Requirements for submitting Therapeutic Antibody samples (mAbs) for QC testing

A. *For products whose testing capability is* ***NOT YET ESTABLISHED*** *at NIB*

1. For non-pharmacopoeial products/ Biosimilars received at NIB for the first time, the concerned lab will first assess the feasibility of testing the QC parameters based on their Methods of Analysis (MOA), based on which may request the manufacturer to supply specific reagents/ consumables/ reference standards/ cell lines for QC testing. Completion of testing of new mAabs may take at least 4 months.
2. The time of submission of the samples will be considered from the date of receipt of all the requested reagents/ consumables/ reference standards/ cell lines from the manufacturer.
3. Failure to supply the requested reagents/ consumables/ reference standards/ cell lines within 3 months shall automatically cause the manufacturer to withdraw the sample from NIB.
4. The concerned lab shall undertake new molecules based on the number of products under standardisation and their detailed testing procedures.

B. *For products whose testing capability is established at NIB but* ***received after a gap of 1 year***

NIB may request the manufacturer to send the specific reagents/ chemicals/ reference standards for QC testing.

C. *For products whose testing capability is* ***already established at NIB (as per the testing fee document)***

The laboratory may ask for manufacturer-specific reagents including reference standards from the manufacturers. The Turn Around Time (TAT) will commence from the day of the last logistics received at NIB.

Effective from: 22.02.2024 **Validity: Till further revision**