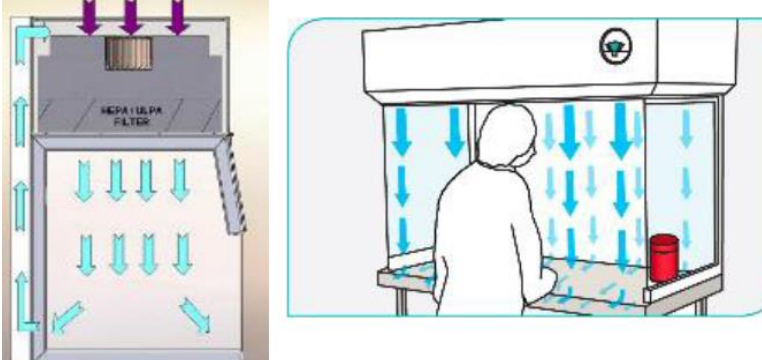
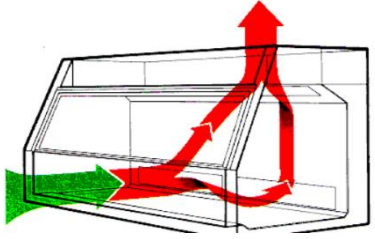
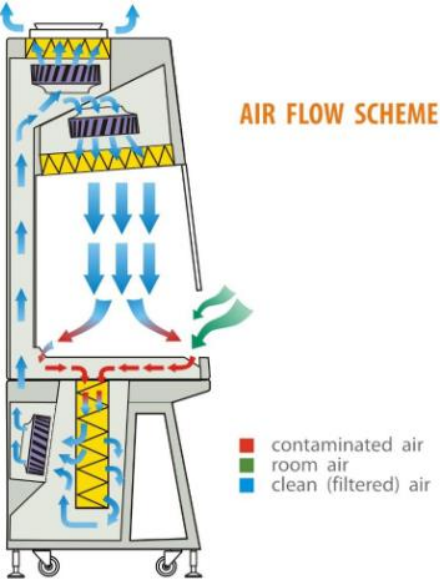



Aseptic Technique

- Refers to use of methods & procedures that prevent microbial contamination while performing a given task
- Refers to procedures performed in:
 - Hospital (operating theatres, nursing care)
 - Research laboratories (e.g. working with cell culture)
 - Pharmacy: Industry (in production of parenteral dosage forms, ophthalmic preparation etc.) & Hospital pharmacy (preparation of parental solutions)
- Requires use of personal protective equipment (PPE): Disposable latex/nitrile gloves, Lab coat, Safety glasses, Face mask, Hair net & Appropriate footwear
- Use of PPE is essential to protect both personnel & product

Aseptic Workstations

<p>Laminar Flow Hood</p>	<ul style="list-style-type: none"> • Air flows in one direction without turbulence • HEPA (High Efficiency Particulate Air) filter: Removes particles $>0.3 \mu\text{m}$ • Provide protection only to product • No protection for personnel 
<p>Class I Biosafety Cabinets</p>	<ul style="list-style-type: none"> • Open fronted • Negative pressure systems • Provide personal protection & environmental protection • With HEPA filtration system fitted • Do not provide product protection 
<p>Class II Biosafety Cabinets</p>	<ul style="list-style-type: none"> • Negative pressure system ventilated cabinet: Provides personnel protection • HEPA-filtered air circulated into cabinet: Provides product protection • Exhaust air is HEPA filtered: Provides environmental protection

	
<p>Class III Biosafety Cabinets</p>	<ul style="list-style-type: none"> • Totally enclosed, ventilated systems with gas-tight construction • Air into cabinet through HEPA filters • Exhaust air is filtered by two HEPA filters installed in a series • Use with high risk infectious agents & toxic volatile chemicals 

