Ferrous Sulphate and Folic Acid Tablets
(For NCB/ICB)

A. Specific requirements

Item:

Iron and Folic acid tablets (By brand name of **WIFS JUNIOR**) shall conform to the requirements given in IP 2014 given under Iron & Folic Acid (IFA) Tablets and the general requirements of Tablets given in IP 2014. In addition it should comply with the requirements given in the Annexure.
The drug shall be currently registered in India and shall meet all requirements of the licensing authorities of India.

Description:

Iron and Folic Acid Tablets (WIFS - JUNIOR) contain Ferrous Sulphate and Folic Acid. They are **'Sugar Coated'** and **'Pink'** coloured tablets. Only Edible colours should be used.

Each sugar coated WIFS Junior IFA tablet shall contain:

	Small
Dried Ferrous Sulphate IP equivalent to ferrous iron	45 mg
Folic Acid IP	0.4 mg

The quality of each constituent should conform to the requirements of IP.

Protocol and Testing:

Complete Test Protocol and samples are taken and sent to the laboratory (identified by the purchaser) by the Inspecting Officer duly sealed and signed by him or his authorized representative.

Protocols of tests should include the requirements given in IP 2014 under Iron & Folic Acid Tablets and the general requirements for Tablets including those specified in the Annexure.

The drug should be dispatched to the consignee only on clearance from the Testing Laboratory. The drug shall be released on the basis of Protocol scrutiny by the authorized representative of the Purchaser and testing of the drugs by authorized laboratory.

Each batch should be accompanied with a certificate from the manufacturer that the drugs meet the specified requirements.

Random batches will be taken from the supplies of the State (post-delivery) and will be periodically tested (quarterly/six monthly) by DoHFW / MoHFW in identified labs separately for monitoring quality assurance.

Storage:

Iron and Folic Acid Tablets (IFA) should be protected from light/moisture/rodents/damage to packaging.

Shelf-life:

24 months, at least 5/6th of the shelf life of IFA must remain at the time of receiving the shipment. The supplier will provide manufacturer's stability test data substantiating the claimed shelf life in the offered package.

Labelling:

The label on each strip of WIFS - JUNIOR shall conform to the requirements of Rule 96 of Drug & Cosmetic Rules and shall appear in English.

All labelling of WIFS - JUNIOR should be in weatherproof ink and shall withstand immersion in water and remain intact. In addition to the requirements given in Rule 96 of Drug & Cosmetic Rules, all labels shall state the amount of ferrous sulphate and equivalent amount of Ferrous iron & Folic Acid, the name of the manufacturer, manufacturing license number, address of manufacturer, batch number, and expiry date.

Labelling for secondary packaging:

A label of WIFS - JUNIOR must be affixed either on the top and/or front surface of the secondary package. It should indicate the number of strips/tablets, the amount of ferrous sulphate and equivalent amount of Ferrous iron & Folic Acid, the name of WIFS – JUNIOR drug manufacturer, batch number, date of manufacture, date of expiry, and storage conditions.

Labelling for tertiary packaging (insulated packaging):

The external surface of insulated packages should be either white or in the natural colour of corrugated carton. The label should in both English and Hindi/local language of the State.

The labels of WIFS – JUNIOR on tertiary packaging must be attached to at least two sides. The label should include the name of the product "IFA WIFS - JUNIOR", the number of secondary packages (boxes)/strips/tablets, the name of the manufacturer, batch number, date of manufacture, and date of expiry.

Numbering of tertiary packaging:

All boxes should be numbered consecutively. Shipping documents should be included in the box labelled number 1.

Additional Labelling:

All the containers and other outer containers shall be marked with the statement "GOVT. SUPPLY-NOT FOR SALE" in English and Local language.

All labels on containers i.e. strips, cartons etc. should be marked with the statement "GOVT. SUPPLY-NOT FOR SALE" in bold letters in English and local language.

B. Quality assurance

Compliance:

The Supplier shall guarantee that the products as packed for shipment (a) comply with all provisions of the specification and related documents; (b) meet the recognized standards for safety, efficacy and quality; (c) are fit for the purposes made known to the Seller (d) are free from defects in workmanship and in materials and (e) the product has been manufactured as per cGMP included in Schedule M of Drugs & Cosmetic Rules.

Evidence:

The Supplier shall provide objective evidence, acceptable to the Purchaser, of the satisfaction of the requirements of this document for which no specific inspection has been mentioned.

The Supplier shall provide a copy of the Certificate of Analysis for each lot intended for shipment**.**

The Supplier shall provide the validation data of the analytical procedure used for assaying the components.

The test data for raw materials, in-process, finished product and packaging material testing must be on record for each lot shipped and must be made available to Purchaser's representatives when requested.

Inspection:

The Purchaser may inspect and sample, or cause to be sampled, the product at the Supplier's factory and/or warehouse at a mutually agreeable time prior to / after the shipment of the product.

Testing:

The Purchaser may cause independent laboratory testing of the samples picked randomly from pre and post-delivery shipment to be performed as deemed necessary to assure that the goods conform to the prescribed requirements. The said laboratory testing shall be of the Purchaser's choice if suitably equipped and qualified to conduct quality assurance tests on the product.

C. Packing

Primary Package:

15 Tablets should be packed in an Aluminium-Aluminium strip with IFA-WIFS JUNIOR name displayed prominently.

Aluminium Strips: Thickness of Aluminium foil: 40 micron, with LDPE 25 micron coating/heat seal lacquer.

- Toll free number must be indicated on every strip for contacting in case of product complaints.

