

Minutes of Meeting Technical Specification Committee, NACO for review and revision of specifications of the programmatic commodities under BSD and STI components of NACP

Date: 02nd & 30th March 2022

Venue: NACO Office/ virtual cum physical

A Meeting on Technical Specification for Commodities under the BSD & STI division, was conducted in two steps using virtual & hybrid modes under the Chairpersonship of Dr. Sunil Gupta, Principal Consultant, NCDC, Government of India. First meeting was held on 02 March 2022 to finalize the technical Specification of HIV test kit 1, HIV test kit 2, HIV test kit 3 & RPR test kit for syphilis.

In continuation of above second part of meeting was done on 30th March 2022 to finalize the technical specifications of Whole Blood Finger prick test kit for HIV, STI colour coded drugs kit 1, 2, 4, 5, 6 and 7, Injection Benzathine Penicillin, Tab Azithromycin, Syrup Nevirapine, Syrup Zidovudine, Syrup Lopinavir & Ritonavir, DBS card & DSB consumables, Ice Lined Refrigerator & Draft specification for Mobile van), under BSD & STI division:

All members were present and quorum was complete. After due discussions and deliberations, the committee approved the technical specifications as detailed Agenda wise.



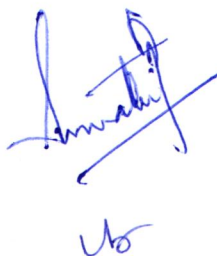
Agenda 1:

Technical Specifications of HIV (Rapid) Test kits -1 By the Principal Dot Immune Assay:

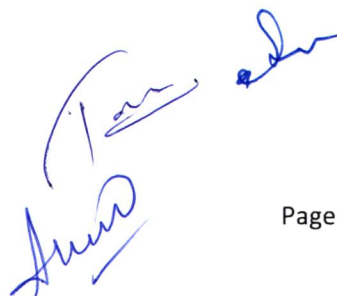
1. Should be solid phase coated HIV 1 & 2 recombinant and / or synthetic peptide antigens.
2. The assay should detect HIV 1 & 2 antibodies in serum, plasma or whole blood.
3. Adequate documents detailing the principal component, detail of antigen for antibody detection of HIV 1 & 2, bio safety methodologies, validity criteria, interpretation of results, performance characteristics, storage conditions, limitation of assays, manufacturing & expiry dates should be provided with each kit.
4. The kit should have approval of the statutory authority from the country of origin.
5. Imported kits, it should be registered and licensed by the DCG(I).
6. Indigenous manufacturer should be licensed by the competent authority defined under Drugs & Cosmetic Act 1940 & Rule 1945 and / or medical devices rule 2017.
7. The time required for the performing the test should not be more than 30 minutes.
8. The kits should have a shelf life of 24 months, at least 5/6th of the minimum shelf life must remain at the time of dispatch to the consignee.
9. The Control dot / band should be able to detect the presence of human immunoglobulins and should not merely check the flow of reagents or integrity of the antigen except for the kits based on the principal of lateral flow.
10. The assay should have sensitivity of 100% and specificity of $\geq 98\%$.
11. The manufacturer should ensure that:
 - a. The test kit should be packed such that there is a provision to conduct the single test at a time.
 - b. The assay component should include HIV positive & negative serum controls, sufficient for conducting 20% of the test (10% negative & 10% positive controls)
 - c. The pack size of HIV rapid test kits should be not more than 50 tests per kit.
12. The manufacturer/authorized agent should ensure maintenance of cold chain during storage & transport the kits at 2 - 8^o C. The cumulative time temperature indicator technology used should be pre-qualified by WHO.



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Agenda 2:

Technical Specification of HIV (Rapid) Test kits -2, (Principal Agglutination)

1. Should be solid phase coated HIV 1 & 2 recombinant and / or synthetic peptide antigens.
2. The assay should detect & differentiate HIV 1 & 2 antibodies in serum, plasma or whole blood.
3. Adequate documents detailing the principal component, detail of antigen for antibody detection of HIV 1 & 2, bio safety methodologies, validity criteria, interpretation of results, performance characteristics, storage conditions, limitation of assays, manufacturing & expiry dates should be provided with each kit.
4. The kit should have approval of the statutory authority from the country of origin.
5. In case of Imported kits, it should be registered and licensed by the DCG(I).
6. Indigenous manufacturers should be licensed by the competent authority defined under Drugs & Cosmetic Act 1940 & Rule 1945 and / or medical devices rule 2017.
7. The time required for the performing the test should not be more than 30 minutes.
8. The kits should have a shelf life of 24 months, at least 5/6th of the minimum shelf life must remain at the time of dispatch to the consignee.
9. The Control dot / band should be able to detect the presence of human immunoglobulin's and should not merely check the flow of reagents or integrity of the antigen except for the kits based on the principal of lateral flow.
10. The assay should have sensitivity of 100% and specificity of $\geq 98\%$.
11. The manufacturer should ensure that:
 - a. The test kit should be packed such that there is a provision to conduct the single test at a time.
 - b. The assay component should include HIV positive & negative serum controls, sufficient for conducting 20% of the test (10% negative & 10% positive controls)
 - c. The pack size of HIV rapid test kits should be not more than 30 tests per kit.
12. The manufacturer/authorized agent should ensure maintenance of cold chain during storage & transport the kits at 2 - 8^o C. The cumulative time temperature indicator technology used should be pre-qualified by WHO.

Agenda 3:

Technical Specification of HIV (Rapid) Test kits -3 (Principle excluding Agglutination and (Dot Immune Assay)

1. Should be solid phase coated HIV 1 & 2 recombinant and / or synthetic peptide antigens.
2. The assay should detect HIV 1 & 2 antibodies in serum, plasma or whole blood.
3. Adequate documents detailing the principal component, detail of antigen for antibody detection of HIV 1 & 2, bio safety methodologies, validity criteria, interpretation of results, performance characteristics, storage conditions, limitation of assays, manufacturing & expiry dates should be provided with each kit.
4. The kit should have approval of the statutory authority from the country of origin.
5. In case of Imported kits, it should be registered and licensed by the DCG(I).
6. Indigenous manufacturers should be licensed by the competent authority defined under Drugs & Cosmetic Act 1940 & Rule 1945 and / or medical devices rule 2017.
7. The time required for the performing the test should not be more than 30 minutes.
8. The kits should have a shelf life of 24 months, at least 5/6th of the minimum shelf life must remain at the time of dispatch to the consignee.
9. The Control dot / band should be able to detect the presence of human immunoglobulin's and should not merely check the flow of reagents or integrity of the antigen except for the kits based on the principal of lateral flow.
10. The assay should have sensitivity of 100% and specificity of $\geq 98\%$.
11. The manufacturer should ensure that:
 - a. The test kit should be packed such that there is a provision to conduct the single test at a time.
 - b. The assay component should include HIV positive & negative serum controls, sufficient for conducting 20% of the test (10% negative & 10% positive controls)
 - c. The pack size of HIV rapid test kits should be not more than 30 tests per kit.
12. The manufacturer/authorized agent should ensure maintenance of cold chain during storage & transport the kits at 2 - 8^o C. The cumulative time temperature indicator technology used should be pre-qualified by WHO.