Disinfectants & Antiseptics

Characteristics of Disinfectants, Antiseptics & Preservatives

	Disinfectant	Antiseptic	Preservative
	<ul style="list-style-type: none"> • Used on surface of inanimate objects (e.g. table, floor) 	<ul style="list-style-type: none"> • Used on living tissue (e.g. skin, mucous membranes) 	<ul style="list-style-type: none"> • Not disinfectant/antiseptic • Additives that prevent microbial growth (bacteriostatic)
Activity	Biocidal	Biocidal	Biostatic
Toxicity	Can be toxic	Non-Toxic	Non-Toxic
Irritant	Can be an irritant	Non-Irritant	Non-Irritant
Stability	Can be kept in stable form until required	Can be kept in stable form until required	Needs a long shelf-life
Reactivity	Non-reactive with non-living items	Non-reactive with live tissues	Non-reactive with other ingredients

Levels of Disinfection

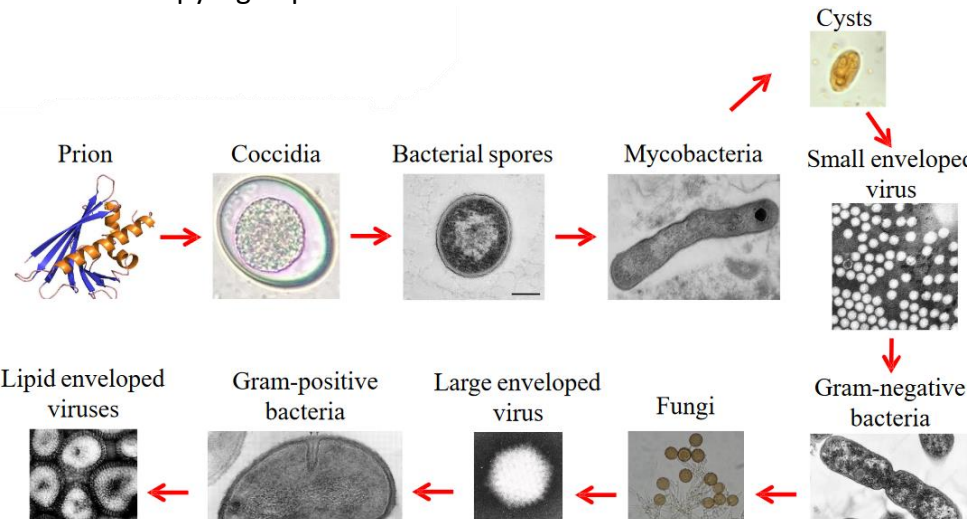
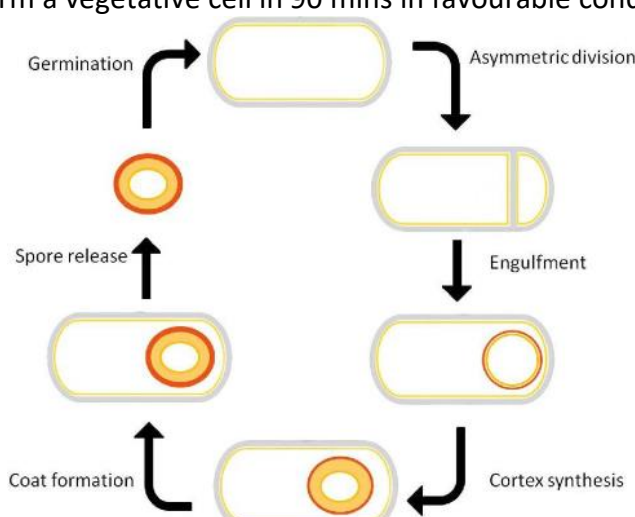
	Low	High
Microorganisms Killed	<ul style="list-style-type: none"> • Most vegetative bacteria • Most viruses • Most fungi 	<ul style="list-style-type: none"> • All microorganisms • Most bacterial spores
Microorganisms Surviving	<ul style="list-style-type: none"> • Mycobacteria • Bacterial spores • Prions 	<ul style="list-style-type: none"> • Some bacterial spores • Prions
When to Use	<ul style="list-style-type: none"> • Non-critical medical devices (e.g. wheelchair, blood pressure cuffs) 	<ul style="list-style-type: none"> • Critical medical devices

