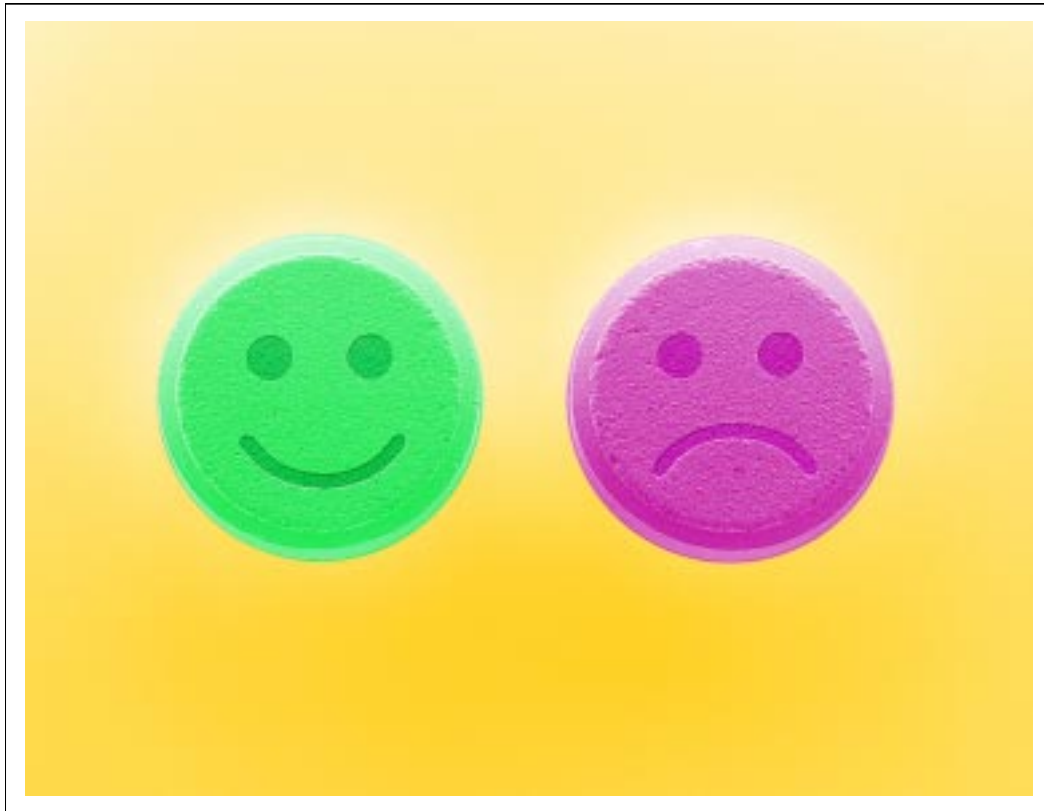


A Concise Quality Control Guide On Essential Drugs

Manual

Accompanying The GPHF-Minilab[®]

Volume I Colour Reactions



An Initiative of Research Based Pharmaceutical Companies in Germany

in cooperation with the



MEDICAL MISSION INSTITUTE

3.1.2 Description aid for the visual inspection of labels

If the shipment covers several pallet loads: Are all pallets properly labelled and identifiable? Are the shippers properly labelled and identifiable? Is the drug product itself properly labelled describing at least (1) the name of the drug, (2) the drug's strength, (3) the pack size, (4) the manufacturer's name and address, (5) the batch number

and (6) the expiry date? Does the label and other packaging material have its usual appearance/layout such as colour and format? Are the text and letters formatted as usual? Is the spelling correct? Is there any deviation from the usual company logo? Is the company stated on the label known as a reliable supplier of reputable drug products? Does the

