

الصيدلة	الكلية
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Pharmaceutical Technology	المادة باللغة الانجليزية
تقانة الصيدلة	المادة باللغة العربية
الثالثة	المرحلة الدراسية
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Pharmaceutical Water	عنوان المحاضرة باللغة الانجليزية
الماء المستخدم في التصنيع الدوائي	عنوان المحاضرة باللغة العربية
9	رقم المحاضرة
Pharmaceutical Dosage forms and Drug Delivery Systems By Haward A. Ansel; latest edition.	المصادر والمراجع
Sprowel's American Pharmacy.	

محتوى المحاضرة

Introduction – Solvents

- Water is the most widely used substance / raw material.
- Used in production, processing, formulation, cleaning, and quality control.

Contaminants of water:

There is no pure water in nature, as it can contain up to 90 possible unacceptable contaminants.

Contaminant groups:

- Inorganic compounds
- Organic compounds
- Solids
- Gases
- Microorganisms

- Minerals
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Grades of Water

Different grades of water quality available according to pharmacopoeia specifications.

Types of water include:

- Bulk forms (produced on site when used).
- Packaged forms (produced, packaged, and sterilized to preserve microbial quality through shelf life).

Examples:

- Drinking water / potable water
 - Purified Water (PW)
 - Highly Purified Water (HPW)
 - Water for Injection (WFI)
 - Bacteriostatic Water for Injection (B-WFI)
 - Sterile Water for Injection
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Bulk Forms

Drinking water / Potable water

- Must comply with WHO, ISO, and national/regional agency specifications.
- Requires regular testing.
- Supplied under continuous positive pressure.
- Distribution system designed to prevent contamination.
- Source: public water supply system or natural sources (springs, wells, rivers, lakes).

- Treatment: softening, ion removal, particle reduction, antimicrobial treatment.
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Purified Water (PW)

- Prepared from potable water source.
 - Meets pharmacopoeia specifications for chemical and microbial purity.
 - Must be protected from recontamination and microbial proliferation.
 - Not intended for parenteral administration.
 - Uses: cleaning of equipment.
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Highly Purified Water (HPW)

- Prepared from potable water source.
 - Specification only in the European Pharmacopoeia.
 - Same quality standard as WFI (including endotoxin limits).
 - But treatment method considered less reliable than distillation.
 - Prepared by combination of methods: reverse osmosis (RO), ultrafiltration (UF), deionization (DI).
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Water for Injection (WFI)

- Prepared from potable water source by distillation.
 - Free from chemicals, microorganisms, and pyrogens.
 - Not sterile.
 - Intended for parenteral administration within 24 hours after collection.
 - Must be protected from microbial contamination.
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Packaged Forms

Bacteriostatic Water for Injection (B-WFI)

- Sterile water intended for injection containing one or more suitable preservatives.
 - Not for neonates due to possible preservative toxicity.
 - Not intended for IV injection unless diluted.
 - Supplied in multiple-dose containers.
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Sterile Water for Injection

- Pyrogen-free water, used for injection.
- Contains no bacteriostatic agents or preservatives.
- Supplied in single-dose containers