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Agenda 4:

Technical Specification of Whole Blood Finger Prick test kit for HIV, kit -4

1. The assay should be able to detect antibodies to HIV 1 & HIV 2, including all the subtypes by the rapid test in whole blood/ and serum/ plasma.
2. The assay should have sensitivity of 100% and specificity of $\geq 98\%$.
3. The clinical data to determine the performance characteristics of the kit on whole blood sample should be made available by the manufacturer.
4. The assay should have solid phase/particles coated with synthetic and or recombination or both types of antigens of HIV 1 and HIV 2.
5. Total procedure time should not be more than 30 minutes
6. The kits should have a shelf life of 24 months, at least 5/6th of the minimum shelf life must remain at the time of dispatch to the consignee
7. The Control dot / band should be able to detect the presence of human immunoglobulins and should not merely check the flow of reagents or integrity of the antigen except for the kits based on the principal of lateral flow
8. Adequate documents detailing the principal component, detail of antigen for antibody detection of HIV 1 & 2, bio safety methodologies, validity criteria, interpretation of results, performance characteristics, storage conditions, limitation of assays, manufacturing & expiry dates should be provided with each kit.
9. The manufacturer/ authorized agent should ensure maintenance of cold chain during storage & transport the kits at 2-8°C. The cumulative time temperature indicator technology used should be pre - qualified by WHO.
10. Indigenous manufacturers should be licensed by the competent authority defined under Drugs and Cosmetics Act 1940 & Rule 1945 and/or Medical device rule 2017
11. The imported rapid test kits should have the approval of the statutory authority in the country of Origin/ manufacturers and should satisfy the requirements of Drugs & Cosmetics Act in India. The imported kits should also get evaluated in our country
12. The manufacturers should ensure that:
 - a) The test kit should be packed such that there is a provision to conduct single test at a time
 - b) The assay components should include HIV positive and negative serum controls sufficient for conducting 20% of the test (10% negative and 10% positive controls); and
 - c) The pack size of HIV rapid test kits should not be more than 50 tests per Kit

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Agenda 5:

Technical Specification of Rapid Plasma Reagin (RPR) for Syphilis Testing

1. The indigenous RPR (Rapid Plasma Reagin) kits should have been manufactured under manufacturing license issued by the State Licensing Authority under the Drugs and Cosmetics Act, the imported kits should have been imported under import license issued by the DCG(I) under the Drugs and Cosmetics Act 1940 & Rule 1945 and / or medical devices rule 2017.
2. Literature detailing the components, methodologies, validity criteria, performance characteristics, storage conditions, manufacturing, limitations and expiry date should be provided with each kit.
3. The assay should be calibrated to WHO reference standards from a third party accredited laboratory.
4. The assay should be suitable to perform with either serum or plasma.
5. The assay should allow for qualitative and semi quantitative determination of Reagin antibodies in serum or plasma for sera-diagnosis of syphilis based on flocculation principle using non - treponemal antigens.
6. The assay should have sensitivity of $\geq 85\%$ or more in primary syphilis and a specificity of $\geq 93\%$ or more.
7. The test should be able to yield results within 30 minutes.
8. The pack size of RPR test kit should be less than or equal to 50 tests per kit.
9. The assay components should include positive and negative serum controls sufficient for conducting 20% of the tests (10% negative and 10% positive controls).
10. The kit should have all essential accessories required for the test such as cards, droppers, applicator, etc. in adequate quantities for the number of tests to be performed.
11. The kits should have a shelf life of 24 months, at least 5/6th of the minimum shelf life must remain at the time of dispatch to the consignee.
12. The kit should have a storage temperature of 2° C to 8°C and supplier/ local agent should have the facility to store kits at 2° C to 8°C.
13. Cumulative Time Temperature Indicator should be part of the kit as per specifications defined in the terms and conditions.

Agenda 6:

Technical Specification of pre – Packed Colour Coded STI/ RTI drug kits

KIT Description:

S. No.	Colour	Description of Kit	Unit
1	Grey	Tab Azithromycin 1 gm and Tab Cefixime 400 mg	One Tablet of each drug in one kit
2	Green	Tab Secnidazole 1 gm and Tab Fluconazole 150 mg	Two Tablets of Secnidazole and One Tablet of Fluconazole
4	Blue	Cap/tab Doxycycline 100 mg and Tab Azithromycin 1 gm	Thirty Tablets of Doxycycline and One Tablet of Azithromycin in each drug in one kit
5	Red	Tab Acyclovir 400 mg	Twenty one tablets of drug in one kit
6	Yellow	Tab Cefixime 400 mg and Tab Metronidazole 400 mg and Cap/Tab Doxycycline 100 mg	One tablet of Cefixime and Twenty Eight Tablets of Metronidazole and Doxycycline each drug in one kit
7	Black	Cap/Tab Doxycycline 100 mg and Tab Azithromycin 1 gm	Forty Two Tablets of Doxycycline and One tablet of Azithromycin in each drug in one kit
3	White	Inj. Benzathine Penicillin 2.4 MU with equal number of sterile water 10 ml	Vial
3	White	Tab Azithromycin 1 gm	Tablet
3	White	Disposable syringe 10 ml with disposable needle	Number









Product Code Number	Product Name (Generic)	Pharmacopeia standards	Strength	Dosages Form	Number of generic product per each kit	Product Description
Product code 1: STI/RTI treatment kit 1 for UD; ARD and Cervicitis, PT	Azithromycin	I.P. or Equivalent	1 gm	Tablet	1	Treatment kit 1 for UD; ARD and Cervicitis, PT. Colour of Pouch is Grey (25%).
	Cefixime	I.P. or Equivalent	400 mg	Tablet	1	
Product code 2: STI/RTI treatment kit 2 for Vaginitis	Secnidazole	I.P. or Equivalent	1 gm	Tablet	2	Treatment kit 2 for Vaginitis. Colour of Pouch is Green.
	Fluconazole	I.P. or Equivalent	150 mg	Capsule / Tablet	1	
Product code 3: STI/RTI treatment kit 3 for GUD (Genital Ulcer Diseases)	Azithromycin	I.P. or Equivalent	1 gm	Tablet	1	Treatment kit 3 for GUD (Genital Ulcer Diseases). Colour of Pouch is White.
	Benzathine Penicillin	I.P. or Equivalent	2.4 MU	Vial	1	
	Disposable Syringe	-	10 ml capacity	NA	1	
	Disposable Needle	-	21 gauze	NA	1	
	Distilled Water	I.P. or Equivalent	10 ml	Plastic Phial	1	
Product code 4: STI/RTI treatment kit 4 for GUD (Genital Ulcer Diseases)	Azithromycin	I.P. or Equivalent	1 gm	Tablet	1	Treatment kit 4 for GUD (Genital Ulcer Diseases). Colour of Pouch is Blue.
	Doxycyclin	I.P. or Equivalent	100 mg	Capsule / Tablet	30	
Product code 5: STI/RTI treatment kit 5 for GUD (Genital Ulcer Diseases)	Acyclovir	I.P. or Equivalent	400 mg	Tablet	21	Treatment kit 5 for GUD (Genital Ulcer Diseases). Colour of Pouch is Red.

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Penicillin

Product code 6: STI/RTI treatment kit 6 for LAP (Lower Abdominal Pain)	Cefixime	I.P. or Equivalent	400 mg	Tablet	1	Treatment kit 6 for LAP. Colour of Pouch is Yellow.
	Doxycycline	I.P. or Equivalent	100 mg	Capsule / Tablet	28	
	Metronidazole	I.P. or Equivalent	400 mg	Tablet	28	
Product code 7: STI/RTI treatment kit 7 for IB (Inguinal Bubo)	Azithromycin	I.P. or Equivalent	1 gm	Tablet	1	Treatment kit 7 for IB. Colour of Pouch is Black.
	Doxycycline	I.P. or Equivalent	100 mg	Capsule / Tablet	42	

Note: For ease of procurement, the individual components of Kit 3 may be procured separately conforming to the colour code.