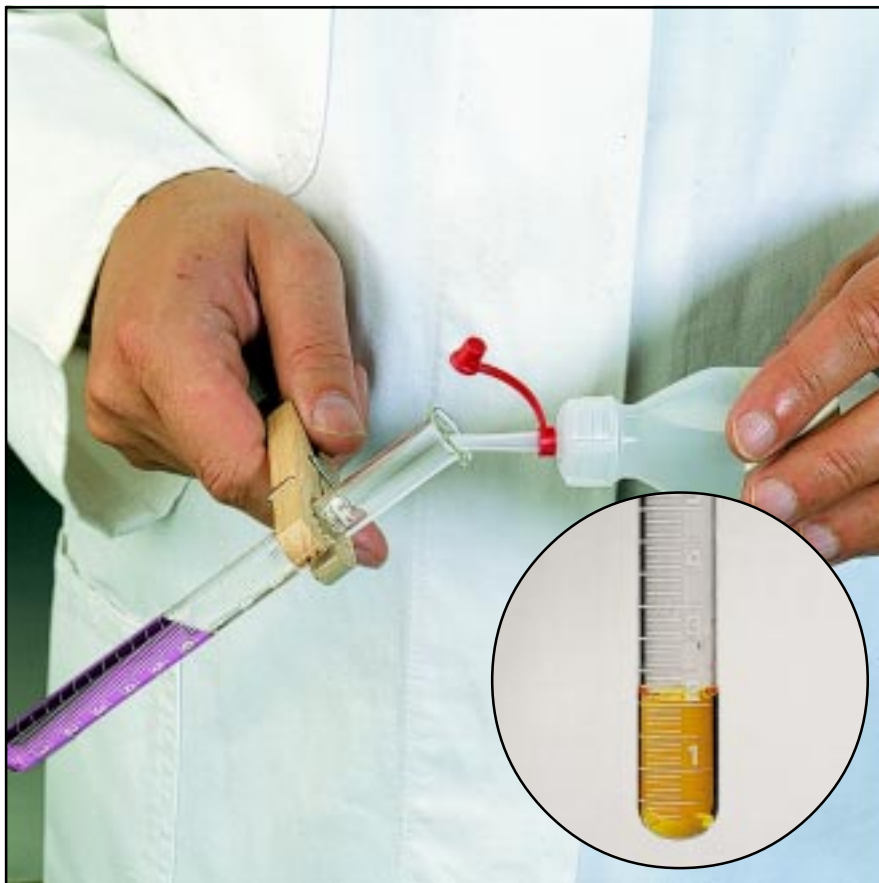
number of tablets or capsules stated on the label match the amount of units counted?

Drug products with incomplete, damaged or missing labels or with labels written in an unknown foreign language should be subjected to an identity test.



A label of an acceptable standard. This picture may give you an idea of how a label should look.

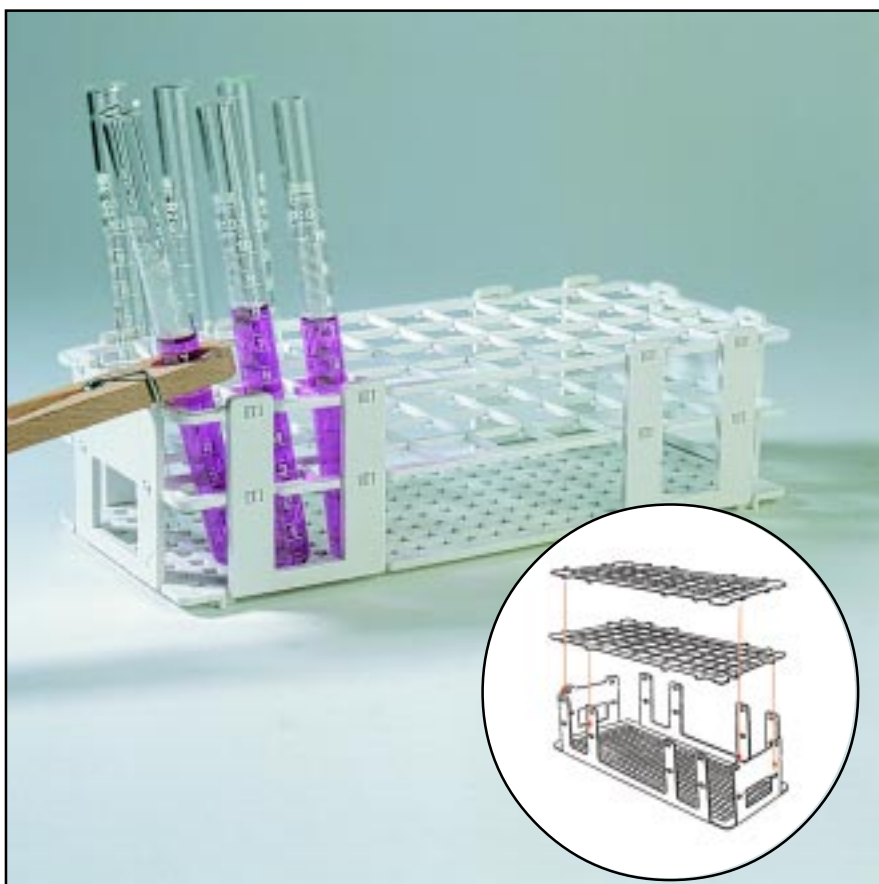
IV. Colour Reactions: 3. Test Performance



