



DRUGS & COSMETICS

-COPY OF-
NOTIFICATION
Dated 12th August, 2016

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

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- (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:-

(Ayurvedic medicines)

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 Ghan Vati)	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

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(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	2 years
	(II) Containing only Thathu Porutkal/Parpam/Centuram/Cunnam Kattu/Kalanku	10 years
(iv)	Parpam/Centuram	
	(I) Containing only Mooligai ingredients (eg. KungiliyaParpam)	2 years
	(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)	5 years
	(II) Rasa based Patankam (eg. Rasa Centuram)	10 years
(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
	Based on Process-	
	(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)	2 years
	(II) Satthu derived from Thathu Porutkal (eg. Aya Satthu, Eya Satthu, Thurusu Satthu)	10 years
	(III) Satthu derived from Jeeva Porutkal (eg. Sembu Satthu derived from Poonagam, Mayiliragu)	5 years

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(1)	(2)	(3)
(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)	1 year
(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
(xxvii)	Marham/Zimad/Qairrooti	2 years
(xxviii)	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

Sd / -
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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.

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