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General Specifications:

1. Product specifications indicate dosage form (e.g. tablet, liquid, injectable, emulsion, suspension etc.) and the drug content (exact number of mg or percentage v/v with acceptable range).
2. The products should conform to standards specified in one of the following compendia: Indian Pharmacopoeia, the British Pharmacopoeia, the United States Pharmacopoeia, the French VIPAL Pharmacopoeia or the International Pharmacopoeia.
3. Not only the pharmaceuticals or vaccine items, but also the packaging components (bottles and closures) should also conform to specifications suitable for use in a climate similar to that prevailing in the country of the purchaser. All packaging must be properly sealed and tamper-proof.
4. The manufacture should obtain and submit the approval for packaging the drug kit from concerned drug control authorities.
5. Pharmaceuticals requiring refrigeration or freezing for stability must specifically indicate storage requirements on labels and containers and be shipped in the special containers to ensure stability in transit from point of shipment to the port of entry.
6. All product must indicate the date of manufacture and expiry.
7. All products must arrive at the consignee point with a remaining shelf life of at least five-sixths (5/6th) of the total stipulated shelf life at the time of manufacture.
8. Shelf life of the various drugs would be as follows:
 - a) Azithromycin: shelf life should not be less than 36 months from the date of manufacture.
 - b) Cefixime: shelf life should not be less than 36 months from the date of manufacture.
 - c) Acyclovir: shelf life should not be less than 36 months from the date of manufacture.
 - d) Doxycycline: shelf life should not be less than 36 months from the date of manufacture.
 - e) Fluconazole: shelf life should not be less than 36 months from the date of manufacture.
 - f) Secnidazole: shelf life should not be less than 36 months from the date of manufacture.
 - g) Metronidazole: shelf life should not be less than 36 months from the date of manufacture.
 - h) Benzathine Penicillin: shelf life should not be less than 24 months from the date of manufacture.
 - i) Distilled Water of Water for Injection: shelf life should not be less than 24 months from the date of manufacture.

Labelling Instructions:

1. The label for each pharmaceutical and vaccine products shall meet the WHO GMP standards and include:
 - 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) The active ingredient per unit dose, tablet or capsule etc.
 - c) The applicable pharmacopeia standards.
 - d) Content per pack.
 - e) Special storage requirements.
 - f) Batch number and
 - g) Date of manufacture and date of expiry.
 - h) Colour coding as mentioned in schedule of requirement.
2. The outer case or carton should also display the above information.

Case Identification:

1. All cases should prominently indicate the following:
 - a) Purchaser's line and code numbers.
 - b) The generic name of the product, if any
 - c) Date of manufacture and expiry (in clear language not code)
 - d) Batch number
 - e) Quantity per case.
 - f) Special instructions for storage.
 - g) Name and address of manufacturer with license number.
 - h) Any addition cautionary statements.
2. No case should contain kits from more than one batch.

General requirements for standards and Quality Assurance requirements:

All products must **conform** to specifications, meet the requirements of the manufacturing legislations and regulations of pharmaceuticals or vaccine in the country of origin and must undergo strict raw material inspection, in process checks, appropriate material handling to eliminate cross contamination (of molecules) and final product testing to ensure quality and consistency of the products.

With each consignment, a certificate of quality assurance test results concerning quantitative assay, chemical analysis, sterility, pyrogenic quantity uniformity, microbial limit and other tests as applicable to the product being supplied must be provided.

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Special Instructions:

1. Each kit, inner carton and nested cartons to have the following words printed **DIAGONALLY ACROSS THE LABEL** in the red ink with bold letters.

“GOVERNMENT OF INDIA SUPPLY – NOT FOR SALE”

The supplier should also ensure marking of unique number on each kit, inner carton and nested cartons.

2. Life of the product, indicating the date of manufacture and date of expiry should be printed as per Drug & Cosmetic Act – India.
3. Equivalency of standards and codes:

Wherever reference is made in the Technical Specifications to specific standards and codes to be met by the product to be furnished or tested, the provisions of the latest current edition or revision of the relevant standards or codes in effect shall apply, unless otherwise expressly stated in the contract. Where such standards and codes are national or authoritative standards that ensure **substantial** equivalence to the standards and codes specified will be acceptable.

4. Packaging Instruction: The supplier will have to make unit packing for each kit. Each unit package will be marked on three sides with proper paints / indelible ink, the following:

- a) Project :
- b) Purchase order number :
- c) Country of origin of Goods :
- d) Supplier's name and :
- e) Packaging list reference number :

5. Each outer packing containing the unit packing should have the following label printed in bold letters in large size.

- a) Purchaser's name :
- b) Project :
- c) Purchase order no :
- d) Country of origin of Goods :
- e) Supplier's Name :

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Specification of Packaging Material:

General Specifications:

- a) The blister is TROPICALIZED with moisture barrier properties for drug stability under field condition.
- b) Quality Assurance is according to Norms ISO 9001/EN 2901 of aluminium-foil.
- c) Standard coloured BCP's.
- d) Spacing between tablets allowing removal by patients with finger deformities.
- e) Complete with self-adhesive patient labels.
- f) Outside kit label with health care instructions, if any, colour coded.
- g) Perforation and folding lines, to allow the packet use.
- h) The pharmaceuticals under product codes 1, 2, 3, 4, 5, 6 & 7 will be supplied as blister pack separately for each pharmaceuticals product and duly packed in pre specified laminated colour coded kits which thereafter would be packed in Millboard/grey board boxed, 20 kits per box.

These Millboard/grey board boxes would be put in 5-ply respective shippers for dispatch. The Kit no.3 containing pharmaceuticals (a tablet and an injection) under product code 7 will have separately Schedule 1 and Schedule 5 in same colour coded kit.

Complex constructions with PVC films

Rigid PVC film thermo formable

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Polyethylene

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Polyvinylidenechloride compound with particularly high water vapour barrier.

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Technical Specification data for the Standards Complexes

Complex:

Rigid PVC film gauge (Microns)	200
PE coating (Microns)	25
PVDC coating (gsm)	60
Total weight (gsm)	356
Complex gauge (mm)	0.280

Water Vapour Transmission Rate (W.V.T.R.)

Thermoformed:

20°C, 85% r.h., gsm/24 h 0.15

38°C, 90% r.h. , gsm/24 h 0.7

Not Thermoformed:

