Hashemite University

Faculty of Pharmaceutical Sciences

Department of PharmaceuticalChemistry

Practical Pharmaceutical Instrumental Analysis (131703316) Reports

Section number : _____

Group number: _____

Student name	Student number
1.	
2.	
3.	
4.	
5.	

Complied by: MSc. Mai Jaber

2024

Experiment 1
Pharmacopoeia Report Sheet

Section number: **Group number:**

Referring to the USP:

1) From general notices, what is the meaning of:

Well closed container:

A container that protects the contents from contamination by extraneous solids and from loss of the article under ordinary conditions of handling, shipment, storage, and distribution.

Tamper evident packaging:

Packaging having one or more indicators or barriers to entry that, if breached or missing, provide visible evidence that tampering has occurred.

Freezer:

A place where the temperature is maintained between −25°C and −10°C.

Cool:

Any temperature between 8°C and 15°C.

Controlled room temperature:

A temperature maintained between 20°C and 25°C, with permitted brief excursions between 15°C and 30°C that do not compromise the product.

Dry place:

A place that does not exceed 40% average relative humidity (RH) at 20°C, or the equivalent water vapor pressure at other temperatures.

2) From general chapters, what is the title of <197> chapter?

USP General Chapter <197>: Spectroscopic Identification Tests

3) From general chapters, List **2 names** of volumetric apparatus described along with their available volumes only.

No.	Volumetric Apparatus	Available Volumes
1	Volumetric Flask	10, 25, 50, 100, 250, 500, 1000, 2000 mL
2	Volumetric Pipette	1, 2, 5, 10, 20, 25, 50 mL

4) From the Reagents section, how would you prepare an alkaline borate-buffer at **2 different** pHs of your choice?

pH	Procedure of Preparation
9	Place 50 mL of the boric acid and potassium chloride solution (0.2 M) in a 200-mL volumetric flask, add 20.8 mL of 0.2 M sodium hydroxide solution, then add water to volume.
10	Place 50 mL of the boric acid and potassium chloride solution (0.2 M) in a 200-mL volumetric flask, add 43.7 mL of 0.2 M sodium hydroxide solution, then add water to volume.

5) From the reference tables, determine the approximate solubilities of:

Caffeine(hydrous) in water 50 mL Slightly soluble
Busulfan in acetone 45 mL Freely soluble
Ascorbic acid in water 3 mL Freely soluble

6) From dietary supplements section, list **2 inorganic impurities** of Glutathione along with their limits.

Inorganic Impurity	Limit
Ammonium	not more than (NMT) 0.02%
Residue on Ignition / Sulfated Ash	not more than (NMT) 0.1 %

7) From the national formulary, and relevant to Saccharin, fill thetable below.

Test	Limit (Acceptance Criteria)
Heavy metals	not more than (NMT) 0.001% (or 10 ppm)
Assay	not less than 98.0% and not more than (98% – 101%) Calculated on the dried basis.

8) From the official monographs, fill the table below.

Substance / Product	Test	Limit (Acceptance Criteria)
Clarithromycin tablets	Assay	90% – 110% of the labeled amount of Clarithromycin
	Loss on drying	not more than (NMT) 6.0 %
	Packaging and storage	Preserve in well-closed containers.
	pH	Between 7.5 and 10.0 (in a 1 in 500 mixture of methanol and water).
	Loss on drying	not more than (NMT) 2.0 %
Clavulanate Potassium	Organic impurities: - Total - Clavam-2-Carboxylate - Aliphatic Amines	not more than (NMT) 2% not more than (NMT) 0.01 % Meets the requirements (via Gas Chromatography).
	Packaging and storage	Preserve in tight containers.

Referring to the BP:

1) From general notices, what is the meaning of:

Freshly prepared: Indicates that the substance or solution must be prepared immediately before use and should not be stored.

Recently prepared: Indicates that the substance or solution should have been prepared within a relatively short time before use, so that no significant deterioration has occurred.

2) From general notices, write down **3 different** solubility descriptive terms

1) Less than 1 very soluble.
2) From 1 to less than 10 Freely soluble.
3) From 10 to less than 30 Soluble.

3) What is the assay limit of Atenolol raw material and what are the limits of the following Atenolol related substances

Imp B: NMT 0.5% Imp F: NMT 0.3% Total impurities: NMT 1% Assay: 99% - 101% calculated on the dried substance.

4) Determine the following for Isotretinoin raw material.

Action & use: Anti-acne agent.

Assay: 98% – 102% (on the dried substance).

5) Determine the following for Thymol raw material.

Total impurities limit: (NMT) 1% via Gas Chromatography

Residue on evaporation limit: maximum 0.05%

6) Determine the following for Captopril oral solution:

Storage: Store in airtight containers, protected from light.

Assay limit: 95% – 105% of the stated amount of Captopril ($C_9H_{15}NO_3S$)

Captopril disulfide limit: (NMT) 3%

7) Determine the following for Zinc sulfate eye drops:

Definition: **Zinc Sulfate Eye Drops are a sterile aqueous solution of Zinc Sulfate Heptahydrate ($ZnSO_4 \cdot 7H_2O$) in Purified Water.**

Content: **95.0%–105.0% of the stated amount of zinc sulfate heptahydrate ($ZnSO_4 \cdot 7H_2O$).**

Experiment Report Workload Distribution Table

Coordinator for Current Experiment[1]:		
Section[2]	**Student Name[3]**	**Percentage of the Performed workload[4]**

[1]Mention the name of the student/ group member who did arrange the work related to the current experiment group report/work management.
[2]Section or part of the group report
[3]Mention the name of student/the group member who took responsibility of the specified group report section
[4]Relative to the whole workload used to prepare the current group report.