

Final specification of Diethylcarbamazine Citrate Tablets (100 mg) & its packing

Description of stores:

Diethylcarbamazine Citrate Tablets containing not less than 93.0% and not more than the equivalent of 107% of the stated amount of Diethylcarbamazine Citrate – as per IP 1996.
Strength of each tablet – 100 mg.

Shelf Life/Efficacy:

The shelf life of DEC tablets should be accepted as three years or more. (Not to exceed 60 months)
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 not be less than 5/6th of total of five years.

Packing & Marking:

Packing: Thirty tablets should be packed in one blister trip packing with transparent top and aluminum back. 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 the main strip.

Twenty five blister strips should be placed in one pack. Each pack of 25 strips should contain leaflet/ product insert as follows:

**INSTRUCTION AND DOSAGE SCHEDULED OF
Tablets DEC 100 mg for “MASS DRUG
ADMINIASTATION”**

Who should take DEC tablets?

Everyone living in filariasis affected areas, even if apparently healthy should take a single dose of DEC tablets.

However, the following groups should not be given the medicine:

- Children below two years of age.
- Pregnant women. &
- Seriously ill persons.

How often DEC tablets are to be taken?

DEC tablets are to be taken once a year during MASS Drug Administration campaign for 5-7 years consecutively.

DEC tablets should be taken as per age group and dosage scheduled indicated below:

<u>Age group</u>	<u>Dosage</u>
2-5- years	1 tablets of 100 mg
6-14 years	2 tablets of 100 mg
15 years & above	3 tablets of 100 mg

Marking: All tablets should carry the legend “NVBDGP” on one side and cross line on the other side. Printing/marking on blister strip/catch cover / box and pack should be as per drug and Cosmetics Rules. Each Blister strip/Catch Cover/box and pack should be marked “NVBDGP SUPPLY - NOT FOR SALE”.

Final Packing:

One hundred packs (of 25 strips each) should be placed in normal trade packing of corrugated boxes to avoid loss or damage during the transit by rail/road.