



FS - 94454
ISO 9001:2000 Certified
British Standards Institution

DRUGS & COSMETICS

Shakun Sl.No.9

-COPY OF-
NOTIFICATION
Dated 9th July, 2008

Whereas the draft of certain rules further to amend the Drugs and Cosmetics Rules, 1945 was published as required by section 33-N of the Drugs and Cosmetics Act, 1940 (23 of 1940), in the Gazette of India, Extraordinary, dated the 19th October, 2006, vide Number GSR 651(E) inviting objections and suggestions from persons likely to be affected thereby and notice was given that the said draft will be taken into consideration after 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 18th October, 2006;

And whereas, objections and suggestions received from the public on the said draft rules Drugs & Cosmetics Act, 1940 (23 of 1940) have been considered by the Central Government;

Now, therefore, in exercise of the powers conferred by section 33-N of the Drugs & Cosmetics Act, 1940 (23 of 1940) the Central Government, after consultation with the Ayurveda, Siddha and Unani 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 **Drug and Cosmetics (First Amendment) Rules, 2008.**
- (2) They shall come into force from the date of their publication in the Official Gazette.
2. In the Drug and Cosmetics Rules, 1945 (herein referred to as the said rules), after rule 157, the following rule shall be inserted, namely:-

“157A. Maintaining of records of raw material used by licensed manufacturing unit of Ayurveda, Siddha and Unani drugs in the preceding financial year. Each licensed manufacturing unit of Ayurveda or Siddha or Unani drugs shall keep a record of raw material used by each licensed manufacturing unit of Ayurveda, Siddha or Unani drugs the case may be in the performa given in Schedule TA in respect of all raw materials utilized by that unit in the manufacture of Ayurveda or Siddha or Unani drugs in the preceding financial year, and shall submit the same by the 30th day of June of the succeeding financial year to the State Drug Licensing Authority of Ayurveda, Siddha and Unani drugs and to the National Medicinal Plants Board or any agency nominated by the National Medicinal Plant Board for this purpose”

3. In the said rules, after Schedule T, following Schedule shall be inserted, namely:-

**“Schedule TA
(See rule 157 A)**

Form for record of utilization of raw material by Ayurveda or Siddha or Unani licensed manufacturing units during the financial year.

Identification Particulars:

Manufacturing License No.....
Issued by

Name:

Address:

State: Pin Code:

Telephone: Fax:

Email:

1. **Quantity of Medicinal Plants/Extracts/Essential Oils/Metals/Animal By-Products/Minerals Used During 1st April, to 31st March, of the proceeding year (For Productions at the identified facility)**

.../2

(a). Herbs Used

Common Name as in AFI/ API*	Plant's Botanical Name	Quantity Used/per annum (in Kgs.)	Sources of Supply					Part Used			
			Traders/ Manufacturers	Forest Collectors	Cultivators	Imported	Total	Whole plants	Root	Leaf	Others

*Ayurvedic Formulary of India/Ayurvedic Pharmacopoeia of India

(b). Extracts Used

Name of Extracts		Quantity Used/ Per annum (in Kgs.)	Sources of Supply			
Common Name as in AFI/API*	Botanical Name		In-House	Export Suppliers	Imported	Total

* Ayurvedic Formulary of India/ Ayurvedic Pharmacopoeia of India

(c) Metals/Minerals Used

Name of Mineral		Quantity Used/ per annum (in Kgs.)	Sources of Supply		
Common Name	Chemical Name		Manufactures Traders (Domestic)	Importers	Total

(d) Animal By-Products Used

Name of By-Product		Quantity Used/per annum (in Kgs.)	Sources of Supply		
Common Name	Biological/ Chemical Name (if any)		Manufactures Traders (Domestic)	Importers	Total

2. Shortage of raw material(s)/inputs during the preceeding year.

Yes

No

If yes, please indicate name(s) of such raw material(s) by level of importance starting from most important to least important, reason for shortage [availability, quality or any other (please specify)]

Name of Raw Material	Approx. Qty of shortage (in Kgs)	Reason
Name of the drug and part used as mentioned in official formulary/ Pharmacopoeial/Schedule I books	Biological/Chemical Name (if any)	

Sd/-
(Shiv Basant)
Jt. Secy.**G.S.R.512(E)****No.K.11020/2/2006-DCC(Ayush)****Issued by:****Ministry of Health and Family Welfare****(Department of Ayurveda, Yoga and Naturopathy,****Unani, Siddha and Homeopathy)****New Delhi****Foot Note:** The Principal rules were published in the Gazette of India vide notification number F.28-10/45-H (I), dated the 21st December, 1945 and subsequently amended vide notification number G.S.R. No. 678(E) dated 31-10-2006.

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