

**Minutes of the Technical Specification Committee meeting on DEC & Ivermectin**  
**Date: January 24<sup>th</sup>, 2023, Nirman Bhawan, New Delhi**

A hybrid meeting was held on 24/01/2023 (4.00pm to 5.00pm) at Resource Centre (445-A), Nirman Bhawan under the Chairmanship of DGHS with members of the Technical Specification Committee for review/finalize technical specification of Filaria Drugs. **The list of participants is annexed.**

The main discussion points are given below:

- NCVBDC presented the draft Technical Specification of DEC and Ivermectin to the Technical Specification Committee experts. The experts provided inputs on the technical specifications of DEC and Ivermectin (IVM) and suggested the incorporation of the same
- Dr Rupak Chatterjee, Advisor MSO suggested the following changes:
  - DEC specifications - Citrate to be removed from title of DEC
  - DEC specifications - Spelling in Insert to be corrected to **ADMINISTRATION**
  - DEC & IVM specifications - There should be separate headings for Shelf life and efficacy
  - DEC & IVM specifications - GMP clause should be removed as it makes the technical specifications restrictive and is implied in the procurement process.
- Dr Rupak Chatterjee and Dr Atul Goel, DGHS suggested the following modifications for shelf life in both DEC & IVM technical specifications
  - **The shelf life of DEC tablets should be based on stability.**
  - **The required shelf life should be preferably more than 24 months to less than or equal to 36 months.**
- Sr Sanjeev Kumar DDC (I) DCGI mentioned the following changes:
  - IVM is now available in IP 2022 and DEC is available in IP 2018. It was requested to provide the latest Indian Pharmacopeia monograph for DEC and Ivermectin
  - Marking should be modified in both technical specifications as - Printing/markings on blister strip/catch cover / box and pack should be as per **Drugs and Cosmetics Act 1940 and Rules made thereunder and as amended from time to time**
- Dr Rinku Sharma, JD NCVBDC mentioned IP to be included in title
- Dr K Krinshnamoorthy suggested that Inset should be prepared for IVM too
- Dr Anil Kumar suggested modification under leaflet/ Insert - Who should take DEC tablets? **It is contraindicated in the following groups:**

Handwritten signatures and initials in blue ink at the bottom of the page, including names like Anil Kumar, Rinku Sharma, and others.

- The Draft Technical Specifications of DEC and Ivermectin will be updated post incorporation of suggestions of the experts and the same will be circulated to experts for their final inputs (if any)

The meeting ended with a vote of Thanks to the Chair



Dr. Rinku Sharma, Officer in Charge,  
Procurement NCVBDC



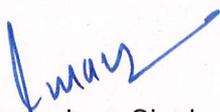
Dr. Chhavi Pant Joshi, Officer in Charge,  
LF Division, NCVBDC



Dr. Rupak Chatterjee  
Advisor (Store), Dte.GHS



Dr Kamalakar Arjun Lashkare  
Representative from WHO Country office



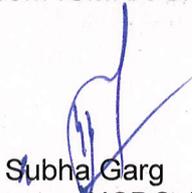
Dr. Amandeep Singh  
Expert from AIIMS, Delhi



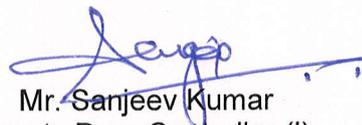
Dr. Nishant Verma  
Expert from AIIMS, Delhi

Dr. Krishnamoorthy  
Expert from ICMR/VCRC

Dr. Nishant Dev  
Expert from Safdarjung hospital, Delhi



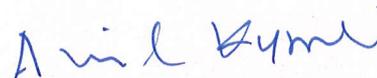
Dr. Subha Garg  
Deputy Director, NCDC, Delhi



Mr. Sanjeev Kumar  
Deputy Drug Controller (I),



Dr. Tanu Jain  
Director NCVBDC, Delhi



Dr. Anil Kumar Addl. DGHS, Dte.GHS



Dr. Atul Goel  
Director General of Health Services (MoH&FW)

