12 ANALYSIS OF PHARMACEUTICAL INJECTABLE DOSAGE FORMS

12.1 Introduction:

12.1.1 The analysis of cases involving pharmaceutical injectable dosage forms may require more than just the identification of the contents.

12.1.2 Tampering can involve the dilution, contamination, or removal of the contents of a Tubex®, Carpuject®, injection vial, pharmacy intravenous (IV) preparation, IV stock solution, or IV supplies and apparatus.

12.2 Procedure:

12.2.1 Carefully visually inspect the item. Note stopper condition (for small punctures), plunger location and condition, fill volume, appearance, color and consistency of the contents.

12.2.2 If possible, a standard of the same brand and lot number should be requested from the submitting agency for comparison of the visual characteristics, chemical contents and concentration.

12.2.3 Any controlled substance present will be identified in the usual manner.

12.2.4 Analyses for concentration are normally run with semi-quantitative TLC, UV quantitation, or standard GC quantitation methods.

12.3 Reporting:

12.3.1 The concentration of the sample will normally be addressed in the report with one of the two following statements for suspected tampering cases.

12.3.1.1 Meets label specifications.

12.3.1.2 Does not meet label specifications.

12.3.1.3 Any pharmaceutical substitutions or adulterants, properly identified, should be reported as usual. Their concentrations will not normally be required. (e.g., Diazepam substituted into a device labeled to contain morphine would be identified and reported with no concentration value required).

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