Disinfectant Types

Hospital Disinfectants	<ul style="list-style-type: none"> • Bactericidal efficacy is mandatory (excluding Mycobacteria) • Must be general purpose suitable for many surfaces • Alcohols & phenols are not high-level disinfectants unlike hydrogen peroxide, glutaraldehyde • Hospital grade disinfectant should be able to kill common hospital pathogens <p>MICROBIOLOGICALLY TESTED: [REDACTED] has been proven to kill:</p> <table style="width: 100%; border: none;"> <tr> <td style="width: 50%; vertical-align: top;"> <ul style="list-style-type: none"> ✓ Staphylococcus aureus (MRSA or Golden Staph) ✓ Pseudomonas aeruginosa ✓ E coli ✓ Enterococcus Faecalis (VRE) ✓ Acinetobacter ✓ Acetobacter </td> <td style="width: 50%; vertical-align: top;"> <ul style="list-style-type: none"> ✓ Salmonella choleraesuis ✓ Proteus vulgaris ✓ Influenza virus ✓ Herpes Simplex virus ✓ Hepatitis B Group virus </td> </tr> </table>	<ul style="list-style-type: none"> ✓ Staphylococcus aureus (MRSA or Golden Staph) ✓ Pseudomonas aeruginosa ✓ E coli ✓ Enterococcus Faecalis (VRE) ✓ Acinetobacter ✓ Acetobacter 	<ul style="list-style-type: none"> ✓ Salmonella choleraesuis ✓ Proteus vulgaris ✓ Influenza virus ✓ Herpes Simplex virus ✓ Hepatitis B Group virus
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Household Disinfectants	<ul style="list-style-type: none"> • No mandatory levels • General purpose 		

Choosing Right Antimicrobial Agent

Toxicity	<ul style="list-style-type: none"> • Particularly important for antiseptic & preservatives • When is chemical toxic? (MSDS) • Everything is toxic at high enough conc. • Should be considered for disinfectants: <ul style="list-style-type: none"> ○ Is it volatile? Will inhalation be an issue? ○ What personal protective equipment will be required?
Properties of Chemical Agent	<ul style="list-style-type: none"> • Is it a solvent? Will it stain/corrode? Are these acceptable? • What is rate & extent of microbial killing over time? • Is it affected by temperature/pH? • Does it have a negative effect on living tissue? If so, it cannot be an antiseptic/preservative. • Is it toxic once ingested? If so, it cannot be a preservative
Intended Application	<ul style="list-style-type: none"> • How long does it require to be effective? • Is it compatible with intended surface? • Is it compatible with other formulation ingredients? Especially important for preservatives. (e.g. not using bleach with hot water) • Is it still effective at non-toxic conc? • Are there any long-term effects?

<p>Microbial Challenge</p>	<ul style="list-style-type: none"> • What is the bioburden? (Bioburden is level of microbial contamination) • What types of organisms are present? • Is there a pyrogen present? 
	<p>Prions</p> <ul style="list-style-type: none"> • Transmissible infective proteins • Exist in two forms (native form PrP^C & misfolded infective form PrP^{Sc}) • PrP^{Sc} can refold native/healthy PrP^C • Extremely stable <p>Bacterial Endospores</p> <ul style="list-style-type: none"> • Gram+ bacteria (e.g. Clostridium tetani & C. botulinum) form spores • Very resistant to environmental factors • Bacteria can form endospores in 6-8 hours • Remain viable for a long period of time • Form a vegetative cell in 90 mins in favourable conditions 
<p>Environmental Factors</p>	<ul style="list-style-type: none"> • Item must be cleaned before it can be disinfected • Organic matter disrupts antimicrobial effect as organic matter protects microbes, adsorbs disinfectant & chemically inactivates disinfectant • Bodily fluids can prevent affect disinfection • Biofilms can tolerate disinfectants