BATCH CERTIFICATION OF ANTIBIOTICS

Read online (full-text search, related cases, audio case brief): https://batas.org/library/bbe2156a8a9e/

The BFAD is currently devising methods to facilitate batch certification of antibiotics.

For this purpose, all applicants for batch certification are requested to submit the following documents with their letter of request:

- Complete production record of the batch concerned.

- In process control record of the batch concerned.

- Complete terminal quality control record of the batch to include all requirements of the official monograph.

- Samples for validation:

4.1 six (6) bottles for suspension/syrup

4.2 one (1) bottle x 100’s or 2 bottles x 50’s for tablets/capsules or equivalent no. of stripped/blister packed form

4.3 six (6) vials/ ampules for injectible form

4.4 four (4) tubes for ointment/cream

For your guidance and compliance.

Adopted: 7 May 1990

(SGD.) CECILE P. GONZALEZ

Director

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