In Person Participation

1. Dr. Atul Goel, DGHS
2. Dr. Anil Kumar, Additional DGHS
3. Dr. Tanu Jain, Director, NCVBDC
4. Dr. Chhavi Pant Joshi, Joint Director, NCVBDC
5. Dr. Rinku Sharma, Joint Director, NCVBDC
6. Dr. Rupak Chatterjee, Advisor (Store), Dte. GHS
7. Mr. Sanjeev Kumar, Deputy Drug Controller (I)
8. Dr. Shubha Garg, Deputy Director, NCDC, Delhi
9. Dr. Amandeep Singh, Expert from AIIMS, Delhi
10. Dr. Nishant Verma, Expert from AIIMS, Delhi
11. Mr. Anil Kumar Mehta, Procurement, NCVBDC
12. Mr. Rajat, Procurement, NCVBDC
13. Mr. Banit Kumar, Procurement, NCVBDC
14. Dr. Manik Relan, Consultant, NCVBDC

Virtual Participation

1. Dr. Krishnamoorthy, Expert from ICMR/VCRC
2. Dr. Kamalakar Arjun Lashkare, Representative from WHO Country office
3. Dr. Nishant, Expert from Safdarjung hospital Delhi

**National Centre for Vector Borne Diseases Control**

Date: 24.01.2023

**Technical specification of Diethylcarbamazine (DEC) Tablets IP (100 mg) & its packing**

<b>Description of product</b>	Strength of each tablet –100 mg.																														
<b>Shelf Life</b>	a) The shelf life of DEC tablets should be based on stability. b) The required shelf life should be preferably more than 24 months to less than or equal to 36 months.																														
<b>Efficacy</b>	The articles would not pass more than 1/6th of effective life from the date of manufacture at the time when articles are offered for inspection and the remaining useful life that shall be left would <u>not be less than 5/6th of the assigned shelf life.</u>																														
<b>Packing &amp; marking</b>	Packing: Thirty tablets should be packed in one blister strip packing. The tablets in each strip should be arranged in three rows of ten tablets each with perforated line across each three tablets to facilitate easy breaking away of three tablets at a time from the main strip  <table border="1" data-bbox="443 1032 1193 1160"> <tr><td>O</td><td>O</td><td>O</td><td>O</td><td>O</td><td>O</td><td>O</td><td>O</td><td>O</td><td>O</td></tr> <tr><td>O</td><td>O</td><td>O</td><td>O</td><td>O</td><td>O</td><td>O</td><td>O</td><td>O</td><td>O</td></tr> <tr><td>O</td><td>O</td><td>O</td><td>O</td><td>O</td><td>O</td><td>O</td><td>O</td><td>O</td><td>O</td></tr> </table> Twenty-five blister strips should be placed in one pack amounting to a total of 750 tablets	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O
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<b>Each of 25 strips contains leaflet/product insert as follows:</b>	<p align="center"><b>Instruction And Dosage Scheduled of Tablets DEC 100 mg for “MASS DRUG ADMINISTRATION”</b></p> <p><b><u>Who should take DEC tablets?</u></b></p> <p>Everyone living in filariasis-affected areas, even if apparently healthy should take a single dose of DEC tablets along with other MDA drugs as per NCVBDC guideline.                  It is contraindicated in the following groups:</p> <ul style="list-style-type: none"> <li>• Children below two years of age.</li> <li>• Pregnant women.</li> <li>• Seriously ill persons.</li> </ul> <p><b><u>What is the dosage schedule of DEC tablets?</u></b></p> <p>DEC tablets should be taken as per age group and dosage scheduled indicated below:</p> <p><b><u>Age group - Dosage</u></b>                  2- ≤5-years - 1 tablet                  5- ≤15years- 2 tablet                  15 years &amp; above- 3 tablet</p>																														

