

**Minutes of the Meeting of Technical Specification Committee, NACO for
Injection Crystalline Penicillin and Procaine Penicillin under National AIDS and
STD Control Program**

A Meeting of Technical Specification Committee for Injection Crystalline Penicillin and Procaine Penicillin was convened under the Chairpersonship of Dr. Lalit Kumar Gupta, HoD, Department of Pharmacology, LHMC, New Delhi on 8th November 2024 through hybrid mode at 6th floor committee Room, NACO. All members were present in the meeting and quorum was complete.

The participants' list is enclosed at **Annexure 1**. The agenda for the meeting was to formulate the Technical Specifications for Injection Crystalline Penicillin and Procaine Penicillin. The discussions held during the meeting are as below.

- 1 At the onset, the Chairperson gave the opening remarks and set the context of the meeting. The Deputy Director, NACO placed the objective of convening the meeting. It was informed to the participants that the NACP has rolled out the guidelines for Elimination of Vertical Transmission of HIV and Syphilis (EVTHS) across India. These guidelines recommends use of Crystalline Penicillin and Procaine Penicillin for management of Congenital Syphilis. As per the National Technical Guidelines for STI and RTI 2024, these drugs are also crucial for management of neurosyphilis, oto-syphilis and oculo-syphilis among adults seen in tertiary stage of Syphilis.
- 2 It was informed to the participants that these drugs are not procured in the program nationally, due to lack of sufficient scale for national level procurement. However, the State AIDS Control Societies in their Annual Action Plan are regularly provided with the budget for local procurement of these drugs as per the need. Therefore, the meeting has been convened to develop technical specifications of Inj Crystalline Penicillin and Inj Procaine Penicillin which will be provided to SACS for further action.
- 3 The draft technical specifications were presented in the meeting and the major discussions and decision of the meeting are as below:
 - a. The names of drugs used in the Technical Specifications will be aligned to the Indian Pharmacopoeia (IP). Crystalline Penicillin, Benzyl Pencillin or

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(Dr. Anju Seth)

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(Dr. Lalit)

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(Dr. A. Bisht)

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(Dr. A. Bisht)

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(Dr. Anju Seth)

Penicillin G refers to the same drug and the terms are used interchangeably. Since the Indian Pharmacopoeia (IP) uses the term Inj Benzyl Penicillin, the same should be used in the technical specifications. It was further recommended to also mention the term Inj Penicillin G for avoiding confusion in the fields.

- b. The committee recommended that IP standards (for the time being in-force) are applicable for drugs which are available in IP. For drugs which are not available in IP, other official Pharmacopoeia(s) are applicable. If not available in any of the official Pharmacopoeia, 'In House' standards specified are applicable as per Drugs and Cosmetics Act, 1940 and Rules there under.
 - c. Since there is limited manufacturing in the country and the availability of these crucial drugs is scarce, it was recommended that if more than one strength of these formulations is available in the market, the Technical Specifications should provide the necessary flexibility to SACS to procure the drugs in required strength(s) according to the available market landscape.
- 4 After due discussions and deliberations, the committee approved the technical specifications as detailed below.

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Technical Specifications of Benzyl Penicillin Injection (for Pediatric Use only)

Product Name (Generic)	Pharmacopoeia Standards*	Strength**	Dosage Form	Number of generic products per kit	Product Indication and Description
Benzyl Penicillin Injection	I.P.	0.5 million units or 1 million units	Vial (Powder)	1	For treatment of Congenital Syphilis; for intravenous use only among children (Also called as Penicillin G Injection)
Sterile water for injection	I.P.	10 ml	Vial	1	

* Indian Pharmacopoeia (IP) standards are applicable for drugs which are available in IP (for the time being in-force). For drugs which are not available in IP, other official Pharmacopoeia(s) are applicable. If not available in any of the official Pharmacopoeia, 'In House' standards specified are applicable as per Drugs and Cosmetics Act, 1940 and Rules there under.

** If more than one strength is available in the market, required strength (s) to be procured as per the requirement and market availability.

General Technical Specifications:

1. The product specifications indicate dosage form (e.g., tablet, powder, liquid, injectable, emulsion, suspension etc.) and the drug content (exact number of mg or Unit or percentage v/v with acceptable range).
2. Not only the pharmaceuticals or vaccine items, but also packaging components (e.g., vials, bottles and closures etc.) should also confirm to specifications

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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.

3. 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).
4. 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.
5. All products must indicate the dates of manufacture and expiry.
6. All products must arrive at the consignee point with a remaining shelf life of at least five/ sixth ($5/6^{\text{th}}$) of the total shelf life at the time of manufacture.
7. Shelf life of Drug:
 - i) Benzyl Penicillin Injection: shelf life should be at least 24 months or more from the date of manufacture.
 - ii) Sterile Water for Injection: shelf life should be at least 24 months or more from the date of manufacture.

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Technical Specifications of Procaine Penicillin Injection (for Pediatric Use only)

Product Name (Generic)	Pharmacopeia Standards*	Strength**	Dosage Form	Number of generic products per kit	Product Indication and Description
Procaine Penicillin Injection	Any official Pharmacopoeia(s) or 'In House' standards	0.4 million units or 0.6 million units in 0.2 ml	Vial (Liquid)	1	For treatment of Congenital Syphilis; for intramuscular use only among children

* Indian Pharmacopoeia (IP) standards are applicable for drugs which are available in IP (for the time being in-force). For drugs which are not available in IP, other official Pharmacopoeia(s) are applicable. If not available in any of the official Pharmacopoeia, 'In House' standards specified are applicable as per Drugs and Cosmetics Act, 1940 and Rules there under.

** If more than one strength is available in the market, required strength (s) to be procured as per the requirement and market availability.

General Technical Specifications:

1. The product specifications indicate dosage form (e.g., tablet, powder, liquid, injectable, emulsion, suspension etc.) and the drug content (exact number of mg or Unit or percentage v/v with acceptable range).
2. Not only the pharmaceuticals or vaccine items, but also packaging components (e.g., vials, bottles and closures etc.) should also confirm 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.

Technical Specifications of Benzyl Penicillin Injection (for Adult Use only)

Product Name (Generic)	Pharmacopeia Standards*	Strength**	Dosage Form	Number of generic products per kit	Product Indication and Description
Benzyl Penicillin Injection	I.P.	5 million units	Vial (Powder)	1	For treatment of Neuro-Syphilis, Oculo-Syphilis and Ocular Syphilis; for intravenous use only among adults. (also called as Penicillin G injection)
Sterile water for injection	I.P.	10 ml	Vial	1	

* Indian Pharmacopoeia (IP) standards are applicable for drugs which are available in IP (for the time being in-force). For drugs which are not available in IP, other official Pharmacopoeia(s) are applicable. If not available in any of the official Pharmacopoeia, 'In House' standards specified are applicable as per Drugs and Cosmetics Act, 1940 and Rules there under.

** If more than one strength is available in the market, required strength (s) to be procured as per the requirement and market availability.

General Technical Specifications:

1. The product specifications indicate dosage form (e.g., tablet, powder, liquid, injectable, emulsion, suspension etc.) and the drug content (exact number of mg or Unit or percentage v/v with acceptable range).

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2. Not only the pharmaceuticals or vaccine items, but also packaging components (e.g., vials, bottles, and closures etc.) should also confirm 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.
3. 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).
4. 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.
5. All products must indicate the dates of manufacture and expiry.
6. All products must arrive at the consignee point with a remaining shelf life of at least five/ sixth (5/6th) of the total shelf life at the time of manufacture.
7. Shelf life of Drug:
 - iii) Benzyl Penicillin injection: shelf life should be at least 24 months or more from the date of manufacture.
 - iv) Sterile Water for Injection: shelf life should be at least 24 months or more from the date of manufacture.

Technical Specifications of Procaine Penicillin Injection (for Adult Use only)

Product Name (Generic)	Pharmacopeia Standards*	Strength**	Dosage Form	Number of generic products per kit	Product Indication and Description
Procaine Penicillin Injection	Any official Pharmacopoeia(s) or 'In House' standards	2.4 million units or 1.2 million units	Vial (Liquid)	1	For treatment of Neuro-Syphilis, Oto-Syphilis and Ocular Syphilis; for intramuscular use only among adults.

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** If more than one strength is available in the market, required strength (s) to be procured as per the requirement and market availability.

General Technical Specifications:

1. The product specifications indicate dosage form (e.g., tablet, powder, liquid, injectable, emulsion, suspension etc.) and the drug content (exact number of mg or Unit or percentage v/v with acceptable range).
2. Not only the pharmaceuticals or vaccine items, but also packaging components (e.g., vials, bottles, and closures etc.) should also confirm to specifications

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5. All products must indicate the dates of manufacture and expiry.
6. All products must arrive at the consignee point with a remaining shelf life of at least five/ sixth ($5/6^{\text{th}}$) of the total shelf life at the time of manufacture.
7. Shelf life of Drug:
 - ii) Procaine Penicillin Injection: shelf life should be at least 24 months or more from the date of manufacture.




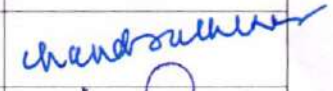
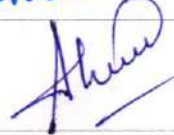






Annexure 1: List of Participants

- Dr Lalit Kumar Gupta, HOD Pharmacology, LHMC, New Delhi
- Mr Chandrashekar Ranga, Joint Drugs Controller(India), CDSCO
- Ms Akansha Bisht, Scientist Grade –I, National institute of Biologicals, MOHFW, GOI
- Dr. Abhijit Vasantrao Kadam, Scientist D, ICMR-NITVAR formerly known as ICMR-NARI, Pune
- Dr. Sumit Aggarwal, Scientist D/ Asst Director General, Indian Council of Medical Research, DHR,
- Ministry of Health and Family Welfare, New Delhi
- Dr Shobini Rajan, CMO (SAG) and HOD, BSD, STI and Prevention, NACO, MoHFW, GoI
- Dr Anju Seth, Director Professor & Head, Department of Pediatrics. Program Director, Pediatric Center of Excellence in HIV, Lady Hardinge Medical College, New Delhi
- Dr Deepika Pandhi, Director Professor, Department of Dermatology and STD, UCMS and GTBH, New Delhi
- Dr. Surendra Bisht, HOD Pediatrics and Neonatology, Swami Dayanand Hospital, MCD, Delhi
- Dr Taru Garg, Director Professor, Dermatology & Venereology, Lady Hardinge Medical College New Delhi
- Dr Saiprasad Bhavsar, Deputy Director-BSD, Prevention and STI, NACO
- Dr Jay Prakash, External Expert, Indian Pharmacopoeia Commission
- Dr Abhishek Royal, Technical Expert – STI, NACO
- Dr Vishal Yadav, Consultant – STI, NACO
- Ms. Hansa Lala, Associate Consultant, BSD, NACO



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Signatures

Sr N	Name	Designation and Affiliation	Signature
1.	Dr Lalit Gupta, Chairperson	HOD Pharmacology, Lady Harding, Medical College, New Delhi)	
2.	Mr Chandrashekar Ranga Member	Joint Drugs Controller(India), CDSCO	
3.	Dr Akanksha Bisht, Member	Scientist Grade -I, National institute of Biologicals, MOHFW, GOI	
4.	Dr. Abhijit Vasatrao Kadam, Member	Scientist D, ICMR-National Institute of Translational Virology and AIDS Research formerly known as ICMR- National AIDS Research Institute, Pune	Approval provided by email. Appended
5.	Dr. Sumit Aggarwal, Member	Scientist D/ Asst Director General, Indian Council of Medical Research, DHR, Ministry of Health and Family Welfare, New Delhi	Approval provided by email. Appended
6.	Dr Shobini Rajan, Member	CMO (SAG) and HOD, BSD, STI and Prevention, NACO, MoHFW, Gol	
7.	Dr Anju Seth, Expert	Director Professor & Head, Department of Pediatrics. Program Director, Pediatric Center of Excellence in HIV Lady Hardinge Medical College, New Delhi	
8.	Dr Deepika Pandhi, Expert	Director Professor, Department of Dermatology and STD, UCMS and GTBH, Delhi	
9.	Dr. Surender Singh Bisht, Expert	HOD Pediatrics and Neonatology, Swami Dayanand Hospital, MCD, Delhi	
10.	Dr Taru Garg, Expert	Director Professor Dermatology & Venereology, Lady Hardinge Medical College New Delhi	
11.	Dr Saiprasad Bhavsar, Member Secretary	Deputy Director, BSD, STI and Prevention, NACO, MoHFW, Gol	



Vishal Yadav <drvishalyadav23@gmail.com>

Re: Constitution of a Technical Specification Committee for procurement of Inj' Crystalline Penicillin and Procaine Penicillin under National AIDS Control...

Sat, Nov 23, 2024 at 3:55 PM

Dr. Abhijit Kadam <akadam@nariindia.org>

To: Saiprasad Bhavsar <spbhavsar.phs@yahoo.com>

Cc: taru garg <tarugarg4@yahoo.co.in>, anjuseth.peds@gmail.com, surender1 bisht <drbisht03@gmail.com>, deepika pandhi <pandhi.deepika@gmail.com>, "lkg71@rediffmail.com" <lkg71@rediffmail.com>, "director@nariindia.org" <director@nariindia.org>, "sgodbole@nariindia.org" <sgodbole@nariindia.org>, "info@nib.gov.in" <info@nib.gov.in>, "lab.ipc@gov.in" <lab.ipc@gov.in>, "Dr. Sumit Aggarwal" <doc.sumi84@gmail.com>, Dr Shobini Rajan <drshobini.naco@gmail.com>, Vishal Yadav <drvishalyadav23@gmail.com>, "dci@nic.in" <dci@nic.in>, Sella Senthil <senthilcdsco@gmail.com>, "Hekali Vikiye Zhimomi (dgoffice@naco.gov.in)" <dgoffice@naco.gov.in>, "jsofficenaco@gmail.com" <jsofficenaco@gmail.com>, "dghs@nic.in" <dghs@nic.in>, Dr Anoop Kumar Puri <ddgiecnaco@gmail.com>, "dr.ubdas.naco@gmail.com" <dr.ubdas.naco@gmail.com>, Chinmoyee Das <drchinmoyee.naco@gmail.com>, dsrk4321 <dsrk4321@gmail.com>, "sarkar.anjan@gov.in" <sarkar.anjan@gov.in>, "sarkar.anjan@nic.in" <sarkar.anjan@nic.in>, "paosectt-mhfw@nic.in" <paosectt-mhfw@nic.in>, "Dr.Manisha Ghate" <mghate@nariindia.org>

Dear Dr. Bhavsar,

Please find attached the minutes with addition of my name in the file circulated by Dr. Bisht Sir.

I approve the minutes

With best regards

Dr. Abhijit Vasanttrao Kadam

MBBS, MD (Pharmacology)

Scientist D

ICMR-National Institute of Translational Virology and AIDS Research formerly known as ICMR-National AIDS

Research Institute, Pune

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**Dr. Kadam name addition_Dr SSBISHT - three crrectins.docx**

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Vishal Yadav <drvishalyadav23@gmail.com>

Re: Constitution of a Technical Specification Committee for procurement of Inj' Crystalline Penicillin and Procaine Penicillin under National AIDS Control...

Sat, Nov 23, 2024 at 1:10 PM

Dr. Sumit Aggarwal <doc.sumi84@gmail.com>

To: taru garg <tarugarg4@yahoo.co.in>

Cc: anjuseth.peds@gmail.com, surender1 bisht <drbisht03@gmail.com>, deepika pandhi <pandhi.deepika@gmail.com>, Saiprasad Bhavsar <spbhavsar.phs@yahoo.com>, "lkg71@rediffmail.com" <lkg71@rediffmail.com>, "director@nariindia.org" <director@nariindia.org>, "sgodbole@nariindia.org" <sgodbole@nariindia.org>, "info@nib.gov.in" <info@nib.gov.in>, "lab.ipc@gov.in" <lab.ipc@gov.in>, Dr Shobini Rajan <drshobini.naco@gmail.com>, Vishal Yadav <drvishalyadav23@gmail.com>, "dci@nic.in" <dci@nic.in>, Sella Senthil <senthilcdsco@gmail.com>, "Dr. Abbhijit Kadam" <akadam@nariindia.org>, "Hekali Vikiye Zhimomi (dgoffice@naco.gov.in)" <dgoffice@naco.gov.in>, "jsofficenaco@gmail.com" <jsofficenaco@gmail.com>, "dghs@nic.in" <dghs@nic.in>, Dr Anoop Kumar Puri <ddgiecnaco@gmail.com>, "dr.ubdas.naco@gmail.com" <dr.ubdas.naco@gmail.com>, Chinmoyee Das <drchinmoyee.naco@gmail.com>, dsrk4321 <dsrk4321@gmail.com>, "sarkar.anjan@gov.in" <sarkar.anjan@gov.in>, "sarkar.anjan@nic.in" <sarkar.anjan@nic.in>, "paosectt-mhfw@nic.in" <paosectt-mhfw@nic.in>

Dear Dr Saiprasad Bhavsar

The attached minutes of the meeting for formulation of Technical Specifications of Inj Crystalline and Procaine Penicillin are approved from my end.

Regards

Sumit

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Dr. Sumit Aggarwal,

MBBS MD

Scientist D/ Asst Director General,
Indian Council of Medical Research, DHR,
Ministry of Health and Family Welfare,
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