# Gazette Notification issued under the Drugs & Cosmetics Rule 1945

| S. No. | G.S.R. No. | Year & date | Subject |
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| 1. | 755(E) | 23.10.2008 | Considering the growing demand for ASU drugs and to increase palatability longevity & stability of ASU drugs, the matter regarding allowing excipients, preservatives, antioxidants, flavoring agents, chelating agents in ASU drugs was taken up and discussed in various forums. On the recommendation of Ayurvedic, Siddha and Unani Drug Technical Advisory Board (ASUDTAB), the **amendment to Rule 169 for permitting excipients, preservatives, antioxidants, flavoring agents, chelating agents etc in Ayurvedic, Siddha and Unani medicines was carried out.**<br>**The Final Notification has been issued in this regard on 23rd October, 2008.** |
| 2. | 893(E) | 24.12.2008 | Growing popularity and acceptability of ASU drugs globally and adherence to various regulatory provisions has led to the need for categorization of Ayurvedic, Siddha and Unani drugs and other traditional medicines in India and their Pre- Clinical safety guidelines etc. Since there were no existing guidelines on the subject, a technical Committee was constituted with members of ICMR and Research Councils. As per suggestions of the Committee and ASUDTAB recommendations,<br>**Rule 170 has been amended regarding issuance of guidelines for evaluation of Ayurvedic, Siddha & Unani Drugs and other traditional medicines of India.**<br>The purpose of issue of these guidelines is to develop methodologies for record and valuation, improve quality, valuable research for providing appropriate evaluation methods to facilitate the development of regulation and registration.<br>**Draft Notification has been issued on 24th December, 2008.** |

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| 3. | 157(E) | 04.03.2009 | To establish the authenticity of raw drugs, minerals and metals in processing of validation and quality control parameters, it is ensured that these formulations are processed and prepared in accordance with clinical tests and for which safety measures are complied with in accordance with **GMP guidelines for manufacturing of "Rasaushadhies or Rasamarunthukal and Kushtajat (Herbo - mineral - metallic compounds)" used in Ayurveda, Siddha and Unani medicines.**<br>**The Final Notification has been issued on 4th March, 2009.** |
| 4. | 764(E) | 15.10.2009 | The potency of ASU preparations is lost/reduced after a certain period of time. Hence to make full use of these preparations and as per textual reference, ASUDTAB has recommended Shelf life /Expiry date for ASU drugs.<br>**Shelf life / Expiry date under rule 161(B) has been amended in respect of Ayurveda, Siddha & Unani medicines.**<br>**The Final Notification has been issued on 15th October, 2009.** |
| 5. | 765(E) | 16/10/2009 | As per advice of the Subordinate legislation of Parliament, **Corrigendum of notification GSR No. 512(E) dated 9th July, 2008 have been published on manufacturing records of raw materials used by licensed manufacturing units of ASU drugs.** |
| 6. | 16(E) | 07.01.2010 | The books entitled "**Rastantra Sar Va Siddha Prayog Samgraha Part II (Edition 2006), Ayurvedic Pharmacopoeia of India and its part, Siddha Pharmacopoeia of India and its part"** have been **amended in Schedule I of the Drugs and Cosmetics Act, 1940.**<br>**The Final Notification has been issued on 7th January, 2010.** |
| 7. | 17( E) | 07.01.2010 | In response to demand of ASU drugs manufacturers for increasing validity period of GMP license and harmonization in date of issuance of GMP and Schedule 'T' license, and in accordance with ASUDTAB recommendations, **Amendment in Rule 155(B), 156,156(A), 157 & Form 13A and Form 26E-I have** |

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| | | | **been carried out.**<br>The validity of GMP Certificate has been extended to five years from 3 years. GMP certificate in Form 26E-(I) and grant or renewal of license in Form 25-D are proposed for simultaneous issuance.<br>**Draft Notification has been issued on 7th January, 2010** |
| 8. | 322 (E) | 13.04.2010 | Schedule E of Drugs & Cosmetics Rule 1945 contains list of poisonous substances under the Ayurvedic (including Siddha) and Unani Systems of medicine. In the list, only some parts of the plants are found poisonous whereas rest of the plant is not poisonous and some of the names were found incorrect. The matter was examined in detail and finally as per recommendations of ASUDTAB, **Schedule E (I) has been revised and necessary amendments in the list of plants and names etc for Ayurveda, Unani & Siddha poisonous drugs have been carried out.**<br>**Draft Notification has been issued on 13th April, 2010.** |
| 9. | 337 (E) | 15.04.2010 | **The books entitled "Rastantra Sar Va Siddha Prayog Samgraha Part II (Edition 2006), Ayurvedic Pharmacopoeia of India and its part, Siddha Pharmacopoeia of India and its part" have been amended in Schedule I** of the Drugs and Cosmetics Act, 1940.<br>**The Final Notification issued on 15th April, 2010.** |
| 10. | 338(E) | 15.04.2010 | As per advice of the Subordinate legislation of Parliament, **Corrigendum under Rule 157 (E) dated 9th March, 2009 have been issued on** GMP guidelines for manufacturing of "Rasaushadhies or Rasamarunthukal and Kushtajat ( Herbo - mineral - metallic compounds)" used in Ayurveda, Siddha and Unani medicines. |
| 11. | 376( E) | 03.05.2010 | **Rules 155(B), 156, 156(A), 157, Form 13 A and Form 26E-I regarding validity of GMP Certificate for five years and simultaneous issuance of Form 25-D and Form 26E-I have** |

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| | | | **been amended. The Final Notification issued on 3rd May, 2010.** |
| 12. | 377(E) | 03.05.2010 | At present various kind of ASU products licensed in the country are being sold claiming to be safe. These ASU plant based medicines/products which are being used as Neuraceutical, food supplement (Balya/Poshak) without causing any systemic and topical adverse effects. In the classical ASU texts references can be traced. The Drugs & Cosmetics Act does not define these ASU products which fall under category Neutraceutical, food supplement and cosmetics etc. These ASU plants based Medicines/Product are also marketed in different doses from like extracts etc. There is urgent need to regulate Standards and Quality etc. There is no regulation existing regarding said ASU products under above said category. The matter was debated in different various committees. As per recommendation of Ayurveda, Siddha and Unani Drug Technical Board, **the Amendment to Rule 158(B) regarding guidelines for issue of license in respect of Ayurveda, Siddha or Unani drugs have been carried out.**<br>**Draft Notification has been issued on 3rd May, 2010.** |
| 13 | | 19.08.2010 | Schedule E I of Rule 161 of Drugs & Cosmetics Rule, 1945 describe poisonous substances used in Ayurvdic (including Siddha) and Unani System of Medicine. Comments were invited on draft notification issued on 13th April, 2010. The comments received on the draft were examined in the Department of AYUSH and in cooperated accordingly.<br>**The final Notification is under issue.** |