

A. Specific requirements**Item:**

Product Code 25 (PC 25) consists of sachets of Sodium Aminosalicylate Granules (10 gm.). The drug contained in the product shall be currently registered in the country of manufacture and shall meet all requirements of the licensing authority of the country of manufacture. The drug contained in the product shall also be currently registered in India and shall meet all the requirements of the licensing authority in India.

Description:

Sodium Aminosalicylate Granules contained in sachets shall conform to the general requirements of Granules (under its subhead Gastro-resistant Granules) given in BP and the requirements under individual monograph given in IP.

Sodium Aminosalicylate Granules contain Sodium Aminosalicylate.

Each Gram of the Granules shall contain -

Sodium Aminosalicylate IP 800 mg

The granules are **enteric coated**.

The quality of Sodium Aminosalicylate should conform to the requirements of the individual monograph given in IP or other Pharmacopoeia of equivalent accuracy in case of international transactions.

Protocols and Testing:For International manufacturers:

Complete test protocols along with the samples of all the batches should be sent to the Head of a Testing laboratory identified and specified by the purchaser.

For local manufacturers:

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 for Granules (under its subhead Gastro-resistant Granules) given in BP as the case may be and those included under individual monograph given in IP, besides the following tests.

Package Integrity Test:

Check 10 sachets. Bundle up the sachets and submerge them under water in a vacuum desiccator or equivalent device. Draw a vacuum of about 18k Pa (15 cm of mercury or -0.8 bar) and hold for a minute. Examine for the air leakage indicated by a fine stream of bubbles. Reestablish 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.

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.

B. Labelling:

General requirements of the labels:

- Shall meet WHO GMP standards.
- All the labels should be peel proof.
- **“RNTCP- Central Government Supply- NOT FOR SALE” and “Schedule H Drug”** to be imprinted on the labels of sachets, Millboard/Greyboard Boxes & 5 Ply Shippers.

Labelling on Sachets:

The label shall indicate the content of Sodium Aminosalicylate IP in mg per gram of granules.

All labelling should be in weatherproof ink and shall withstand immersion in water and remain intact.

The label shall incorporate manufacturing license no., batch no., date of mfg., date of expiry of the individual drug and storage requirements.

The label shall conform to the requirements of Rule 96 of Drugs & Cosmetics Act.

Labelling on Millboard/Greyboard Box:

The label shall indicate the content of Sodium Aminosalicylate IP in mg per gram of granules.

The label shall incorporate manufacturing license no., batch no. date of mfg., date of expiry, of the drug and storage requirements along with the number of the sachets. The label shall include Bar Code and be tear proof, to be pasted on smooth surface to enable it to be read by Bar Code reader.

The label shall conform to the requirements of Rule 96 of Drugs & Cosmetics Act.

MILLBOARD/GREYBOARD BOX

MDR-TB TREATMENT DRUG CONTAINS PRODUCT CODE 25 SODIUM AMINOSALICYLATE GRANULES 800mg per gram (100 Sachets)	
Each sachet Contains 10 Grams of Sodium Aminosalicylate Granules	
Batch No.: Mfg. Date: Exp. Date:	 <div style="border: 1px solid black; padding: 5px; width: fit-content; margin: 10px auto;">SCHEDULE H DRUGS</div> <p style="text-align: center;">“RNTCP – Central Government Supply – Not for Sale” Manufacturer’s Name Manufacturing Lic. No.</p>

Labelling on 5-Ply Shipper:

The labels on shipper package must be attached to at least two sides. The label should include the name of the product, the number of Millboard/Greyboard Boxes, the number of sachets, the name of the manufacturer, batch number, Mfg. date & Expiry date of the drug. The label shall also include storage handling instructions. The label shall include Bar Code and be tear proof, to be pasted on smooth surface to enable it to be read by Bar Code reader.

The label shall conform to the requirements of Rule 96 of Drugs & Cosmetics Act.

5 – PLY SHIPPER

MDR-TB TREATMENT DRUG CONTAINS PRODUCT CODE 25 (10 gm. sachets)

SODIUM AMINOSALICYLATE GRANULES 800 mg per gram

20 Millboard/Greyboard Boxes



Batch No. :

Mfg. Date:

Exp. Date:

SCHEDULE H DRUGS

**“RNTCP - Central Government Supply
– Not for Sale”**

Manufacturer’s Name

Manufacturing Lic. No.

Numbering of shipper packaging:

All 5 Ply Shippers should be numbered consecutively. Shipping documents should be included in the shipper numbered first (consignee wise)

C. 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) meet the requirements of manufacturing legislation and regulation of pharmaceuticals in the country of origin; (e) are free from defects in workmanship and in materials and (f) have been manufactured as per WHO GMP requirements.

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 manufacturing record and procedures to the Purchaser for each lot intended for shipment.

The Supplier shall provide a copy of Validation records with regards to process validation demonstrating batch to batch consistency.

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

The Supplier shall provide to the Purchaser a copy of the approval of each source material, constituent material and component for each lot intended for shipment.

The Supplier shall provide evidence of basis for expiration dating and other stability data concerning the commercial final package upon request.

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.