20°C, 85% r.h., gsm/24 h 0.06

38°C, 90% r.h. , gsm/24 h 0.4

Shrinkage longitudinally

T = 140°C, t = 20 min. (%) 5-6

Application temperature (C) 68-74

r.h. = relative humidity

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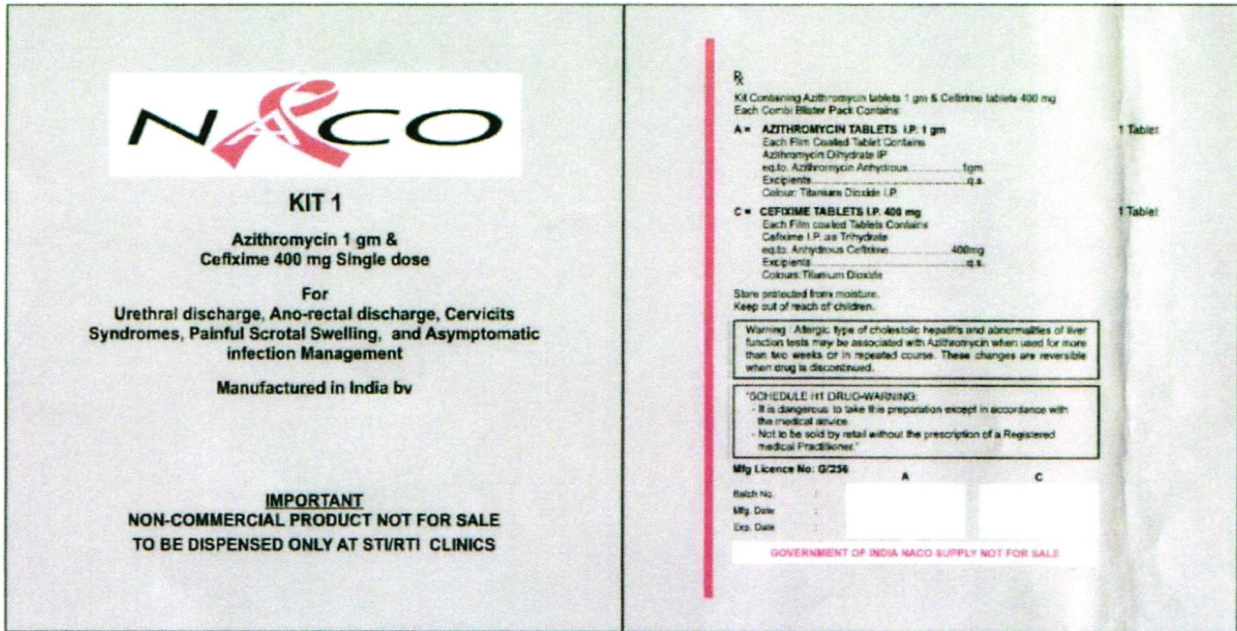
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Images of STI/RTI kits

Size : L-75 x H-90 mm

Front

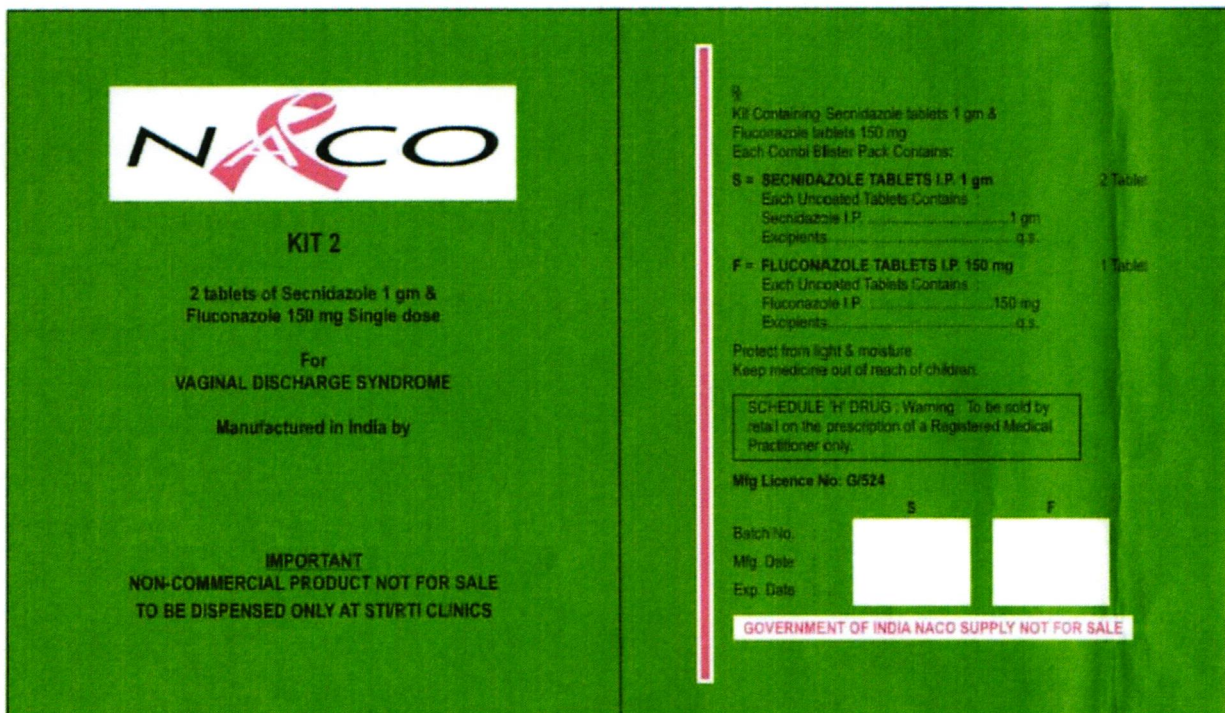
Back



Size : L-75 x H-90 mm

Front

Back



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KIT 3

Tablet Azithromycin 1 gm single dose
For
GENITAL ULCER DISEASE
(Non-HERPETIC SYNDROME)

Not to be used alone.
To be used along with Injection Benzathine Penicillin 2.4 million units
with equal number of vials of sterile water for injection 10ml.

IMPORTANT
NON-COMMERCIAL PRODUCT
NOT FOR SALE
TO BE DISPENSED ONLY AT RTVSTI
CLINICS

Manufactured in India by

Each film coated tablet contains:
Azithromycin (As Dihydrate) IP
Eq. to Azithromycin Anhydrous.....1gm
Excipients.....q.s.
Colour: Titanium Dioxide IP
Dosage : As directed by the Physician.
**Storage: Store protected from light & moisture,
at a temperature not exceeding 30°C.**
Keep out of reach of children.

Mfg. Lic. No.: G/28/967

Warning: Allergic type of cholestatic hepatitis and abnormalities
of liver function tests may be associated with Azithromycin when used for
more than two weeks or in repeated course.
These changes are reversible when drug is discontinued.

CAUTION Not to be sold by retail without the prescription
of a Registered Medical Practitioner

Batch No.:
Mfg. Date :
Exp. Date :

GOVERNMENT OF INDIA NACO SUPPLY NOT FOR SALE

Size : L-95 x H-140 mm

Front

Back



KIT 4

Doxycycline 100 mg BID for 15 days +
Azithromycin 1 gm Single dose

For
GENITAL ULCER DISEASE-NON-HERPETIC
SYNDROME

Manufactured in India by

IMPORTANT
NON-COMMERCIAL PRODUCT NOT FOR SALE
TO BE DISPENSED ONLY AT STI/RTI CLINICS

Rx
EACH KIT CONTAINS
D = DOXYCYCLINE HYDROCHLORIDE
CAPSULES IP: 100 mg 30 Capsules
Each Capsules Contains
Doxycycline Hydrochloride IP
Eq to Doxycycline 100 mg
Excipients q.s.

A = AZITHROMYCIN TABLETS IP: 1 gm 1 Tablet
Each Film Coated Tablet Contain
Azithromycin Dihydrate IP
eq to Azithromycin Anhydrous 1 gm
Excipients q.s.
Colour: Titanium Dioxide IP

Store protected from light and
moisture at a temperature not exceeding 30°C.
Keep medicine out of reach of children.

Warning: Allergic type of cholestatic hepatitis and abnormalities of liver
function tests may be associated with Azithromycin when used for
more than two weeks or in repeated course. These changes are
reversible when drug is discontinued.

SCHEDULE H DRUG: Warning: To be sold by retail on the
prescription of a Registered Medical Practitioner only.

Mfg Licence No: G/256

Batch No: D A
Mfg. Date:
Exp. Date:

GOVERNMENT OF INDIA NACO SUPPLY NOT FOR SALE.

