Ozone Use in Pharmaceutical Water

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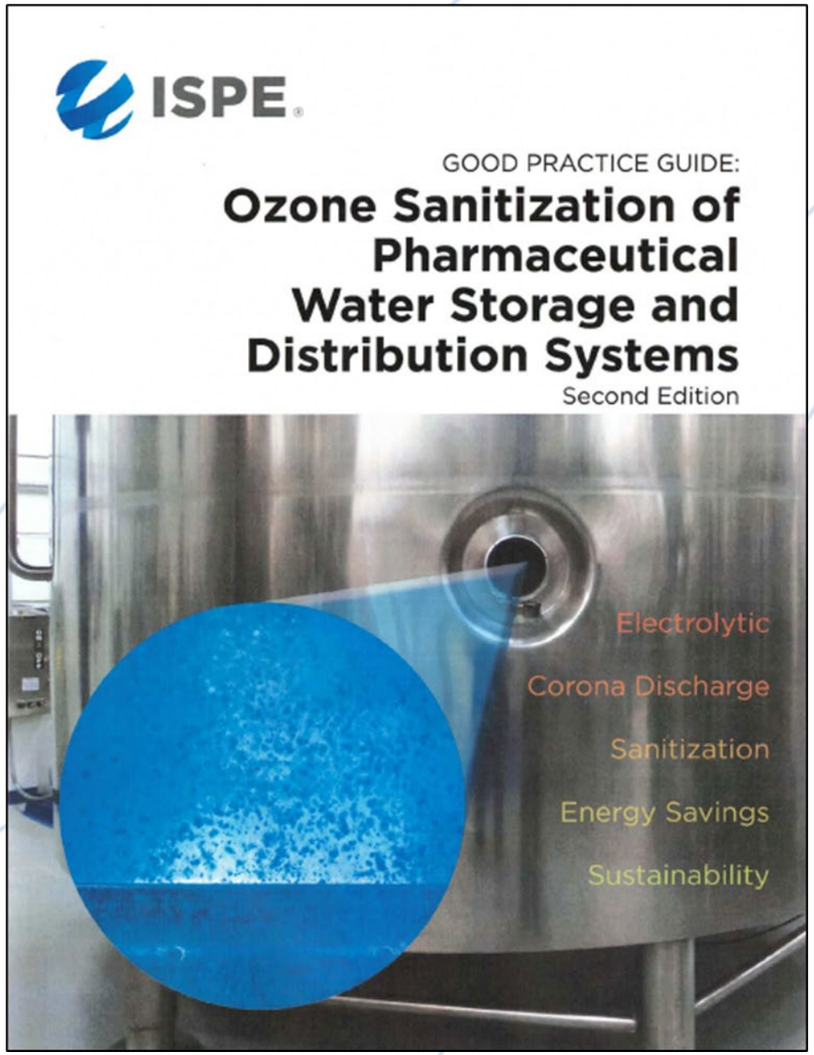
Membrane Based WFI

The creation of the ISPE Good Practice Guide; Membrane Based WFI, is the culmination of decades of work towards the true implementation of risk-based design while also overcoming industry inertia.

The acceptance of ambient WFI has also opened the door for the acceptance of ozone sanitization for WFI which has been used for Purified Water for more than 30 years.

Ozone Sanitization GPG – Second Edition - published 10/25/24



Ozone Use in Pharmaceutical Water

Ozone is an effective sanitizer if utilized properly.

Recognizing there are differences between the way heat and ozone function and capitalizing on ozone's strengths while addressing its limitations is the key to success.

Heat and ozone are different and not simply interchangeable.

