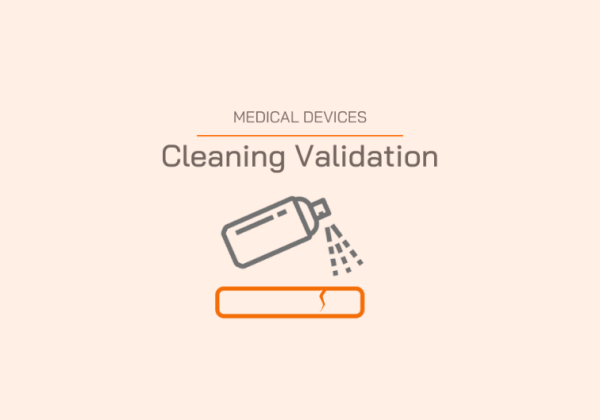
Cleaning Validation for Medical Devices



What Is Cleaning Validation for Medical Devices?

As one of the most critical processes in batch release testing services, **cleaning validation** ensures the cleanliness and suitability of equipment for producing safe and effective products. In other words, this process effectively removes **residues of the active pharmaceutical ingredients (APIs), excipients, and cleaning agents** from the medical devices.

It is a necessary part of our **batch release testing services**, ensuring for consistency and uniform quality, and it is included with our other batch release testing services:

- Biocompatibility testing
- Material and Chemical Characterisation
- Packaging validation
- Stability validation

In Applus+ Laboratories we make sure your product **is safe and ready for certification**, through a comprehensive testing service, which will help you improve the development of your medical devices.

What Cleaning Validation Services Do We Offer?

At Applus+ Laboratories we offer a detailed cleaning validation process through different tests. These tests are performed against two main standards: ISO 10993-18 and ISO 19227.

Routine Analysis Tests According to ISO 19227 Standard

ISO 19227 is a standard that specifically addresses the cleanliness of different medical implants, detailing methods for evaluating and verifying cleanliness levels to ensure patient safety and regulatory compliance.

- **HCT/TOC analysis according to NF EN 1484 and NF EN ISO 9377-2 standards:** HCT /TOC analysis refers to the determination of **Hardness (HCT)** and **Total Organic Carbon (TOC)** levels in water samples. The standards NF EN 1484 and NF EN ISO 9377-2 provide guidelines and methods for conducting these analyses.
  - **NF EN 1484**
    NF EN 1484 specifies the method for the determination of Hardness (HCT) in water by complexometric titration with EDTA (ethylene diamine tetraacetic acid).
  - **NF EN ISO 9377-2**
    NF EN ISO 9377-2 specifies the method for the determination of Total Organic Carbon (TOC) in water samples using high-temperature catalytic oxidation and infrared detection. TOC analysis is important as it measures the total amount of carbon in organic compounds present in water, which can include contaminants or by-products from industrial processes.
- **Analysis by ICP or ion chromatography for inorganic pollutants measurement**
  Analytical techniques such as **Inductively Coupled Plasma (ICP)** and **Ion Chromatography (IC)** are widely used for the measurement and analysis of inorganic pollutants in medical devices.
  - **Inductively Coupled Plasma (ICP)-OES or ICP-MS**
    ICP spectroscopy is utilised in the analysis of inorganic pollutants in medical devices, focusing primarily on metals and metalloids.
  - **Ion Chromatography (IC)**
    IC is a valuable analytical technique employed in the field of medical devices primarily for the analysis of ions, including both inorganic and organic ions.

What Are the Benefits of Cleaning Validation for Medical Devices?

Performing cleaning validation for medical devices is a critical procedure aimed at ensuring the effectiveness of cleaning procedures and the safety of products intended for patient use. This validation process is essential to verify that equipment and facilities are thoroughly cleaned and free from residues that could potentially compromise product quality or patient safety. Key benefits of cleaning validation include:

- **Assurance of Product Quality**
  By confirming the removal of cleaning agents, residues, and contaminants, cleaning validation ensures that subsequent batches of medical devices are not compromised by carryover substances that could alter their efficacy or safety.
- **Compliance with Regulatory Standards**
  Cleaning validation demonstrates compliance with stringent regulatory

requirements and guidelines, such as those set forth by health authorities like the FDA (Food and Drug Administration) and EMA (European Medicines Agency).

- **Risk Mitigation**
  Thorough cleaning validation reduces the risk of cross-contamination between different products or batches, thereby minimising the potential for adverse effects on patient health and ensuring consistent product performance.
- **Confidence in Patient Safety**
  Ultimately, cleaning validation provides healthcare providers and patients with confidence in the safety and reliability of medical devices, supporting improved patient outcomes and overall public health.

Why Choose Applus+ Laboratories for Cleaning Validation for Medical Devices?

When you choose Applus+ Laboratories for your cleaning validation needs, you're selecting a **renowned leader in medical device testing solutions**. Our commitment to excellence is evident in our **high-quality, ISO-compliant testing services**, which ensure the accuracy and reliability of your medical devices.

We offer a comprehensive suite of testing capabilities aimed at meeting your specific requirements and accelerating your time to market. Whether you need development testing, lifecycle testing, product and process qualification including batch release tests, or Contract Manufacturing Organisation services, Applus+ Laboratories is your trusted partner.

Operating **across multiple countries**, we provide global reach without compromising on the quality of our services. This ensures that wherever you are located, you have access to top-tier medical device testing expertise.

Count on Applus+ Laboratories to support your projects with our unwavering commitment to quality, reliability, and expert guidance. Partner with us today and experience the difference in medical device testing excellence.