)	0.67±0.94* (45.53)	0.44±0.66* (64.23)
Feeling of Acidity	0.97±1.01	1.06±0.98 (9.28)	0.93±1.00 (4.12)	0.76±0.97 (21.65)	0.55±0.93* (43.30)	0.44±0.76* (54.64)
Loss of Appetite	1.34±1.28	1.20±1.16 (10.45)	0.97±1.12* (27.61)	0.93±1.16* (30.60)	0.83±1.11* (38.06)	1.72±1.07* (46.27)
Stomach Pain	1.16±1.17	1.23±1.23 (6.03)	1.00±1.13 (13.79)	0.83±0.97* (28.45)	0.53±0.73* (54.31)	0.39±0.58* (66.38)
Upper Abdominal Bloating	1.20±1.03	1.20±0.91 (0.00)	0.74±0.75* (38.33)	0.67±0.94* (44.17)	0.44±0.66* (63.33)	0.30±0.59* (75.00)
Upper Abdominal Dull Ache	0.95±0.97	1.02±0.93 (3.59)	0.90±0.86 (2.56)	0.65±0.65* (15.38)	0.53±0.66* (21.54)	0.37±0.65* (29.74)
Stomach Pain when Anxious	1.39±0.69	1.58±0.85 (13.67)	1.39±0.76 (0.00)	1.34±0.61 (3.60)	1.32±0.71 (5.04)	1.23±0.61* (11.51)
Stomach Pain before Meals	0.39±0.69	0.58±0.85 (48.72)	0.39±0.76 (0.00)	0.34±0.61 (12.82)	0.32±0.71 (17.95)	0.23±0.61 (41.0)
Vomiting	0.37±1.64	0.39±0.79 (5.41)	0.34±0.71 (8.11)	0.27±0.62 (27.03)	0.23±0.52 (37.84)	0.18±0.50 (51.35)
Nausea	1.06±0.96	0.97±1.01 (8.49)	0.67±0.94* (36.79)	0.48±0.73* (54.72)	0.32±0.68* (69.81)	0.32±0.71* (69.81)
Belching	1.04±1.02	0.95±0.95 (8.65)	0.93±0.91 (10.58)	0.69±0.86* (33.65)	0.53±0.76 * (49.04)	0.48±0.66 * (53.85)
Fullness of Stomach	2.69±1.12	2.60±1.19 (3.35)	2.34±1.17* (13.01)	2.04±1.11* (24.16)	1.79±1.10* (33.46)	1.67±0.91* (37.92)
Flatulence	2.69±1.18	2.55±1.25 (5.20)	2.34±1.17* (13.01)	2.09±1.19* (22.30)	1.81±0.93* (32.71)	1.69±0.86* (37.17)
Intensity of pain	4.00±2.39	3.68±2.24 (8.00)	3.31±2.15* (17.25)	2.71±2.05* (32.25)	2.26±2.00* (43.50)	1.84±2.12* (54.00)

at study completion. Stomach pain and upper abdominal dull ache showed significant reduction from day 3 onwards. Subjects in both the groups showed significant reduction day 2 onwards in intensity of pain. Response, though little, was also observed in stomach pain before meals and stomach pain when anxious.

A significant improvement in nausea was observed day 2 onwards. In case of belching, both the study products were equally effective. PHP was also effective in relieving fullness of stomach, flatulence and upper abdominal bloating (Table 2).

Subject's & Physician's Global Evaluation: Global evaluations by patients' and Investigator showed improvement ($p<0.05$) in the treated group results from day 2 onwards to study completion.

Individually, all the subjective symptoms improved in the treatment groups in comparison to the baseline. None of the patients discontinued treatment because of adverse events. All safety parameters were within the normal limits at the end of the trial.

Treatment of functional dyspepsia has been a preferential niche for natural remedies. Due to the paucity of effective conventional medication for the treatment of functional disorders of the alimentary tract, natural remedies and herbal preparations have been tested for these conditions during the past few years8,9. Herbal products seem to be effective and safe in non-ulcer dyspepsia due to their carminative, stomachic and antispasmodic properties10. For indigestion spices as food additives have been used widely since ancient time. Apart from enhancing the taste and flavor of food spices have been widely believed to exert digestive stimulant action. A few medicinal properties of spices such as tonic, carminative, stomachic and antispasmodic have long been recognized. These attributes, largely empirical, nevertheless efficacious, have earned them pharmacological application in the indigenous system of medicine as digestive stimulant and to relieve digestive disorders. Spices such as Pudinah (mint), ajowain, cumin, ginger, mint, hing, garlic, fennel, coriander and pepper are the usual ingredients of digestive stimulant as both commercial and home remedies.

Pudinah, an ingredient of Pudin Hara Pearls possesses anti-spasmodic, anti-emetic, digestive10 and anti- oxidant13, 14 properties which may have contributed to the overall effect of drug in relieving symptoms of dyspepsia.

CONCLUSION

Pudin Hara Pearls were significantly effective in relieving symptoms related to indigestion such as heart burn, acid regurgitation, nausea and upper abdominal bloating. No adverse events were reported during the course of study in any of the study subjects. It could be concluded that Pudin Hara Pearls are effective in the management of indigestion and can be used safely.

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