GELATIN IDENTIFICATION TEST METHOD

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1. PURPOSE

This document describes the procedure for the identification of Gelatin. The test method is based on the Identification A test of the European Pharmacopoeia Gelatin Monograph (Monograph 01/2020:0330). This is compliant with the currently used edition of the EP.

2. SCOPE

This test method applies to the identification test of Gelatin Capsules.

3. ASSOCIATED DOCUMENTS

- FM-131 Gelatin Identification Test Record
- RPP-020 Carbon Dioxide Free Water
- RPP-021 Copper Sulphate Solution (EP, 125g/L in Water)
- RPP-022 Dilute Sodium Hydroxide Solution (EP, 85g/L in Water)
- TD-027 Training on Gelatin Identification Test Method

4. REFERENCED DOCUMENTS

- SOP-021 Document Control Procedure
- SOP-047 Balances & Certified Masses
- SOP-087 General Laboratory Procedure
- SOP-151 Use of Pharmacopoeial Methods
- SOP-170 Use and Calibration of Thermometers and Thermocouples
- SOP-180 Use and Calibration of Glass Pipettes
- SOP-181 Use and Calibration of Volumetric Flasks
- SOP-245 Operation and Maintenance of the Milli-Q Water System in the QC Laboratory
- SOP-311 Procedure for Storage and Collection of Pharmaxis WFI for use in the QC Laboratory
- FM-186 Approved QC Laboratory Chemical & Consumables List
- ELB-069 Reagent Preparation Log
- ELB-074 Issue of QC Laboratory Forms (QA Issue)

5. DEFINITIONS

Term	Definition
EP	European Pharmacopeia
SDS	Safety Data Sheet
WFI	Water for Injection

6. SAFETY

6.1. Refer to the current version of SOP-087, the General Laboratory Procedure.

6.2. Safety glasses and a lab coat should be worn at all times when in the laboratory.

6.3. Take care when working with hot liquids, do not leave the hotplate, thermometer or samples unattended. Ensure thermometer is of an appropriate range.

6.4. Take care when working with liquids and electrical apparatus.

6.5. Consult all SDS before commencing work, wear appropriate personal protective equipment and be prepared to safely clean up and dispose of waste and spills. Nitrile gloves are to be worn when preparing and using Copper Sulphate ($CuSO_4.5H_2O$) and Sodium Hydroxide.

7. EQUIPMENT AND REAGENTS

All reagents and consumables used must be on the approved QC Laboratory chemical & consumable list, refer to FM-186.

7.1. EQUIPMENT

7.1.1. Hotplate
7.1.2. Heatproof Beakers
7.1.3. Thermometer (0 to 100°C)
7.1.4. 100mL lidded bottle (e.g. Schott Bottle)
7.1.5. 100mL measuring cylinder
7.1.6. 10 and 100mL volumetric flasks
7.1.7. 1L/2L lidded bottle (e.g. Schott Bottle)
7.1.8. Volumetric Pipette
7.1.9. Graduated Pipette
7.1.10. Analytical Balance

7.2. REAGENTS

7.2.1. Carbon Dioxide Free Water

- Water for Injection or Milli-Q Water that has been boiled for 5 minutes and protected from the atmosphere during cooling and storage, 100mL is required

for each test.
- Prepare in accordance with RPP-020.

7.2.2. Copper Sulphate Solution (EP Reagent, 125g/L in Water)
- 1.25g Copper Sulphate ($CuSO_4.5H_2O$) in 10mL of Milli-Q Water or WFI, 0.05mL is required for each test.
- Prepare in accordance with RPP-021.

7.2.3. Dilute Sodium Hydroxide Solution (EP Reagent, 85g/L in Water)
- 8.5 g Sodium Hydroxide in 100mL Milli-Q Water or WFI, 0.5mL is required for each test.
- Prepare in accordance with RPP-022.

8. PROCEDURE

8.1. PREPARATION OF REAGENTS AND TEST SOLUTIONS

8.1.1. Gelatin identification testing is to be performed on each individual sample/container and documented on the current version of FM-131.

8.1.2. Each working copy of FM-131 is to be issued in accordance with ELB-074; Issue of QC Laboratory Forms (QA Issue).

8.1.3. One copy number of FM-131 is to be used for each batch/delivery tested (with additional pages 2 and 3 might be required depending of the number of samples/containers to be tested) if using the same reagents/equipment.

Note: For each different batch/delivery and whenever different reagents or equipment are used, a new copy number of FM-131 is to be issued.

8.1.4. Prepare Carbon Dioxide Free Water if necessary in accordance with the current version of RPP-020. Determine the volume of Carbon Dioxide Free Water required based upon the number of samples/containers to be tested.

Note: Ensure that the heatproof beaker used for preparation of carbon dioxide free water is large enough to ensure the water will not spill when boiling. Cool the Carbon Dioxide Free Water and maintain at a temperature of about 55°C.

8.1.5. Prepare the Copper Sulphate and Dilute Sodium Hydroxide solutions if necessary in accordance with the current version of RPP-021 and RPP-022 respectively.