Secondary Package:

The strips should be packed in boxes for easy handling, transport and distribution with WIFS name displayed prominently. The box may contain 10 strips. It shall be fabricated from Millboard/ grey board/ cardboard with a minimum of bursting strength of 400gsm.

- Toll free number must be indicated on every secondary package for contacting in case of product complaints.

Tertiary Package:

The boxes shall be packed in weather resistant triple walled insulated corrugated 5-ply cartons, each ply having strength of minimum 150gsm with WIFS name displayed prominently. It should be fabricated from virgin quality 'A' grade material. The overall dimension of the carton should be such that the product does not get damaged during transportation and storage.

- Toll free number must be indicated on every tertiary package for contacting in case of product complaints.

D. Qualification of the Manufacturer:

The Bidder shall furnish a certificate from the competent Regulatory Authority that the manufacturer of the pharmaceutical product is licensed to manufacture these products. The

manufacturing facility must conform to cGMP Standards and Schedule M of Drugs & Cosmetic Rules.

E. Recalls:

If products must be recalled because of problems with product quality or adverse reactions to the drug, the Supplier will be obliged to notify the purchaser providing full details about the reason leading to the recall and shall take steps to replace the product in question at its own cost with a fresh batch of acceptable quality, or withdraw and give a full refund if the product has been taken off the market due to safety problems.

In case the quality of the product is found to be sub-standard or unsatisfactory in quality checks, stringent action would be taken against them and the supplier can be black-listed for future supplies of the product.

F. Colour Coding:

The labels on secondary packing, tertiary packing and shipper package shall be identified by background. **(Standard PINK colour).**

G. Bar Coding

Bar code shall be used to track down the product. It shall be printed on the label of Millboard/Grey board Boxes and 5 – Ply shipper containing

1) Product identification(GTIN 14) using application identifier (01)
2) Expiry Date in YYMMDD format & using application identifier (17)
3) Master batch number using application identifier (10)

Complete details on GS1 standards along with technical guidelines can be downloaded from www.gs 1india.org or www.gs1.org

4) Bar-coding to be put on all both Tertiary and Secondary Packing.

H. Markings

All containers and invoices must bear the IFA – WIFS JUNIOR name of the product, expiry dates of and appropriate storage conditions.

Inner boxes:

The inner boxes shall be marked with the following information in a clearly legible manner which is acceptable to the Purchaser:

- Name IFA-WIFS JUNIOR
- Generic name of the product
- Manufacturer's name and registered address
- Manufacturer's License number
- Lot or batch number
- Number of strips contained in box
- Date of manufacture (month and year)
- Expiration date (month and year)
- Instructions for storage and handling
- Place of manufacture
- Barcode

Exterior Shipping Cartons:

The following information shall be stencilled or labelled on the exterior shipping cartons on all four sides in bold letters at least **Ariel font size 14** with waterproof indelible ink in a clearly legible manner which is acceptable to the Purchaser:

- Name IFA -WIFS JUNIOR
- Generic name of the product
- Lot or batch number
- Date of manufacture (month and year)
- Expiration date (month and year)
- Manufacturer's name and registered address
  Consignee's address and emergency phone number including mobile number
- Contract number
- Number of tablets/strips/boxes contained in the carton
- Gross weight of each carton (in kg)
- Carton containing no. of…. secondary packages
- Instructions for storage and handling
- Place of manufacture
- Barcode

I. Documentation

Supplier shall provide to Purchaser a copy of the batch record, including all quality assurance documentation for the product being supplied.

Advance notice of arrival and advance shipping documentation:

Copies of the documentation for the goods to be supplied must be sent at least seven days in advance of arrival of the consignment. In the case of an individual contract for a specific destination that requires a longer period of advance notice, a longer period should apply. The consignee(s) shall be intimated well in advance

by registered letter/e-mail/ telephone, so that the products are collected immediately after arrival.

The documentation must include the following:

- Pre-advice defined by the Purchaser
- Airway bill (AWB) if applicable;
- Supplier's invoice;
- Packing list;
- Lot release certificate (LRC) as per the requirements issued by the Regulatory authority for each lot and
- Any other document, certificate or instruction specified in the individual order.

The documents shall be sent by e-mail and fax by the freight forwarder or the manufacturer to the consignee, the Purchaser, and any other parties specified in the individual contract.

The pre-advice must contain the following information:

- Purchase order reference;
- Consignee requisition reference;
- Number of packages and gross weight (in kilograms).
- Value of shipment (in Indian Rupees);
- AWB and Flight number(s) if applicable;
- Date and time for place of departure, transit (if applicable), and arrival;
- Instructions for collection;
- Any other information specified in the individual contract must also be included for the consignee.
- Invoice

The following information shall be stated on the invoice:

- Consignee's name, address, telephone number (including mobile no.) and e-mail ID.
- Purchase order reference;
- Consignee's requisition reference;

• Instructions to: "Telephone consignee upon arrival *(repeat telephone number);*

J. Dispatch

Consignments should be scheduled to arrive outside weekends and/or public holidays.

Annexure

Additional tests: Ferrous Sulphate and Folic Acid Tablets

The method of analysis should be validated as per ICH guidelines.

Seals Integrity Test:
Check 10 strips. Bundle up the strips and submerge them under water in a vacuum desiccator or equivalent device. Draw a vacuum of about 18k Pa and hold for a minute. Examine for the air leakage indicated by a fine stream of bubbles. Re-establish normal pressure and open strips to examine for water penetration

Microbial Count:
When the test is conducted as per IP
-Total viable aerobic count- Not more than 10^3 bacteria and not more than 10^2 fungi per gram
-Absence of Escherichia coli