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Size : L-100 x H-160 mm

Front

Back



KIT 7

Doxycycline 100 mg BID for 21 days & Azithromycin 1 gm Single dose

For
INGUINAL BUBO SYNDROME

Manufactured in India by

IMPORTANT
NON-COMMERCIAL PRODUCT NOT FOR SALE
TO BE DISPENSED ONLY AT STI/RTI CLINICS

Rx

EACH KIT CONTAINS

D = DOXYCYCLINE HYDROCHLORIDE

CAPSULES I.P. 100 mg

42 Capsules

Each Capsules Contains

Doxycycline Hydrochloride I.P.

Eq. to Doxycycline 100 mg

Excipients q.s

A = AZITHROMYCIN TABLETS I.P. 1 gm

1 Tablet

Each Film Coated Tablet Contains

Azithromycin Dihydrate I.P.

Eq. to Azithromycin Anhydrous 1 gm

Excipients q.s

Colour: Titanium Dioxide I.P.

Store protected from light and moisture at a temperature not exceeding 30°C. Keep medicine out of reach of children.

Warning: Allergic type of cholestatic hepatitis and abnormalities of liver function tests may be associated with Azithromycin when used for more than two weeks or in repeated course. These changes are reversible when drug is discontinued.

SCHEDULE 'H' DRUG. Warning: To be sold by retail on the prescription of a Registered Medical Practitioner only.

Mfg Licence No: G/256

D

A

Batch No.

Mfg. Date

Exp. Date

GOVERNMENT OF INDIA NACO SUPPLY NOT FOR SALE

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STI/RTI kit -1: Packing specification

- a. Blister Packed drugs
PVC film: Transparent, food grade, blister forming PVC film as specified
Aluminium foil: 0.025 mm, VMCH coated aluminium printed as per approved artwork
- b. One laminated kit will be required (either solely or adjuvant) with other essential drugs but kept separately) for each category of STI/RTI treatment as specified in schedule of requirement.
The kit will be in Grey (25%) colour and labelled as per details given under labels
Laminated material Glassine Paper (40gm) Aluminium (9um)/Poly (150 gauze)
Type of kit –Gusseted
Each kit will contain one (1) tablet each of Azithromycin and Cefixime separately each in its own blister pack for use by one patient.
- c. Millboard /Grey Board box:
Board: at least 3mm corrugated card board is to be used, surrounded on inside and outside by tightly affix millboard of at least 40gsm.
Style of: Top and bottom tuck-in flap type
The millboard box should be labelled in Grey as given under para 9.4.5.1-Labels
Each millboard box contains 20 colour coded kits
- d. Five ply shipper: Each shipper will contain 20millboard/grey board/boxes and in Grey (25%).Colour labelled as per details given under labels.
Description: RSC(Universal), type-5ply corrugated box made in narrow flute from (150)5gsm, virgin quality 'A' grade Kraft paper.

STI /RTI KIT-2 Packing specification

- a) Blister packed drugs
PVC film: Transparent, food grade, blister forming PVC film as specified
Aluminium foil: 0.025 mm, VMCH coated aluminium foil printed as per approved artwork
- b) One laminated kit will be required (either solely or as an adjuvant with other essential drugs but kept separately) for each category of STI/RTI treatment as specified in schedule of treatment.
The kit will be in green colour as per details given under Labels.
Laminated material Glassine Paper (40gm) Aluminium (9um)/Poly (150 gauze)
Type of kit –Gusseted
Each kit will contain two (2) tablets of Secnidazole 1gm each and one tablet/capsule of Fluconazole 150mg for single usage for one patient.
- c) Millboard /Grey Board box:
Board: at least 3mm corrugated cardboard is to be used, surrounded on inside and outside by tightly affix millboard of at least 400gsm.
Style of kit: Top and bottom tuck-in flap type.
The millboard box should be labelled in green colour labels as given under para 9.4.5.1-Labels
Each millboard box contains 20 colour coded kits
- d) Five ply shipper: Each shipper will contain 20boxes made of millboard / greybeard boxes and in and in Green Colour as per details given under labels.
Description: RSC(Universal), type-5ply corrugated box made in narrow flute from (150)5gsm, virgin quality 'A' grade Kraft paper.

STI /RTI KIT-3 Packing specification

a) Blister packed drugs

PVC film: Transparent, food grade, blister forming PVC film as specified

Aluminium foil: 0.025 mm, VMCH coated aluminium foil printed as per approved artwork

b) One laminated kit will be required (either solely or as an adjuvant with other essential drugs but kept separately) for each category of STI/RTI treatment as specified in schedule of treatment.

The kit will be in white colour as per details given under Labels.

Laminated material Glassine Paper (40gm) Aluminium (9um)/Poly (150 gauze)

Type of kit –Gusseted

Each kit will contain one (1) tablets of Azithromycin one gram (1gm).

c) Millboard /Grey Board box:

Board: at least 3mm corrugated cardboard is to be used, surrounded on inside and outside by tightly affix millboard of at least 400gsm.

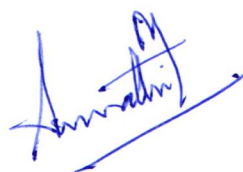
Style of kit: Top and bottom tuck-in flap type.

The millboard box should be labelled in white colour labels as given under para 9.4.5.1-Labels

Each millboard box contains 20 colour coded kits

d) Five ply shipper: Each shipper will contain 20boxes made of millboard boxes and in and in white Colour as per details given under labels.

Description: RSC(Universal), type-5ply corrugated box made in narrow flute from (150)5gsm, virgin quality 'A' grade Kraft paper.



STI/RTI KIT -4 Packing specification

- a. Blister packed drugs
PVC film: Transparent, food grade, blister forming PVC film as specified
Aluminium foil: 0.025 mm, VMCH coated aluminium foil printed as per approved artwork
- b. One laminated kit will be required (either solely or adjuvant) with other essential drugs but kept separately) for each category of STI/RTI treatment as specified in schedule of requirement.
The kit will be in Blue colour and labelled as per details given under labels
Laminated material Glassine Paper (40gm) Aluminium(9um)/Poly (150 gauze)
Type of kit –Gusseted
Each kit will contain one (1) tablet each of Azithromycin 1 gram in Blister pack and 30 tablets doxycycline 100mg in blister pack kept separately each in the kit for use by one patient.
- c. Millboard/Grey Board box:
Board: at least 3mm corrugated cardboard is to be used, surrounded on inside and outside by tightly affix millboard of at least 400gsm.
Style of kit: Top and bottom tuck-in flap type.
The millboard box should be labelled with blue labels as given under para 9.4.5.3-Labels
Style of kit: Top and bottom tuck-in flap type.
The millboard box contains 20 kits and should be labelled in Blue colour as given under para 9.4.5.1-Labels
- d. Five ply shipper: Each shipper will contain 20millboard/grey board/boxes and in Blue Colour labelled as per details given under labels 9.4.5.3.
Description: RSC(Universal), type-5ply corrugated box made in narrow flute from (150)5gsm, virgin quality 'A' grade Kraft paper.

STI/RTI KIT-5 Packing specification

- a. Blister packed drugs
PVC film: Transparent, food grade, blister forming PVC film as specified
Aluminium foil: 0.025 mm, VMCH coated aluminium foil printed as per approved artwork.
- b. One laminated kit will be required for STI/RTI treatment as per specified in the schedule of requirement.
The kit will be in Red colour and labelled as per details given under labels
Laminated material Glassine Paper (40gm) Aluminium (9um)/ Poly (150 gauze)
Type of kit –Gusseted
Each kit will contain twenty-one tablets of Acyclovir 400 mg for usage by one patient.
- c. Millboard/Grey Board box:
As given under labels
Board: at least 3mm corrugated cardboard is to be used, surrounded on inside and outside by tightly affix millboard of at least 400gsm.
Style of kit: Top and bottom tuck-in flap type.
Each red labelled millboard box contains 20kits and labelled as given under labels.
- d. Five ply shipper: Each shipper will contain 20milliboard/grey board/boxes and labelled in Red Colour as per details given under labels
Description: RSC(Universal), type-5ply corrugated box made in narrow flute from (150)5gsm, virgin quality 'A' grade Kraft paper.

