

# **Drugs and Cosmetics (Amendment) Rules, 2005**

## **MINISTRY OF HEALTH AND FAMILY WELFARE**

**[Department of Ayurveda, Yoga and Naturopathy, Unani, Siddha & Homoeopathy (Ayush)]**

### **NOTIFICATION**

New Delhi, the 24<sup>th</sup> November, 2005

\* **G.S.R. 691(E).**— The following draft of certain rules further to amend the Drugs and Cosmetics Rules, 1945 which the Central Government proposes to make, in exercise of the powers conferred by clause (a) of sub-section (2) of section 33-N of the Drugs and Cosmetics Act 1940 (23 of 1940), is hereby published as required by the said Section for the information of all persons likely to be affected thereby and a notice is hereby given that the said draft rules will be taken into consideration after the expiry of a period of thirty days from the date on which copies of the Official Gazette in which this notification is published, are made available to the public;

Any objection and suggestion, which may be received from any person with respect to the said draft rules within the period specified above will be taken into consideration by the Central Government.

Objections or suggestions, if any, may be addressed to the Secretary, Department of Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homoeopathy (AYUSH), Ministry of Health and Family Welfare, Indian Red Cross Society Building, New Delhi-110 001.

### **DRAFT RULES**

(1) These rules may be called the **Drugs and Cosmetics (Amendment) Rules, 2005**.

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

In the Drug and Cosmetics Rules, 1945;

after rule 161A, the following rule shall be added, namely:-

"161B: - The date of expiry of Ayurveda, Siddha and Unani (ASU) medicines shall be conspicuously displayed on the label of container or package of an Ayurvedic, Siddhas and Unani drugs, after which they shall not be in circulation. Shelf-life for Ayurveda, Siddha & Unani (ASU) medicines shall be as follows:

**Shelf life or expiry date for Ayurvedic medicines.**

<b>Sl. No.</b>	<b>Name of the Group of Ayurvedic Medicine</b>	<b>Shelf Life &amp; / Expiry date</b>
1.	Churna / Kwatha Churna	1 year
2.	Gutika (Varti-Gutti / Pills / Tablets except Gutika with Rasa)	2 years
3.	(i) Gutika Tablet containing Kashtha aushadhi	2 years
	(ii) Gutika / Tablet containing Kashth oushadi and Rasa, Uprasa, Metallic Bhasmas, and Guggulu.	5 years
4.	Rasausadhies	No expiry date *
5.	Asava Arista	No expiry date *
6.	Avaleha	2 years
7.	Guggulu	5 years
8.	Mandura-Lauha	10 years
9.	Ghrita	1 year and 6 months
10.	Taila	2 years
12.	Arka	1 year
13.	Dravaka / Lavana / Ksara	5 years
14.	Lepa Churna	1 year
15.	Lepa Gutti	3 years
16.	Lepa Malahar (Ointment) / Liniment / Gels	2 years
17.	Varti	2 years (one time use)
18.	Ghana Vati	2 years
19.	Kupipakva Rasayan	No expiry date *
20.	Parpati	No expiry date *
21.	Sveta parpati	2 years
22.	Pisti & Bhasma	No expiry date *
23.	Svarna, Rajata, Lauha, Mandura, Abhraka bhasma, Godanti, Shankha Bhasma etc.	No expiry date *
24.	Naga Bhasma, Vanga Bhasma, Tamra Bhasma **	5 years **
25.	Capsules made of soft gelatin (depending upon the content material) for Kashtha aushadhi	2 years
26.	Capsules of hard gelatin (depending upon the content material) – containing Kashtha aushdhi with Rasa, Bhasma, Parada-Gandhak	3 years
27.	Syrup/liquid oral	3 years

<b>Sl. No.</b>	<b>Name of the Group of Ayurvedic Medicine</b>	<b>Shelf Life &amp; / Expiry date</b>
28.	(Karna / Nasa Bindu) Ear / Nasal drops Eye drops	2 years 1 year
29.	Khand / Granule / Pak	2 years
30.	Dhoopans-Inhalers	2 years
31.	Pravahi Kwatha	One year 6 months

\* Item at Sr. No. 4, 5, 19, 20, 22, 23 have very long shelf life. They became more efficacious with the passage of time. For keeping record 10 year period should be mandatory for such items.

\*\* These Bhasmas start solidifying after five years. Therefore, they need one or two 'Putra' again before using in the dosage form.

## ii) Shelf life or expiry date for Siddha Medicines

<b>Sl. No.</b>	<b>Name of the Group of Medicine</b>	<b>Shelf Life or expiry date from the date of manufacture</b>
1.	Karpam	No expiry date *
2.	Cunnam	5 years
3.	Kalanku	No expiry date *
4.	Kattu	No expiry date *
5.	Parpam	No expiry date *
6.	Centuram	No expiry date *
7.	Karuppu	1 year
8.	Patankam	5 years
9.	Kulampu	Five years
10.	Meluku	Five years
11.	Tinir	2 years
12.	Tiravakam	5 years
13.	Mattirai	2 years
14.	Tailam	2 years
15.	Ilakam	2 years
16.	Iracayanaam	2 years
17.	Ney	One year and six months
18.	Manappaku	2 years
19.	Venney	2 years
20.	Vatakam	2 years

<b>Sl. No.</b>	<b>Name of the Group of Medicine</b>	<b>Shelf Life or expiry date from the date of manufacture</b>
21.	Curanam	1 year
22.	Pura Maruntukal	No expiry date *

\* Items at sr. No. 1, 3, 4, 5, 6, 22 have very long shelf life. They became more efficacious with the passage of time. For keeping record 10 year period should be mandatory for such items.

### **Shelf life or expiry date for Unani System of Medicines**

<b>Sl. No.</b>	<b>Name of the Group of Medicine</b>	<b>Shelf Life / Expiry date</b>
1.	Habb (Pills)	2 years
2.	Qurs (Tablets)	2 years
3.	Majoon / Dawa	2 years
4.	Khamira	2 years
5.	Itrifal	3 years
6.	Tiryaaq	2 years
7.	Laooq	1 year
8.	Laboob	1 year
9.	Halwa	1 year
10.	Mufarreh / Yaqooti	2 years
11.	Burood / Surma / Kohal	3 years
12.	Kushta	5 years
13.	Raughaniyat	2 years
14.	Marham / Zimad / Qairooti	2 years
15.	Ayarij / Sufoof	1 year
16.	Safoof (Namak wala / containing salt)	6 months
17.	Sharbat / Sikanjabeen	2 years
18.	Jawarish	2 years
19.	Capsule	2 years
20.	Arq	One year
21.	Qutoor	One Year
22.	Nabeez	5 years
23.	Murabba	1 year
24.	Tila	2 years

SHIV BASANT, Jt. Secy.

**Note:** The principal rules were published in the Gazette of India, vide, Notification number F.29-10/45-H dated 21.12.1945 and last amendment vide number G.S.R. 664, dated 14.11.2005.

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