*Handwritten signatures and initials in blue ink at the bottom of the page, including 'mas', '3/13/2023', 'Chant', 'A. Williams', and others.*

<b>Marking</b>	Printing/marketing on blister strip/catch cover / box and pack should be as per Drugs and Cosmetics Act 1940 and Rules made thereunder and as amended from time to time . Each blister strip/Catch Cover/box and pack should be marked "NCVBDC, Dte. GHS SUPPLY -NOT FOR SALE".
<b>Final Packing</b>	One hundred packs (of 25 strips each) amounting to 75000 should be placed in normal trade packing of corrugated boxes to avoid loss or damage during the transit by rail/road.
The technical specification of DEC tablets should be in line with the monograph laid down in Indian Pharmacopeia 2018	



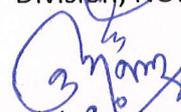
Dr. Rinku Sharma, Officer in Charge,  
Procurement NCVBDC



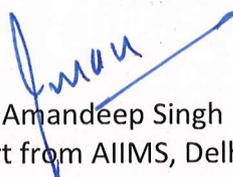
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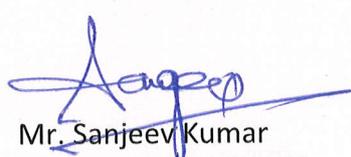
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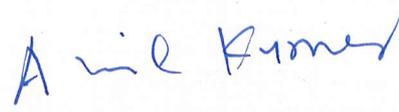
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Director General of Health Services (MoH&FW)

**National Centre for Vector Borne Diseases Control**

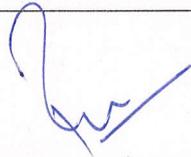
**Date: 24.01.2023**

**Technical specifications of Ivermectin Tablets IP (3mg) & its packing**

<b>Description of product</b>	Ivermectin Tablets containing not less than 90% and not more than the equivalent of 110% of the stated amount of Ivermectin with strength of each tablet – 3mg.																														
<b>Shelf Life</b>	<p>a) The shelf life of Ivermectin tablets should be based on stability.</p> <p>b) The required shelf life should be preferably more than 24 months to less than or equal to 36 months.</p>																														
<b>Efficacy</b>	The articles would not pass more than 1/6th of effective life from the date of manufacture at the time when articles are offered for inspection and the remaining useful life that shall be left would <u>not be less than 5/6th of assigned shelf life.</u>																														
<b>Packing &amp; marking</b>	<p>Packing: Thirty tablets should be packed in one blister strip packing. The tablets in each strip should be arranged in three rows of ten tablets each with perforated line across each three tablets to facilitate easy breaking away of three tablets at a time from the main strip</p> <table border="1" data-bbox="359 929 1077 1052"> <tr><td>O</td><td>O</td><td>O</td><td>O</td><td>O</td><td>O</td><td>O</td><td>O</td><td>O</td><td>O</td></tr> <tr><td>O</td><td>O</td><td>O</td><td>O</td><td>O</td><td>O</td><td>O</td><td>O</td><td>O</td><td>O</td></tr> <tr><td>O</td><td>O</td><td>O</td><td>O</td><td>O</td><td>O</td><td>O</td><td>O</td><td>O</td><td>O</td></tr> </table> <p>Twenty-five blister strips should be placed in one pack amounting to a total of 750 tablets.</p>	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O
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Each of 25 strips contains a leaflet /product insert as follows:	<p align="center"><b>Instruction And Dosage Scheduled of Tablets Ivermectin 3 mg for “MASS DRUG ADMINISTRATION”</b></p> <p><b><u>Who should take Ivermectin tablets?</u></b></p> <p>Everyone living in filariasis affected areas, even if apparently healthy should take a single dose of Ivermectin tablets along with other MDA drugs in Districts where triple drug therapy is administered as per NCVBDC guideline.</p> <p>It is contraindicated in the following groups:</p> <ul style="list-style-type: none"> <li>• Children with a height less than 90 cm.</li> <li>• Children less than 5 years of age.</li> <li>• Lactating mother until one week of birth</li> <li>• Pregnant women.</li> <li>• Seriously ill persons.</li> </ul> <p><b><u>What is the dosage schedule of Ivermectin tablets?</u></b></p> <p>Ivermectin tablets should be taken as per height and dosage scheduled indicated below:</p> <p><u>Dosage as per Height</u> 90cm-119 cm - 1 tablet</p>																														