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STI/RTI KIT-6 Packing specification

- a. Blister packed drugs
PVC film: Transparent, food grade, blister forming PVC film as specified
Aluminium foil: 0.025 mm, VMCH coated aluminium foil printed as per approved artwork
- b. One laminated kit will be required for STI/RTI treatment as per specified in the schedule of requirement.
The kit will be in yellow colour and labelled as per details given under labels
Laminated material Glassine Paper (40gm) Aluminium (9um)/ Poly (150 gauze)
Type of kit –Gusseted
Each kit will contain one tablet of Azithromycin 1gm, twenty-eight tablets each of Doxycycline 100 mg and Metronidazole 400 mg all in their own blister packs and kept separately for usage by one patient.
- c. Millboard/Grey Board box:
Board: at least 3mm corrugated cardboard is to be used, surrounded on inside and outside by tightly affix millboard of at least 400gsm.
Style of kit: Top and bottom tuck-in flap type.
Each box contains 20kits and labelled as yellow colour as given under labels.
- d. Five ply shipper: Each shipper will contain 20milliboard/grey board/boxes and labelled in yellow Colour as per details given under labels
Description: RSC(Universal), type-5ply corrugated box made in narrow flute from (150)5gsm, virgin quality 'A' grade Kraft paper.

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STI/RTI KIT-7 Packing specification

a. Blister packed drugs

PVC film: Transparent, food grade, blister forming PVC film as specified in 9.4.2
Aluminium foil: 0.025 mm, VMCH coated aluminium foil printed as per approved artwork

b. One laminated kit will be required (either solely or with adjunct with other essential drugs) for each category of STI/RTI treatment as per specified in the schedule of requirement.

The lot will be in Black colour and labelled as per details given under labels
Laminated material Glassine Paper (40gm) Aluminium (9um)/Poly (150 gauze)
Type of kit –Gusseted
Each kit will contain one tablet of Azithromycin 1gm and forty-two tablets Doxycycline 100 mg for usage by one patient.

c. Millboard/Grey Board in Black Colour

Labelled as given under labels
Board: at least 3mm corrugated cardboard is to be used, surrounded on inside and outside by tightly affix millboard of at least 400gsm.
Style of kit: Top and bottom tuck-in flap type.
Each black coloured millboard box contains 20kits and labelled as given under labels.

d. Five ply shipper: Each shipper will contain 20milliboard/grey board/boxes and labelled in yellow Colour as per details given under labels

Description: RSC(Universal), type - 5ply corrugated box made in narrow flute from (150)5gsm, virgin quality 'A' grade Kraft paper

Agenda 7

A) Technical Specification of Injection Benzathine Penicillin 2.4

MU (1) and sterile water 10ml (1)

B) Disposable Syringe 10ml with 21-gauge needle (1)

Kit no.	Colour	Description of kit	Unit
3	White	Inj. Benzathine Penicillin 2.4 million units with equal no. of vials of sterile water for injection 10 ml	Vial
3	White	One Disposable syringe 10ml with one 21 gauge disposable needle.	Piece

Product Code no.	Product name generic	Pharmacopoeia standard	Strength	Dosage form	Number of generic product per kit	Product description
STI / RTI treatment Kit 3 for GUD (Genital Ulcer Disease)	Benzathine Penicillin	IP or Equivalent	2.4 Million Units	Vial	1	Treatment kit 3 for treating GUD. The Colour of the Pouch is white
	Auto disable & Non-reusable syringe		10 ml capacity		1	
	Disposable needle		21 gauge		1	
	Sterile water for injection	IP or Equivalent	10ml	vial	1	

General Technical Specification:

1. Product specifications indicate dosage form (e.g. tablet, liquid, inject able, emulsion, suspension etc.) and the drug content (exact number of mg. or Unit or percentage v/v with acceptable range).
2. The products should conform to standards specified in one of the following compendia: Indian Pharmacopoeia, the British Pharmacopoeia, the United States Pharmacopoeia, the French VIPAL Pharmacopoeia or the International Pharmacopoeia
3. Not only the pharmaceuticals or vaccine items, but also the packaging components (e.g. bottles and closures) should also conform to specifications suitable for use in a climate similar to that prevailing in the country of the Purchaser, all packaging must be properly sealed and tamper-proof.
4. The manufacturer should obtain and submit the copy of approval for packaging the drug kit from concerned drug control authorities, (CLA and/ or SLA, wherever applicable)
5. Pharmaceuticals requiring refrigeration or freezing for stability must specifically indicate storage requirements on labels and containers and be shipped in the special containers to ensure stability in transit from point of shipment to the port of entry.
6. All products must indicate the dates of manufacture and expiry.
7. All products must arrive at the consignee point with a remaining shelf life of at least five/sixth (5/6) of the total stipulated shelf life at the time of manufacture.
8. Shelf life of Drug:
 - a) Benzathine Penicillin: Shelf life should be at least 24 months or more from the date of manufacture
 - b) Sterile water for injection: shelf life should be at least 24 months or more from the date of manufacture

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Agenda 8

Technical Specifications of Syrup Nevirapine

1	Formulation of medicine	Oral Suspension
2	Each 5ml suspension contains:	Nevirapine 50 mg I.P or any other pharmacopoeia
3	Standard Shelf-life	2years (24 months)
4	Quantity per container	100 ml (10 mg/ml)
5	Primary Container	Packed in amber coloured PET bottle with a child resistance cap with a liner and a measuring syringe
6	Label	Glazed label in accordance with statutory requirements as per Drugs and Cosmetic Act as per Rule 96. Standard colour of labels to be used as approved by NACO
7	Secondary container	5 ply Shipper to accommodate the bottles as per volume Shipper fabricated from virgin Kraft Paper. 3 Liner -150 GSM, 2 Flute -150 GSM BS:NLT 12.5 KG/sq.cm Each shipper to be labelled as per statutory requirements The supplier should have the facility to store and transport Syrup bottles at temperature less than 30° C. cool & dry place.
8	Certification	The product should be approved by State/Central licensing authority as per the provisions of Drugs and Cosmetic Act and rules their under. Appropriate certificate (GMP / manufacturing license / import license) to this effect is mandatory.

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Agenda 9

Technical Specification for syrup Zidovudine

1	Formulation of medicine	Oral Solution
2	Each 5ml solution contains	Zidovudine 50mg/5ml IP or any other pharmacopoeia
3	Standard Shelf-life	2 years (24 months)
4	Quantity per container	100ml / 240 ml (10 mg/ml)
5	Primary Container	Packed in HDPE opaque bottle with a child resistance cap with a liner and a measuring syringe
6	Label	Glazed label in accordance with statutory requirement as per Drugs and Cosmetic Act as per Rule 96. Standard colour of labels to be used as approved by NACO
7	Secondary container per	5 ply Shipper to accommodate the bottles as volume . Shipper fabricated from virgin Kraft Paper 3 Liner -150 GSM, 2 Flute -150 GSM BS: NLT 12 5 KG/sq.cm Each shipper to be labelled as per statutory requirements The supplier should have the facility to store and transport Syrup bottle at temperature less than 30° C, cool & dry place.
8	Certification	The product should be approved by State/ Central licensing authority as per the provisions of drug and cosmetic act and rules their under. Appropriate certificate (GMP/Manufacturing license/import license) to this effect is mandatory.