Use tweezers/spatula to weigh out 1.0g of the capsules to be tested into a clean dry bottle and dissolve in 100mL of Carbon Dioxide Free Water at about 55°C. Keep the solution at this temperature.

Note: To prevent pressure build up, the bottle must be vented regularly, especially after shaking. When venting the bottle, loosen the cap slowly with the bottle in an

upright position pointing in a safe direction (away from people and electrical connections).

8.2. IDENTIFICATION TEST

8.2.1. Use a volumetric pipette to add 2mL Gelatin Test Solution to a clean dry tube or small beaker, maintaining the temperature at about 55°C.

8.2.2. Using a graduated pipette, add 0.05mL Copper Sulphate Solution, mix thoroughly.

8.2.3. Using a graduated pipette, add 0.5mL Dilute Sodium Hydroxide Solution and mix thoroughly.

8.2.4. A violet colour is produced for a positive gelatin ID test.

8.2.5. Report the colour of the identification test solution and the result as Pass or Fail on FM-131.

8.2.6. Retain the Identification Test solution until result has been reviewed by a second analyst.

9. QUALITY RECORDS

9.1. The Gelatin Identification Test Records and completed RPP-020, RPP-021 and RPP-022 are to be kept with relevant QC records or QA batch release records.

9.2. All documentation will be retained in accordance with the current version of SOP-021.

9.3. Training on Gelatin Identification Testing is to be performed using the Training Document TD-027.

10. CHANGE HISTORY

Version	Date Effective	Section	Description and Rationale
06	30-Apr-21	1	(Monograph 01/2020:0330) version is updated as per current European Pharmacopoeia edition used.
		4	In referenced documents added ELB-074; Issue of QC laboratory Forms (QA Issue).
		7.2	Use of Milli-Q Water or WFI added.
		8.1	Added sentence that testing should be performed on each individual samples/containers.
		8.1.2	Paragraph is re-worded, FM-131 is to be issued in accordance with ELB-074; Laboratory forms (QA Issue)

Version	Date Effective	Section	Description and Rationale
06	30-Apr-21	8.1.3	Added additional pages 2&3 depending of the number of samples tested.
		9	Added information where to keep Quality Records.
		All	Document formatting updated to use current version of controlled template (TE-006-03) in accordance with document control procedure requirements.
05	27-Sep-17	1	Updated the EP monograph to reference current edition.
		4	SOP-311 added as a referenced document as Pharmaxis WFI has been approved for use for testing in accordance with CR 544.
		5	New section created to define abbreviations used in the test method for improved clarity.
		6.5	MSDS updated to SDS in line with current terminology for Safety Data Sheets.
		7	Added statement that reagents and consumables must be approved as this was removed in error during transfer to new template version during previous update.
		9	Information about training added to section to detail requirements for training in the method.
04	06-May-13	All	Updated format to the current version of (TE-006-02).
		1	Updated the EP monograph reference to the most recent.
		5.5	Added reference to safety instructions relating to Copper Sulphate ($CuSO_4.5H_2O$) and Sodium Hydroxide.
		6.1	Removed specified mL after transfer pipettes, as this referred to the volume used in the TM, rather than pipette size. Updated transfer pipette to volumetric and graduated pipettes. Included 1L/2L lidded glass bottle, not in the previous version.
		7.2.1	Updated reference of transfer pipettes to volumetric pipette to clarify the correct glassware to be used.
03	30-Jun-11	All	General update of formatting for compliance with current version of document control procedure: - Document transferred to controlled template TE-006-01. - Document numbers formats updated. Referenced Documents section created and SOP-087, SOP-151 moved to this section from Associated Documents.
		1.	Purpose updated to state method compliance with current EP version.
		3.	RPP-020, RPP-021, RPP-022 added to Associated Documents as these have been created for preparation of reagents for this method.

Version	Date Effective	Section	Description and Rationale
03	30-Jun-11	4.	SOP-021, SOP-047, SOP-170, SOP-180, SOP-181, SOP-245 and ELB-074 added to Referenced Documents as these procedures are required to be referenced when using this Test Method.
		6.	Reference to approved chemicals and consumables list changed from LB-033 to FM-186 as per current version of SOP-203.
		6.2	Preparation of reagents changed from FM-131 to RPP-020, RPP-021 and RPP-022 to improve method documentation. Milli-Q Water included for preparation of Carbon Dioxide Free Water as per CR 273 and RAN 002.
		7.1	Issuing of FM-131 change to require issued copies to be logged in ELB-074 as implemented as part of CR 278 to allow issuing of documents over two laboratory sites. Instructions for use of FM-131 updated to describe use of updated FM-131 and instructions for preparation of reagents updated to reference RPP documents. Volume limit for preparation of Carbon Dioxide Free Water removed as larger volumes can be prepared safely and in accordance with current version of EP.
		8.	Retention requirement of records updated to reference SOP-021 to ensure compliance with current version of Document Control Procedure.

END OF DOCUMENT