Hold the test-tube containing the sample using a wooden clamp, add the required volume of the test solution and shake the tube; a characteristic colour for identification purposes is produced.

Polyethylene dropping bottles or brown glass bottles with an attached transfer pipette are used to accommodate the test solutions for easy dispensing. The graduated test-tube will finally indicate how much of that solution has been applied already. Dispense the required volume as directed in the individual monograph.

Note: Vigorous shaking of the test-tube is often a prerequisite in order to achieve the colour reaction required. Do not swing the test-tube. This may cause poor or anomalous test results. All colours are observed best if holding the test tube into bright light near the window.

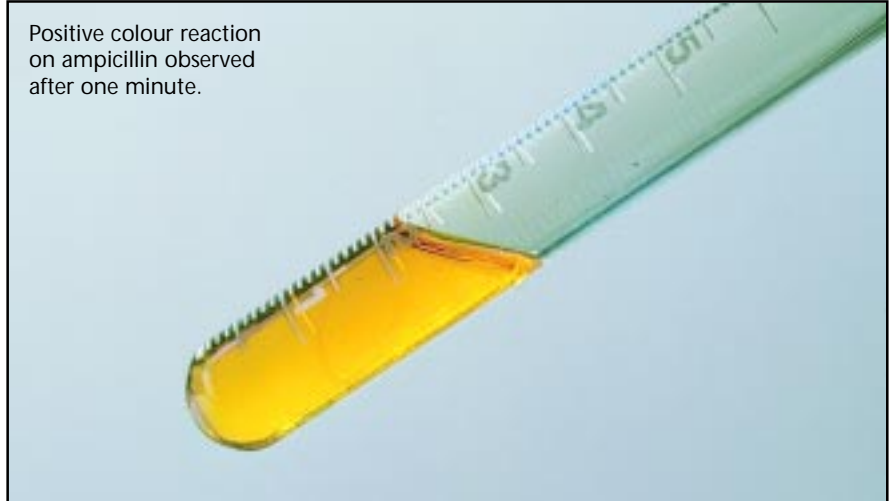


At this stage you might want to place the test-tube into the test-tube rack for a moment.

Warning! Protective clothes and safety spectacles must be worn when handling aggressive test solutions thus avoiding accidental contact with strong acids and alkaline solutions or any other potentially hazardous chemicals.

IV. COLOURS OBSERVED

Positive colour reaction on ampicillin observed after one minute.



...after two minutes.



...after three minutes.



V. RESULTS & ACTIONS TO BE TAKEN

Confirm the drug's identity and verify its potency via a thin layer chromatographic assay if the product shows a positive response on the colour reaction performed. Do not spoil valuable resources from the TLC kit on batches definitely failing to produce the colour requested. In this case, reject the batch and retain some samples. Refer to a fully equipped drug quality control laboratory for further investigation. Put the batch on quarantine till a final decision on rejection or release has been taken.