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Agenda 10

Technical Specification for Paediatric ARV drug Formulation, Lopinavir & Ritonavir

S.no.	Formulation of Medicine		160 ml of formulation should contain		Volume per container
1	Suspension of Lopinavir & Ritonavir (Paediatric)	Oral Suspension	Lopinavir IP	80mg	160 ml
			Ritonavir IP	20mg	

2	Standard Shelf-life	2 years (24 months)
3	Quantity per container	160 ml
4	Primary Container	Suitable opaque plastic bottle according to the packaging size with a tightly fitting suitable screw cap
5	Label	Glazed label in accordance with statutory requirement as per Drugs and Cosmetic Act as per Rule 96. Standard colour of labels to be used as approved by NACO
6	Secondary Container	5 ply Shipper to accommodate the bottles as per volume Shipper fabricated from virgin Kraft Paper. 3 Liner -150 GSM, 2 Flute -150 GSM BS:NLT 12.5 KG/sq.cm Each shipper to be labelled as per statutory requirements The supplier should have the facility to store and transport Syrup bottles at temperature less than 30° C. cool & dry place.
7	Certification	The product should be approved by State/Central licensing authority as per the provisions of Drugs and Cosmetic Act and rules their under. Appropriate certificate (GMP / manufacturing license / import license) to this effect is mandatory.

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Approved packaging for ARV drugs in Tablet/ syrup formulation

Primary Container	Label	Secondary Container
<p>(1) Suitable opaque plastic bottle to contain tablets / capsules according to the packaging size</p> <p>(2) Each bottle duly sealed with plastic plug / diaphragm and may contain desiccant.</p> <p>(3) Tightly fitting suitable screw cap</p> <p>(4) Include barcode at primary packaging. GS I Data Matrix (two dimensional) symbology is the preferred option.</p> <p>(5) Other barcode symbologies (EAN/UPC, GS1- 128 and GS1 Data bar) on primary level packaging shall also be acceptable</p>	<p>(1) Glazed label in accordance with Statutory requirement as per Drug and Cosmetic Act 1940 and rules there under</p> <p>(2) Standard colour of labels to be used as approved by the NACO</p>	<p>(1) 5 ply Shipper to accommodate between 60 - 100 bottles per shipper.</p> <p>(2) Shipper fabricated from Drugs and virgin Kraft paper 3 Liner Cosmetic Act - 150 GSM, 2 Flute - 150 1940 and Rules GSM BS: NLT 12.5 KG/sq.cm</p> <p>(3) Each Shipper to be labels to be used as labelled as per statutory approved by NACO requirements</p> <p>(4) The supplier should have the facility to store and transport syrup bottles at 2-80 C wherever required.</p> <p>(5) It is desirable to include a 2-dimensional Quick Response (QR) code at Secondary level packaging</p>

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Agenda - 11

Technical Specification for Dry Blood Spot Card

1. Intended purpose: HIV serology/- molecular testing
2. No. of circles: Minimum five circles
3. Circle size 12 – 14 mm internal diameter
4. Dimensions: breath: (LxB)3" (76.2mm), 4" ¼ (108mm)
5. Basic Wright (g/m²): 170- 188
6. Expiry: Minimum 3 years (36 months) at the time of delivery
7. PH range should be between 5.5 to 7.5
8. Certification of product: BIS or FDA or CE
9. Packaging: 10 DBS cards per pack
10. Other Information:

Labelling space should be available for

(a) name. (b) Sample Number (c) date of sample collection

11. the card should be imprinted with the universal biohazard symbol

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Agenda 12

Dry Blood Spot (DBS) consumables/collection kits

Technical Specification for Dry Blood Spot (DBS) consumables / collection kits

Sr. No.	Items	Number for a Pack of 1 DBS Collection Kit	Product Description
1	Glassine Envelope	10	Glassine envelope (Light weight, translucent material resistant to moisture in zip lock bag of approx. 180x150 (L x B) mm size)
	Flexible Packaging	1	
2	Silica Gel Packs	50	Silica Gel Pack (Silica Gel sachet 1 gm. complete with opaque non gas permeable bag in zip lock bag of approx. 180x150 (L x B) mm size)
	Flexible Packaging	1	
3	Humidity Indicator Cards	10	Humidity indicator cards (properly packed humidity indicator card with 6 blue circles indicating percentage humidity changes by colour)
4	Sterile Alcohol Swab	20	Sterile Alcohol Swab (Single use alcohol pad saturated with 70% isopropyl alcohol in zip lock bag of approx. 180x150(L x B) mm size) and approved by DCGI
	Flexible Packaging	1	
5	Gauze Swabs	20	sterile Gauze Swabs (Gauze 8 Ply of approx. 50mm x 50mm (L x B)size in and approved by DCGI, in zip lock bag of approx.180x150 mm size) (L x B)
	Flexible Packaging	1	
6	Double Zip Lock Bags	10	Double zip Lock bags (Opaque low gas permeable double Zip Lock bag of approx. 180x150mm size) (L x B)
7	Powder less Gloves	20	Powder less Gloves (Latex examination gloves, powder free. medium size in zip lock bag of approx. 100x80 mm (L x B) size with one pair of gloves)
	Flexible Packaging	10	

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	Flexible Packaging	1	
8	Auto retractable lancets 2 mm blade	20	Auto retractable lancets with 2mm blade in zip lock bag of approx. 150x100 mm size (L x B)
	Flexible Packaging	1	
9	Cardboard Box	1	Cardboard box (white printed corrugated box with tuck in lid. Colour printed NACO logo and list of contents approximately 250x250x160 mm (LxBxH). with expiry date of product with least expiry clearly mentioned)
10	Fabric Bandages	10	Fabric Bandages (individually wrapped fabric adhesive bandage approximately 72 x20 mm (L x B) and approved by DCGI, in zip lock bag of approx. 100x80mm size) (L x B)
	Flexible Packaging	1	
11	Bio Hazard Bag	10 bags (5 Red & 5 yellow)	Bag for discarding Bio Medical Waste bag specification as per extant BMW management rules, size 400x650mm (L x B) approx. with Universal biohazard symbol packed in zip lock bag of approx. 250x150mm size
	Flexible Packaging	1	
12	Bio Hazard Sticker	10	Bio Hazard Sticker (Bio Hazard sticker 2.5x2.5cms (L x B) .approximately with universal bio hazard symbol in zip lock bag of approx. 100x80 mm size, (L x B))
	Flexible Packaging	1	
13	Envelopes (Plain)	10	Envelopes (Plain) as brown envelope, self-sealing in zip lock bag of approx. 250x 200mm size (L x B)
	Flexible Packaging	1	
14	Envelop (Lined)	10	Bubble lined envelope approximately 300x220 mm (L x B), self-sealing in zip lock bag of approx. 300x250 mm size, (L x B)
	Flexible Packaging	1	

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Agenda13

Technical Specification for Vertical Ice Lined Refrigerator (ILR) 200 Litres

Sr. No.	Minimum Specification Requirement
1	Capacity: 200 - 300 Liters
2	Vertical Ice Lined Refrigerator to maintain temperature of +2°C to +8°C at ambient temperature of +5°C to +45°C with intermittent or continuous electricity supply for at least 8 hrs. in a 24 hrs cycle.
3	The temperature difference between any two points in the cabinet should not be more than +2°C once stabilized.
4	Holdover Time (maintain the temperature +2°C to +8°C): 20 hrs or more in a continuous ambient temperature of 43°C
5	Solid /Double Glazed Glass door with lock and handle
6	Type: Compressor cycled. CFC free (both for refrigeration and insulation).All system tubing (suction tube, freezer tube and condensing tube) should be of copper.
7	A microprocessor based control unit should be provided for setting of temperature and display of the following features: Cabinet temperature Power on LED/LCD indicator
8	Auto visual alarm against violation of temperature range (less than +2 degree Celsius and more than 8 degrees Celsius). Door open alarm
9	Adjustable storage wire shelves (minimum three) allowing free circulation of air
10	digital thermometer (temp range -30°C to +50°C)
11	Product should be BIS or USFDA or European CE approved
12	Power supply :220VAC/50Hz
13	Suitable voltage stabilizer should be supplied with each unit
14	Other conditions
15	The supplier will provide the initial 05 years warranty followed by 03 years comprehensive Annual Maintenance Contract (CAMC) including all spare parts, compressor & repairs.

