Technical specification of Ivermectin Tablets (3mg)

1. **Description of stores:** Ivermectin Tablets containing not less than 90% and not more than the equivalent of 110% of the stated amount of Ivermectin in white color tablet with strength of each tablet – 3 mg.

2. **Shelf Life/Efficacy:**

a. Shelf life is the period of time, from the date of manufacture, that a drug product is expected to remain within its approved product specification while stored under defined conditions. **Shelf life of Ivermectin 3 mg will be based on the stability data.**

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 not be less than 5/6th of total shelf life.

3. **Packing & Marking:**

a. ***Packing:*** Thirty tablets should be packed in one blister strip packing with transparent top and aluminum back. The tablet in each strip should be arranged in 3 rows of ten tablets each with perforated line across each three tablets. Twenty five blister strips should be placed in one pack.

b. ***Marking:*** 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 "NVBDCP SUPPLY - NOT FOR SALE".

c. **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.

4. **Good Manufacturing Practices** :
The manufacturing facility must conform to GMP.

5 The technical specification of Ivermectin Tablets should be in line with the monograph laid down in International Pharmacopoeia, 2019 .

29/06/2020.

Joint Director
NVBDCP
Delhi