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1.0 Purpose

This procedure provides the specifications and methodology for the identification of raw materials by current USP <191> Identification on Tests - General.

2.0 Scope

This procedure applies to Process Analytics/Quality Control (PA/QC) personnel who perform testing for the identity of raw materials.

3.0 Authority and Responsibility

3.1 The Director, Process Analytics/Quality Control has the authority to define this procedure.

3.2 PA/QC is responsible for training laboratory personnel.

3.3 PA/QC personnel are responsible for the accurate performance of this procedure.

3.4 PA/QC is responsible for reviewing the data and documentation of the results of this procedure.

3.5 Biopharmaceutical Quality Assurance (BQA) is responsible for quality oversight of this operation.

4.0 Materials

4.1 Centrifuge tubes either 15 mL, (BDP PN 20006 or BDP approved equivalent) or 50 mL (BDP PN 20140 or BDP approved equivalent), as appropriate for the test.

4.2 Glass vials (BDP PN 20278, 20442 or BDP approved equivalent), if appropriate for the test.

4.3 Pipettes of assorted sizes (BDP PN’s 20104, 20100 or BDP approved equivalent).

4.4 Chemicals appropriate to the specific test being performed.

4.5 Boiling Beads.

4.6 Stir Bars (BDP PN 21793 or BDP approved equivalent).

4.7 Safety glasses.

4.8 Gloves (BDP PN 20302 or BDP approved equivalent).

4.9 Spatula (BDP PN 20440 or BDP approved equivalent).

4.10 Transfer pipette BDP PN 21583 or BDP approved equivalent.

4.11 High Purity Lab Water.

5.0 Equipment

- Balance.
- Bunsen burner.
- Flame starter.
- Hot plate/Stir plate.
- Chemical Safety Hood

6.0 Procedure

NOTE: The tests are not intended to be applicable to mixtures of substances unless so specified.

6.1 Consult the current USP to determine the concentration to prepare for the selected test.

6.2 Consult the monograph section of the USP and read any monograph appropriate to the material being tested.

6.3 Prepare sample for testing based upon 6.1 and 6.2.

6.4 Perform the test according to section <191> of the current USP.

7.0 Documentation

7.1 Record QC test number and description of test article; test performed, name of reagent(s), BDP number, expiration date, test preparations, results, initials, and date of test on Form 22701-01, Raw Material Log Sheet in the Raw Material Testing Logbook.

7.2 Record the test result on the QC Form 22714-01, Raw Material Test Form, accompanying the test request and reference the logbook number and page number.

8.0 References and Related Documents

SOP 22714 *Sampling, Testing, and Review of CGMP Materials by Process Analytics/Quality Control*

Form 22701-01 Raw Material Testing Log Sheet

Current USP <191> Identification Tests-General.

Current USP Test Solution Section and References within.

Current USP Monograph Section.

9.0 Change Summary

[redacted]