16	The manufacturer should be able to provide service of equipment at the site of installation within 24 hours after receipt of breakdown report.
17	Purchaser reserves the right to subject the equipment for independent evaluation of performance
18	The bidder will provide installation qualification, operational qualification and performance qualification with log book for maintenance of the equipment at no extra cost
19	Manuals: Operation, maintenance & part list with detailed specifications must be provided in original
20	Onsite comprehensive training: The bidder should provide onsite comprehensive training of lab staff on operation of equipment.

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Summary of discussions:

1. In reference to cross validate the specificity of Whole blood finger prick HIV test kit 4, committee requested to Dr, Madhuri Thakkar, Director, NARI, Pune to undertake a prospective study on same and share the finding with the technical Specification committee.
2. Dr. Akansha Bisht suggested to prepare revised dosing strengthen and schedule when using Cefixime, considering current resistance pattern of pathogens.
3. STI/RTI kit 3 will be procure in de - kited form, Tablet Azithromycin 1 gm and Injection Benzathine Penicillin 2.4m.
4. Dr. Sai Prasad Bhavsar, DD (SCM) agreed to share the revised technical specification of Mobile Van (ICTC) with committee members for inputs.

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Sai Prasad

Bhavsar

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Shailendra Gandharva <shailendra.naco@gmail.com>

Re: Final MoM Technical Specification of commodities under BSD NACO

1 message

Madhuri Thakar <mthakar@nariindia.org>
To: Shailendra Gandharva <shailendra.naco@gmail.com>
Cc: Director NARI <director@nariindia.org>

5 May 2022 at 16:58

Dear Mr Shilendra,
I have gone through the minutes and share herewith my concurrence for all the technical specifications discussed and approved in the meeting.
Sincerely,
Dr. Madhuri Thakar

On Thu, May 5, 2022 at 4:53 PM Shailendra Gandharva <shailendra.naco@gmail.com> wrote:
Respected Ma'am

Greetings from NACO !

I am sharing the final MoM of Technical Specification of commodities under BSD NACO.
Meeting held on 2nd & 30th March 2022, for your kind concurrence.

Thanks with regards
Shailendra Gandharva



Associate Consultant
BSD, NACO
Ministry of Health & Family Welfare
Chandralok Building, 88 Janpath Road,
HC Mathura lane, Delhi: 110001
Mobile: 9999663239

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Dr. Madhuri Thakar
Scientist G
Dept. of Immunology and serology
National AIDS Research Institute,
MIDC, G-73, Bhosari, Pune-411026 (India)
Ph. no.: 020 27331200



Shailendra Gandharva <shailendra.naco@gmail.com>

Meeting Minutes of Technical Specification of BSD & STI under NACP

1 message

Dr. V.G. Somani DCGI <dci@nic.in>

To: shailendra.naco@gmail.com

6 May 2022 at 12:14

Cc: Sanjeev kumar <skgupta_1971@yahoo.com>, Fixed Dose Combination ADC <fdc@cdsco.nic.in>

Sir,

This is with reference to your trailing email dated 12.04.2022 on the subject cited above seeking comments regarding inputs on minutes of meeting of Technical Specifications for which meeting was held on 2nd & 30th of March 2022.

In this regard, it is pertinent here to mention that the technical specifications forwarded by you appears to be appropriate. However, the comments of CDSCO on some of the agendas are as under:

Agenda No	Remarks of CDSCO
No 06	It may be informed that the proposed kits are not approved by CDSCO except the treatment Kit 5 i.e. Acyclovir 400mg Tablet.
No 11	Point No 8 should be revised as under: It should be licensed as per provisions of Medical Device Rules, 2017.

This is for your information.

With kind regards,

O/o. Drugs Controller General (India)

Central Drugs Standard Control Organization (HQ)

FDA Bhawan, Kotla Road, New Delhi-110002

From: "shailendra naco" <shailendra.naco@gmail.com>

To: "drsunilgupta ncdc" <drsunilgupta.ncdc@gmail.com>, director@nariindia.org, "manjubala 2" <manjubala_2@hotmail.com>, rohitchawla75@gmail.com, pandasamiran@gmail.com, "Dr. V.G. Somani DCGI" <dci@nic.in>, sgodbole@nariindia.org, sumu3579@yahoo.com, "icmrhqds" <icmrhqds@sansad.nic.in>, "NIB" <info@nib.gov.in>, tarugarg4@yahoo.co.in, "drbhawna naco" <drbhawna.naco@gmail.com>, "drchinmoyee naco" <drchinmoyee.naco@gmail.com>

Cc: officers-bsd-naco@googlegroups.com, "shobini naco3" <shobini.naco3@gmail.com>, "drbhawani naco" <drbhawani.naco@gmail.com>, "spbhavsar phs" <spbhavsar.phs@yahoo.com>

Sent: Tuesday, April 12, 2022 11:55:47 AM

Subject: Fwd: Meeting Minutes of Technical Specification of BSD & STI under NACP

Respected members

This is a gentle reminder to all members regarding sharing inputs on suggestion/Inputs on meeting of minutes of Technical Specifications Held on 2nd & 30th of March 2022.

I would like to request you all to please share suggestions/Inputs as said above.

With thanks, feedback received from Dr. Sunil Gupta, Dr. Manju Bala & Dr. Aakansha Bisht.

Thanks,

Shailendra Gandharva

Members of Technical Specification Committee:

Sr. No.	Name	Designation and affiliation	Signature	
			02.03.2022	30.03.2022
1	Dr. Shobhini Rajan	Member Secretary, (SAG), DDG, NACO, Delhi		
2	Dr. Sanjeev Kumar	Deputy Drug Controller of India, MoH&FW, Govt. of India		
3	Dr. Sumit Agrawal	Scientist 'D', Indian Council of Medical Research (ICMR) Delhi		
4	Dr. Madhuri Thakkar	Scientist 'F' National AIDS Research Institute (NARI), Pune, (MH)		
5	Dr. Akansha Bisht	Scientist Grade II, National Institute of Biologicals, Noida (U.P)		
6	Dr. Sumathi Murlidhar	Professor & Microbiologist, Apex Regional STD Centre & SRL for HIV, Safdarjung, Delhi		
7	Dr. Manju Bala	Additional Director & HoD, Division of Microbiology, CA & ZD, Center for AIDS & related Disease, NCDC, Delhi		
8	Dr. Rohit Chawla	Professor, Dept. of Microbiology, MAMC, Delhi		
9	Dr. Taru Garg	Director Professor, Lady Harding Hospital, Delhi		

Dr. Sunil Gupta

Additional Director, HAG & HoD NCDC
