

SCHEDULE-II
FORM - IV
PROFORMA FOR SUBMISSION OF THE DETAILS IN
RESPECT OF DISCONTINUATION OF THE
PRODUCTION AND/ OR IMPORT OF SCHEDULED
FORMULATION
(See paragraphs 21(2))

1. Name of the formulation:
2. Name and address of the manufacturer/importer :
3. Name of the Marketing Company, if any:
4. Composition as per label claimed and approved by Drug Control Authorities:
5. Drugs Control Authority Permission Number and Date (copy to be enclosed):
6. Ceiling Price and date of notification:
7. Existing maximum retail price (MRP) and its effective date:
8. Therapeutic category as per NLEM:
9. Date of commencement of production / import
10. Proposed date of discontinuation:
11. Reasons for discontinuation of production / import:
12. Year-wise Production/Import during the last 5 years including current year
13. Year-wise sale during the last 5 years including current year
14. Whether any new drug as defined under Proviso of Definition of "New Drug" under DPCO, 2013 has been launched or intended to be launched. If so, the details thereof:

15. Any other information relevant to discontinuation of scheduled formulation:

Place:

Authorized Signatory:

Date:

Name:

Designation: