

**Subject: Minutes of Technical Specification Committee for revision of technical specifications of plain Buprenorphine and Buprenorphine + Naloxone Tablet under National AIDS Control Program**

Venue: Virtual Meeting

Date: 6<sup>th</sup> February 2023

Time: 2:30 PM

A meeting of the Technical Specification Committee was held under the Chairpersonship of Dr. Sunil Gupta, Principal Consultant, NCDC, Ministry of Health and Family Welfare, Government of India on 6<sup>th</sup> February 2023 to revise the technical specification of Tablet Buprenorphine and Buprenorphine + Naloxone Combination being procured for the Opioid Substitution Therapy (OST) programme for Injecting Drug Users (IDU) under the National AIDS Control Program, Ministry of Health and Family Welfare, Government of India.

Participants to the Technical Specification Committee meeting included the following members:

Dr. Sunil Gupta, Principal Consultant, NCDC, MoHFW

Dr. Shobini Rajan, CMO SAG, NACO

Dr. Bhawani Singh, DD-TI, NACO, MoHFW

Sh. A.K Pradhan, Joint Drugs Controller (India), MoHFW

Dr. Sumit Agarwal, Scientist- D and Program officer, ECD, ICMR-HQ, New Delhi

Dr. Abhijit Kadam, Scientist -C, ICMR-National AIDS Research Institute, (ICMR-NARI) Pune

Dr. Gauri Mishra, Scientist Grade II, National Institute of Biologicals (NIB)

Dr. Atul Ambekar, Professor, Dept.of Psychiatry & NDDTC, AIIMS

Dr. Ravindra Rao, . Professor, Dept. of Psychiatry and NDDTC, AIIMS

Dr. Pooja Gupta, MD, DM, Additional Professor, Dept. of Pharmacology AIIMS













**Agenda I: To revise the Technical Specifications of Buprenorphine sublingual tablet.**

After the discussion and the deliberations between the members, the final specifications approved by the committee for Buprenorphine sublingual tablet are as follows:

<b>Product</b>	<b>Composition</b>	<b>Package requirement</b>
Tablet Buprenorphine, 0.4mg	Each uncoated sublingual tablet contains Buprenorphine Hydrochloride IP equivalent to Buprenorphine 0.4mg	Blister pack of 10 tablets and 10 blister packs per box.
Tablet Buprenorphine, 2mg	Each uncoated sublingual tablet contains Buprenorphine Hydrochloride IP equivalent to Buprenorphine 2mg	Blister pack of 10 tablets and 10 blister packs per box.

- a. The shelf life should be minimum 3 years from the date of manufacture
- b. The manufacturer/supplier shall submit an undertaking of conformance to the rules and regulations laid down in the Narcotic Drugs and Psychotropic Substances ACT 1985 and its amendments, and the Drugs and Cosmetics Act 1940 and the rules thereof. The undertaking should be accompanied with all relevant documents and certifications.
- c. The manufacturer/supplier shall submit certificate of GMP (Good Manufacturing Practice) and Market Standing Certificate.
- d. The manufacturer / supplier shall submit the proof of a valid product license congruent to the Drugs and Cosmetics Act 1940.
- e. The Buprenorphine sublingual tablets should be tasteless and odourless
- f. The Buprenorphine sublingual tablets should fulfill the general and/or individual drug requirements as per Indian Pharmacopoeia (IP)
- g. All blister packs of Buprenorphine sublingual tablets must indicate the dates of manufacture and expiry.
- h. All consignments must arrive at the final consignee point with a remaining shelf life of at least five-sixths (5/6ths) of the total stipulated shelf life at the time of manufacture.

*R. Rao*  
*LA*  
*Hupla*  
*edunt*  
*[Signature]*

**Agenda II: To revise the Technical Specifications of Buprenorphine + Naloxone combination sublingual tablet.**

After the discussion and the deliberations between the members, the final specifications approved by the committee for Buprenorphine sublingual tablet are as follows:

Product	Composition	Package Requirement
Tablet Buprenorphine-Naloxone 0.4/0.1 mg	Each uncoated sublingual tablet contains Buprenorphine Hydrochloride IP equivalent to Buprenorphine 0.4mg and Naloxone Hydrochloride IP equivalent to Naloxone 0.1mg	Blister pack of 10 tablets and 10 blister packs per box.
Tablet Buprenorphine-Naloxone 2/0.5 mg	Each uncoated sublingual tablet contains Buprenorphine Hydrochloride IP equivalent to Buprenorphine 2mg and Naloxone Hydrochloride IP equivalent to Naloxone 0.5mg	Blister pack of 10 tablets and 10 blister packs per box.

- a. The shelf life should be minimum 3 years from the date of manufacture
- b. The manufacturer/supplier shall submit an undertaking of conformance to the rules and regulations laid down in the Narcotic Drugs and Psychotropic Substances ACT 1985 and its amendments, and the Drugs and Cosmetics Act 1940 and rules thereof. The undertaking should be accompanied with all relevant documents and certifications.
- c. The manufacturer/supplier shall submit certificate of GMP (Good Manufacturing Practice) and Market Standing Certificate.
- d. The manufacturer /supplier shall submit the proof of a valid product license congruent to the Drugs and Cosmetics Act 1940.
- e. The Buprenorphine and Naloxone combination sublingual tablets should be tasteless and odourless
- f. The fixed dose combination of Buprenorphine and Naloxone sublingual tablets should fulfill the general and/or individual drug requirements as per the Indian Pharmacopoeia (IP) with effect from date of notification in Indian Pharmacopoeia\*
- g. All blister packs must indicate the dates of manufacture and expiry.
- h. All consignments must arrive at the final consignee point with a remaining shelf life of at least five-sixths(5/6ths) of the total stipulated shelf life at the time of manufacture.

\* for batches manufactured prior to date of notification, as per latest USP.


  







Sh. AK Pradhan,  
Joint Drugs Controller  
(India), MoHFW


Dr. Abhijit Kadam,  
Scientist – C,  
ICMR (NARI)


  
Dr. Sumit Agarwal,  
Scientist- D and  
Program Officer, ECB  
ICMR HQ


Dr. Gauri Mishra  
Scientist Grade II,  
National Institute of  
Biologicals (NIB)

  
Dr. Pooja Gupta, MD, DM,  
Additional. Professor,  
Dept. of Pharmacology,  
AIIMS

  
Dr. Ravindra Rao,  
Professor,  
Dept. of Psychiatry &  
NDDTC, AIIMS

  
Prof. Atul Ambekar,  
Professor,  
Dept. of Psychiatry &  
NDDTC, AIIMS

  
Dr. Bhawani Singh,  
DD-TI, NACO,  
MoHFW

  
Dr. Shobini Rajan,  
CMO SAG, NACO,  
MoHFW

  
Dr. Sunil Gupta  
Principal Consultant,  
NCDC, MoHFW

**Note # 39**

With reference to Note # 38, Minutes of the Technical Specification Committee meeting of NACO for revision of the technical specifications of Buprenorphine tablet and Buprenorphine + Naloxone combination tablet under National AIDS Control Programme (NACP) held on 06.02.2023 are placed at DFA/8456733 these are concurred by all members.

Submitted for kind approval of Chairperson (Technical Specification Committee), please.

01/03/2023 01:42 PM

**BHAWANI SINGH  
DEPUTY DIRECTOR -NACO**

**Note # 40**

For kind approval please

01/03/2023 02:44 PM

**SHOBINI RAJAN  
CMO(SAG)**

**Note # 41**

I agree with the revised technical specifications as mentioned in the draft minutes as these have been agreed to by all the members of the committee

06/03/2023 11:10 AM

**DR. SUNIL GUPTA  
PRINCIPAL CONSULTANT**

**Note # 42**

06/03/2023 01:17 PM

**SHOBINI RAJAN  
CMO(SAG)**

**Note # 43**

06/03/2023 02:33 PM

**BHAWANI SINGH  
DEPUTY DIRECTOR -NACO**

P 5/5

**Mung Ngaihte** <ginmung.naco@gmail.com>

Mon, Feb 6,  
3:43 PM

to drgupta.pooja@gmail.com, drguptanivedita, akadam, guptanivedita.hq, National, drpooja009, Ravindra, drsumiticmr, Atul, sanjeevkumar15, Drug, Sunil, Shobini, Bhawani, Sanjay, Shantanu

Respected Sir/Madam,

First of all we thank you for attending the meeting today.

Please find attached the Revised Technical Specifications as discussed during the meeting.

In this regard, I request all to kindly provide concurrence by mail so that the same can be put up for approval of Chairperson.

Thanking you

On Mon, Feb 6, 2023 at 11:47 AM Anita Guliyani <[anitaguliyani77@gmail.com](mailto:anitaguliyani77@gmail.com)> wrote:

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Best Regards,

Mung Ngaihte

Consultant- TI  
Targeted Intervention Division  
National AIDS Control Organisation  
Ministry of Health & Family Welfare  
6th and 9th Floor, Chandralok Building

**One attachment** • Scanned by Gmail



**Dr  
Sumit**

Mon, Feb 6, 5:45 PM

**Aggar  
wal**

Dear Dr Mung, Thank you for MoM, I am fine with it. Regards Sumit



**Atul Ambekar**

Tue, Feb 7,  
4:41 PM

to Sunil, Shobini, Bhawani, me

Dear Sir / Madam

I regret not receiving the meeting notice in time and hence missing this meeting. However, I agree to the specifications as finalized by the committee.

Regards

**Dr. Atul Ambekar, M.D.**

Professor

National Drug Dependence Treatment Centre and Department of Psychiatry

All India Institute of Medical Sciences,

New Delhi, India - 110029

&

Secretary General

Addiction Psychiatry Society of India (APSI)

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Email: [atul.ambekar@gmail.com](mailto:atul.ambekar@gmail.com)

Website: [Click Here](#)

Twitter: @atulambekar

FB: [fb.com/atul.ambekar](https://www.facebook.com/atul.ambekar)

<https://addictionpsychiatry.in/>

**Dr. Abhijit Kadam**

Mon, Feb 27, 1:00 PM (1  
day ago)

to me

Dear Dr. Mung,

Please find attached the minutes with minor edit in affiliation ( highlighted in yellow) and one comment in agenda 2.

The agenda 2 was primarily discussed on 06 Feb 2023 meeting and I approve the same. Please see if the comment given in agenda 2 could be incorporated.

With best regards

Dr. Abhijit Vasantryo Kadam

Scientist C

ICMR-National AIDS Research Institute

Pune

**One attachment** • Scanned by Gmail

From: **GAURIMISRA** <[gauri.misra@nib.gov.in](mailto:gauri.misra@nib.gov.in)>

Date: Mon, 27 Feb 2023 at 17:37

Subject: Re: Fwd: Meeting to update the Technical Specification of tablet  
Burprenorphine used for OST programme under NACP on 06th February-2023 at  
2.30 PM onwards

To: sanjayverma naco <[sanjayverma.naco@gmail.com](mailto:sanjayverma.naco@gmail.com)>

Dear Dr. Verma,

It's fine from my side.

Approved

Regards,

Gauri

**Pooja Gupta**

Mon, Feb 27, 6:19 PM (22  
hours ago)

to me

I had concurred earlier also. Kindly acknowledge the receipt of this email.

Regards

Pooja

On Wed, 15 Feb 2023 at 3:40 PM, Pooja Gupta <[dr Gupta.pooja@gmail.com](mailto:dr Gupta.pooja@gmail.com)> wrote:  
I concur with the specifications as proposed.

My designation may be updated to Additional Professor.

Regards,

Pooja

Dr Pooja Gupta,

MD, DM (Clinical Pharmacology), MAMS

Additional Professor, Pharmacology,  
Rno 5004, 5th Floor, Convergence Block,  
All India Institute of Medical Sciences  
Ansari Nagar, New Delhi - 110029.  
India

Member Secretary, IEC Subcommittee for clinical trial SAE, AIIMS, New Delhi

Membe

r, National AEFI Subcommittees

(

Causality Assessment; Advocacy & Media), MoH&FW, GoI

Coordinator,  
AIIMS Pharmacovigilance & Materiovigilance Centres, PvPI & MvPI, MoH&FW, GoI  
Former Member, INYAS, INSA (2016-21)

Ph: (O) 011- 26549257/ 26593282,  
(M) 9560569977

Email: [dr Gupta.pooja@aiims.gov.in](mailto:dr Gupta.pooja@aiims.gov.in)

Webpage:

[http://www.aiims.edu/en/2014-12-11-07-55-10/pharmacology\\_faculty/112-pharmacology/2964-dr-pooja-gupta\\_phar\\_9\\_5\\_15.html](http://www.aiims.edu/en/2014-12-11-07-55-10/pharmacology_faculty/112-pharmacology/2964-dr-pooja-gupta_phar_9_5_15.html)

Linkedin:

<https://www.linkedin.com/in/pooja-gupta-55ba1718/>

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**Arun Pradhan**

Tue, Feb 28, 5:23 PM (16  
hours ago)

to me

Sir / Madam,  
It is fine with me.  
Regards,

Sh. A.K. Pradhan  
Joint Drugs Controller (India)  
CDSCO, Directorate General of Health Services, Ministry of Health & Family Welfare, Govt.  
of India  
FDA Bhawan, Kotla Road, New Delhi-2