Details of samples lifted for testing (such as quantity of sachets, Millboard/Greyboard boxes, batch no. etc.) should be pasted on packing of 5 Ply Shipper and records to this effect be also made available to the purchaser.

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 the shipment of the product.

The successful Bidder will also be required to provide the Purchaser with access to its manufacturing facilities to inspect its facilities, quality control procedures for raw materials, test methods, in-process tests, and finished dosage forms.

Testing:

The Purchaser may cause independent laboratory testing 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.

D. Storage:

Store protected from light and moisture at room temperature.

E. Shelf Life:

Shelf life of Sodium Aminosaliclylate would be as follows:-

Shelf life would be 36 months. At least 5/6th of the total stipulated shelf life must remain at the time of arrival at the consignee's warehouse. The supplier will provide manufacturer's stability test data substantiating the claimed shelf life in the proposed package. Not only the pharmaceuticals, but also the packaging components should also conform to specifications suitable for use in a climate prevailing in India. The product supplied should have been subjected to long term stability conditions at 30^o C and 65% RH (relative humidity)

F. 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 WHO-GMP standards.

G. 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.

H. Colour Coding:

The labels on Sachets, Millboard/Greyboard Boxes and 5 Ply Shipper package shall be identified by white background.

I. Bar Coding

Bar code shall be used for better inventory management. It shall be printed on the label of Millboard/Grey board Box 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) Batch number using application identifier (10)

The labels on the Millboard/Greyboard Boxes should contain information about point nos. 1, 2 & 3 above whereas the labels on the 5 Ply-Shippers should contain information about point nos. 1, 2 & 3 above and also be numbered consecutively using application identifier (21).

Complete details on GSI standards along with technical guidelines can be downloaded from www.gsiindia.org or www.gsi.org

J. Packing

The granules are packed in a sachet. Each sachet should contain 10 gram of Sodium Aminosaliclylate granules. The sachet is fabricated from a combination of polyethylene, aluminium and polyester. The polyethylene on the inner side is essential for heat sealing the compound together, the aluminium in the Middle reduce the permeability to gas and steam and the polyester on the outside protects the aluminium, and the ink on the aluminium. The quality and composition of the thickness should be within the following limits

		Micron	mm	g/m^2
Inside	Polyethylene	50	0.040 – 0.050	36.9 – 46.1
Middle	Aluminium	09	0.009 – 0.015	24.3 – 40.5
Outside	Polyester	12	0.012 – 0.015	12.9 – 20.9

100 such sachets would be further packed in white coloured Millboard/Grey board boxes and 20 such Boxes are ultimately packed in 5-Ply Shipper.

The sachets should be tropicalized with regard to moisture barrier properties for drug stability under field conditions. Quality Assurance should be according to ISO 9001 standards for all the packaging material.

Millboard/ Grey board Box:

Each box shall contain 100 sachets. Ten (10) sachets shall initially be packed in a Poly Ethylene bag provided with a zip lock. Ten such bags shall be packed in the box. The boxes shall be labelled and fabricated from 3 mm corrugated cardboard surrounded on inside and outside by tightly affixed millboard of at least 400 gsm. The style of top and bottom shall be tuck-in-flap.

Poly Ethylene Zip-lock bag: Zip-lock bags are clear re-closable bags and should be made from virgin Poly Ethylene provided with quality zip-lock. The material should meet GMP and IS10146-2003 standards.

5-Ply Shipper Package:

Each 5 Ply Shipper shall contain 20 millboard/greyboard boxes. The boxes shall be packed in weather resistant, triple walled, insulated, corrugated, RSC (Universal) type 5-ply Shippers, each ply having strength of minimum 150gsm. It should be fabricated from virgin quality 'A' grade kraft paper. The overall dimension of the carton should be such that the product does not get damaged during transportation and storage.

Each shipping carton when packed should weigh not more than 50 kg.

K. Markings

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

Millboard/Greyboard Box:

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

- Manufacturer's name and registered address
- Manufacturer's License number
- Batch number of the drug
- Number of sachets contained in the box
- Date of manufacture (month and year) of the drug
- Expiration date (month and year) of the drug
- Instructions for storage and handling
- Logo of DOTS
- Place of manufacture (Made in_____)

5 – Ply Shipper:

The following information shall be stenciled or labeled on 5 – Ply Shippers on all four sides in bold letters of at least **Arial font size 18** with waterproof indelible ink in a clearly legible manner which is acceptable to the Purchaser:

- Generic name of the product
- Batch number of the drug
- Date of manufacture of the drug (month and year)
- Expiration date of the drug (month and year)
- Manufacturer's name and registered address
- Manufacturer's national registration number
- Destination country license or registration number
- Consignee's address and emergency phone number including mobile number
- Destination airport (if any)
- Contract number
- Number of Millboard/Greyboard Boxes contained in the carton (5 Ply Shipper)
- Gross weight of each carton (in kg)
- Instructions for storage and handling
- Logo of DOTS
- Place of manufacture (Made in_____)

L. Documentation

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

MILLBOARD/GREYBOARD BOX

3.5x3 cm



- M = 20
Y = 100
- M = 100
Y = 100
- M = 60
Y = 100
- K = 100

5 – Ply Shipper