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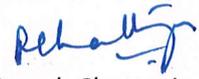
	120cm -140cm- 2 tablets 141cm- 158 cm-3 tablets >158cm- 4 tablets
<b>Marking</b>	Printing/marking on blister strip/catch cover / box and pack should be as per Drugs and Cosmetics Act 1940 and Rules made thereunder and as amended from time to time . Each blister strip/Catch Cover/box and pack should be marked "NCVBDC, Dte. GHS SUPPLY - NOT FOR SALE".
<b>Final Packing</b>	One hundred packs (of 25strips each) amounting to 75000 should be placed in normal trade packing of corrugated boxes to avoid loss or damage during the transit by rail/road.
The technical specification of Ivermectin tablets should be in line with the monograph laid down in Indian Pharmacopoeia-2022	



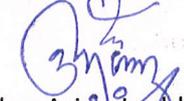
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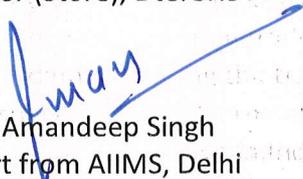
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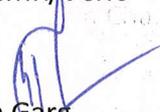
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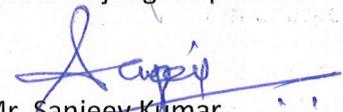
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Addl. DGHS, Dte. GHS



Dr. Atul Goel  
Director General of Health Services (MoH&FW)

Comp. No. 8198226

Note # 57

matter discussed with Director:-

Refer Note #48 wherein DGHS has suggested to incorporate the specific inputs as provided by technical experts, the following is submitted.

1. The meeting of Technical Specification Committee (TSC) for LF drugs and diagnostics was convened on 24.01.23 under Chairpersonship of DGHS. The file with minutes of meeting and revised Technical specifications were submitted vide Note# 41, as per inputs/ agreement (placed at **local reference 4**) of Dr Rupak Chaterjee Advisor MSO, Dr Krishnamurthy VCRC, Dr Nishant Dev AIIMS Delhi, Dr Kamlaker Lashkare NPO Filaria, Dr VG Somani DCGI (sharing the monograph to Ivermectin)

2. As per observation of DGHS, further the modified minutes including specific comments of experts were circulated vide email dated 10 Feb 2023, placed at **local reference 5**. The comments (placed at **local reference 6**) have been received from Dr Krishnamoorthy VCRC, Dr Rupak Chaterjee Advsor MSO and Dr Aswani Kumar, Director VCRC.

Accordingly the draft minutes of meeting are placed at **DFA/8455981** for approval.

The Technical specification of DEC 100 mg are placed at **local reference 7** and Ivermectin 3 mg placed at **local reference 3** for approval pls.

Submitted for approval of DGHS pls, before seeking signature of committee members.

28/02/2023 02:49 PM

CHHAVI PANT JOSHI  
JOINT DIRECTOR

Note # 58

28/02/2023 03:16 PM

NUPUR ROY  
SR. CMO(SAG)

Note # 59

28/02/2023 03:30 PM

TANU JAIN  
DIR(NVBDCP)

Note # 60

28/02/2023 08:48 PM

DR ATUL GOEL  
DIRECTOR GENERAL

Note # 61

28/02/2023 09:43 PM

TANU JAIN  
DIR(NVBDCP)

Note # 62