

# Biogen Specific Teaching Material

Cleaning and Disinfection – Environmental Monitoring





# Questions & Answers

# Cleaning and Disinfection – Environmental Monitoring

1. What do particulates consist of?

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1. Particulates consist of mobile, extraneous substances, other than gas, that cannot be analysed chemically because of their heterogeneous composition.

2. What does total organic carbon (TOC) measure?

2. The TOC measures the total organic material present in a sample.

3. Why does Biogen perform regularly scheduled environmental and utility monitoring?

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3. Biogen performs regular, scheduled environmental and utility monitoring to ensure that the environment where manufacturing occurs is clean and that microorganisms in that environment are within acceptable limits.



4. What are Replicate Organism Detection and Counting (RODAC) plates used to monitor?

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4. RODAC plates are used for monitoring both personnel and surfaces.

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5. Name the four (4) things that the collected data of routine monitoring serves?

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5. Possible answers: Defining new procedures, refining existing procedures, determining equipment maintenance intervals, and initiating further monitoring processes.

6. At Biogen, what typically occurs in enclosed areas where liquids are stored?

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6. Toxic gas monitoring typically occurs in enclosed areas where liquids are stored.

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7. Why should you not sanitize gloves or sampling containers with 70% alcohol when taking a TOC sample?

7. Alcohol is an organic compound and so any alcohol residue would impart a falsified TOC reading.



8. What type of plate contains trypticase soy agar (TSA)?

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8. Settling plates contain trypticase soy agar (TSA).

9. According to the 21 CFR, the premises used in drug manufacturing must be of a suitable size and construction to facilitate what?

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9. They must be of a suitable size and construction to facilitate cleaning, maintenance and proper operations.

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10. Name at least two (2) utilities at Biogen.

10. Possible answers: Purified water system, WFI system, clean steam system, glycol system, heating, ventilation and air-conditioning system (HVAC)

11. What item is placed on the room-temperature TSA plate for incubation?

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11. The operator's gloved fingertips are placed on the room-temperature TSA plate.



# Thank you for your attention!

## D-SCHULE – Your Language School



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