National Tuberculosis Elimination Programme

TECHNICAL SPECIFICATION OF CY-TB SKIN TEST FOR DIAGNOSIS OF TB INFECTION

Technical specification of Cy-Tb vial

PART: A – SPECIFIC

1.	Product:	rdESAT-6 and rCFP-10 injection
2.	Dose:	0.1ml
3.	Strength:	One single test dose (0.1ml) contains: rdESAT-6: 0.05 microgram rCFP-10: 0.05 microgram
4.	Form:	Solution for injection. Clear, colourless to yellow solution
5.	Vial:	Type I Glass vial conforming to the IS0-8362 standard Vial rubber stopper should be made of bromobutyl rubber as per IS0 standard
6.	Vial size:	1.0 ml multidose vial (10 tests)
7.	Shelf Life:	18 months
8.	Available Shelf life:	$5/6^{th}$ of the shelf life should be available at the time of receipt
9.	Packing:	10 vials per box
10.	Storage:	Not to be frozen. Should retain potency while stored at 2°C - 8°C.
11.	Transportation:	Consignment to be supplied under proper cold chain system till the end point

PART: B – GENERAL

1. PRODUCT AND PACKAGE SPECIFICATIONS

1.1 The product should be listed in the national essential drugs list or national formulary and the official International Non-Proprietary Name (INN) (generic) must appear prominently on the label. The product which meets all specifications listed in Part A are fully acceptable. The required packaging standards and labelling should meet the WHO Good Manufacturing Practices (GMP) standards in all respects.

1.2 Product specifications indicate dosage form (e.g., tablet, liquid, injectable, emulsion, suspension, etc.) and the drug content (exact number of mg or % v/v with acceptable conge) The products should conform to standards specified in one of the following compendia: The British Pharmacopoeia, the United States Pharmacopoeia, the French VIPAL pharmacopoeia,

Indian Pharmacopoeia, National Formulary of India, or the International Pharmacopoeia. In case the product is not included in the specified compendium, the Supplier, upon award of the Contract, must provide the reference standards and testing protocols to allow for quality control testing.

1.3 Not only the product, but also the packaging components (e.g., bottles and closures) should also meet specifications suitable for use in a climate similar to that prevailing in India. All packaging must be properly sealed and tamper-proof.

1.4 The product must specifically indicate storage requirements on labels and containers and be shipped in special containers to ensure stability in transit from point of shipment to port of entry.

2 PRODUCT INFORMATION

2.1 The following information will be required:

a) INN (International Non-proprietary Name)
b) Brand name (if it appears on the label)
c) Name and address of the manufacturer
d) Country of Origin
e) Compendia standards (if available)

2.2 Upon award, the successful bidder shall on demand provide a translated version of the product in English.

Failure to include any of the above information may, at the discretion of the Purchaser render the bid non-responsive.

3 EXPIRATION DATE:

3.1 The product must indicate the dates of manufacture and expiry. In addition, unless otherwise stated in Part A of these Specifications, the product must arrive at the ex-factory warehouse with a remaining shelf life of at least five-sixth ($5/6^{th}$) of the total stipulated shelf life at the time of receipt.

4 RECALLS

4.1 If the product must be recalled because of problems with product quality or adverse reactions to the product, the Supplier will be obligated 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 product or withdraw and give full refund if the product has been taken off the market due to safety problems.

5 LABELLING INSTRUCTIONS:

5.1 Labelling on vial:

5.1.1 All labelling should be in weatherproof ink and shall withstand immersion in water and remain intact. The label for the product shall meets the WHO GMP standard and conform to the requirement of Drug & Cosmetic Act, 1940 and rule made thereunder and as amended from time to time, including -

a) the INN or generic name prominently displayed and above the brand name, where a brand name has been given. Brand names should not be bolder or larger than the generic name

b) name of manufacturer

c) manufacturing licence

d) address of manufacturer

e) the active ingredient, per unit, dose, etc.

f) the applicable pharmacopoeia standard

g) National TB Elimination Programme's logo and product code number (section 6). (At least on mono carton and outer carton of packing of 10 vial box, if space constraint on vial)

h) instructions for use in red font "After first opening, the vial can be used for up to 28 days provided it is stored between 2°C - 8°C". "Read the package instruction carefully before use" to also be mentioned.

i) special storage requirements

j) batch number

k) date of manufacture and date of expiry

l) Bold message: "Central Govt. Supply- NOT FOR SALE" should be printed having good visibility on labelling of vial and boxes.

5.2 Labelling on Millboard / Greyboard boxes:

5.2.1 The label must be affixed either on the top and / or front surface of the Millboard / Greyboard box. The label shall conform to the requirements of the Drugs & Cosmetics Act 1940 and Rules made thereunder and as amended from time to time. The labels on the Millboard / Greyboard Box should be readable from a distance. The label should contain the information mentioned in 5.1.1. It should mention the quantity of vial contained in the sealed container.

5.2.2 Material safety data sheet (MSDS) should be affixed on the side of the millboard / Greyboard box. MSDS includes the instructions for the safe use and potential hazards associated with a particular material or product and spill-handling procedures.

5.3 Labelling on 5 Ply Shipper:

5.3.1 The external surface of insulated packages should be either white or in the natural colour of corrugated carton. The label shall conform to the requirements of the Drugs & Cosmetics Act 1940 and Rules made thereunder and as amended from time to time. The labels on the 5 Ply

Shipper must be affixed at least on two sides of the shipper. The label should include the information mentioned in 5.1.1. It should mention the quantity of Millboard / Greyboard Boxes of vail. The label on 5-Ply Shipper should be at least of A-4 paper size with date of manufacture, date of expiry, batch no. etc. mentioned in font size 18 to be readable from a distance.

5.3.2 Material safety data sheet should be affixed on the side of the shipper in at least of A-4 paper size. MSDS includes the instructions for the safe use and potential hazards associated with a particular material or product and spill-handling procedures.

5.4 QR Coding over the label:

5.4.1 QR code encoded with product details and manufacturer details on the mono carton & outer carton, shall be used for better inventory management.

6 UNIQUE IDENTIFIERS:

6.1 The Purchaser shall have the right to request the Supplier to imprint the National TB Elimination Programme's logo on the containers used for packaging. The design of the logo shall be provided to the Supplier at the time of contract award.

7 STANDARDS AND QUALITY ASSURANCE FOR SUPPLY:

7.1 The product must:

a) meet the requirements of manufacturing legislation and regulation of pharmaceuticals or vaccines in the country of origin,

b) conform to all the specifications contained herein, and

c) be certified by a competent authority in the manufacturer's country, if applicable, according to resolution WHO 28-65-B, of the World Health Organization "Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce".

7.2 The successful Bidder will be required to furnish to the Purchaser:

a) With each consignment, a certificate of quality assurance test results in conformity with the WHO Certification Scheme concerning quantitative assay, chemical analysis, sterility, pyrogen content uniformity, microbial limit, and other tests, as applicable to the product being supplied and Part A of these Specifications.

b) Assay methodology of any or all tests if requested.

c) Evidence of bio-availability and/or bio-equivalence for the product upon request.

d) Evidence of basis for expiration dating and other stability data concerning the commercial final package upon request.

7.3 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.