

Schedule TB Proposed for Nasal Sprays of ASU & H Drugs

Schedule TB is set to be inserted under Drugs Rules, 1945, for the purpose of Nasal Sprays of Ayurveda, Siddha, Unani or Homoeopathy medicines.

The Ministry of Health and Family Welfare has issued draft rules under GSR 891 (E) dated 12.12.2023 and it is proposed to insert sub-rule VI after sub-rule V of Rule 158B of Drugs Rules, 1945. The condition for issue of licence to manufacture Ayurveda, Siddha, Unani and Homoeopathy drugs of nasal spray dosage form shall comply with the guidelines as per proposed to be newly inserted under Schedule TB.

It is proposed to insert new Schedule as Schedule TB after existing Schedule TA. Said guidelines shall also be applicable for issue of Licence to manufacture nasal spray of Homoeopathy medicine as said condition is also proposed to be inserted under Schedule M-I applicable for Homoeopathy medicines.

While the medication standards for *nasya* will remain as indicated under Ayurvedic Pharmacopoeia of India, the standards for the new dosage form “*Nasal Spray*” and the guidelines for the usage of the new device are defined in Schedule TB. The differentiation between the *Nasya* and *Nasal Spray* is *Nasya* is a traditional method of using nose as route of administration while *Nasal Spray* is used with support of a specialized device.

Under the Schedule TB following specifications are proposed to be introduced which shall be applicable for the nasal sprays of ASU & H drugs.

1. Guidelines for active ingredient and excipient selection.
2. Specifications for the device to be used for nasal sprays as per parameters of packaging material manufacturer and other detailed specifications for device.
3. Mandatory and optional specifications for the finished products.
4. Mandatory one time study of product development to be submitted while applying for licence.
5. Guidelines to be followed for Safety, Efficacy and Stability studies.