



FINISHED PRODUCT START UP LAB TESTING PROCEDURE

After clean room start-up, the following minimum lab-testing schedule for finished goods must be adhered to:

Outside Lab Testing

- a. One finished product sample from each lot will be collected between the middle and end of each lot run to be sent overnight on a daily basis to the outside testing lab.
- b. Copies of all outside test results will be forwarded to the Product Supervisor.

This side-by-side testing will be performed for four weeks and if passed, the routine testing schedule outlined in section 12 will be adhered to

GENERAL TESTING PROCEDURES:

The following technique shall be used for D/E Neutralizing Test and Yeast and Mould Test.

1. Tear open Bag Bath sample.
2. Select appropriate HYcheck test tube.
3. Loosen cap and remove the HYcheck slide from the test tube taking care not to touch the surface of the slide.
4. Press the slide firmly onto the test surface for a few seconds taking care not to smear over the test area.
5. Repeat the procedure using the second surface of the slide.
6. Replace the slide into the container and close tightly.
7. Label with date, time, sample lot and batch number.
8. Incubate in an upright position.
 - a. D/E Neutralizing: Incubate at 35-37 degrees C.
Read and record results of both sides of slide at 24 and 48 hours.
 - b. Yeasts and Moulds: Incubate at 30 degrees C.
Read and record results of clear side at 48 hours.
Read and record results of pink side at 120 hours.
9. Discard test tube when test has been completed and results have been recorded.

The test is performed according to European Pharmacopoea Category 2.

3 different results can be given:

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|---------------------------|---|-------------|
| a) 0 bacteria/g | = clean plate, no growth at all. | = Approved. |
| b) below 5x100 bacteria/g | = below upper limit of bacteria amount,
no prohibited bacterias. | = Approved. |
| c) over 5x100 bacteria/g | = over limit of allowed bacteria amount,
or any prohibited bacteria. | = REJECTED. |

All BagBath test results so far has been 0 bact/g,