Benefits of Ozone Sanitization

- Ozone is the most powerful oxidizing agent used to sanitize pharma water
- Ozone rapidly & aggressively acts on the surface layers of bacteria
- Does not require significant amounts of energy for generation
- Is usually more cost effective than heat
- Ozone is readily removed from water via UV & leaves no residual* (dual purpose)
- Ozone is safe when applied properly
- Most effective when used with cool/ambient water (Membrane Water Generation)
- Low levels of ozone are adequately effective
- Use of ozone can result in higher productivity
- Reduced Carbon Footprint / Greener
- Advantageous over chemical sanitization methods
- Improved quality reliability
- Capital avoidance / Initial Investment Savings
- Life cycle cost savings

Limitations of Ozone Sanitization

- Ozone does not penetrate deeply into thick biofilms
- Ozone sanitization can result in oxidation by-products when generated by Corona Discharge technology
- Ozone may be considered an added substance based on interpretation
- As a result of ozone's short half-life, sanitization regimes are different from heat
- System design for ozone sanitization is different from heat
- Methods of available ozone generation can impact design, cost, etc.
- Venting of ozone and hydrogen may need to be addressed
- Calibration of ozone monitors may require more frequent maintenance activities
- Conductivity issues in stored ambient water may need to be addressed
- Consideration of oxygen or trace ozone product sensitivity
- New technology training

Ozone Sanitization Combined with Membrane Generation can provide significant benefits

- Understand the technology and design requirements
  - Do not assume ozone is simply interchangeable with heat or chemicals
- Ensure everyone from designers to operations staff are properly educated and trained in ozone application and use.
  - Service and calibration of ozone system components is different
  - Ozone does not destroy bacteria the same way heat does
  - First-timers should read the Ozone Sanitization GPG cover-to-cover

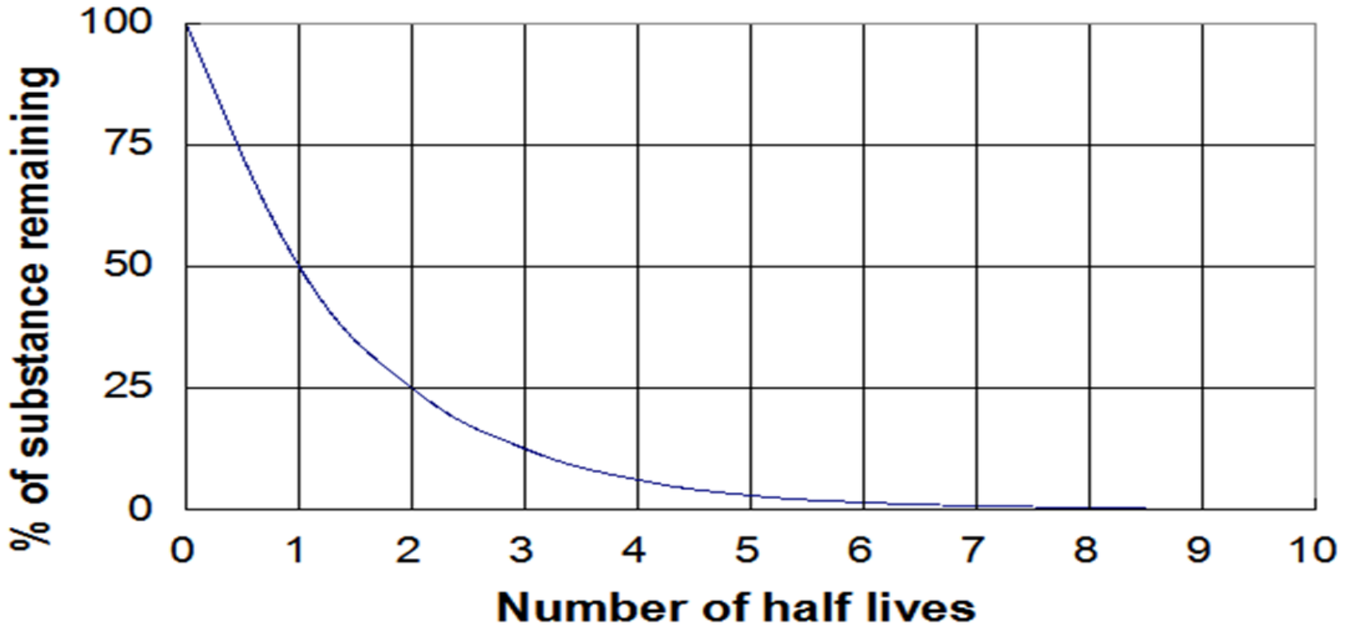
Ozone ≠ Heat

A Serious Concern

- Ozone is an added substance if allowed to remain is the final product water
- Ozone monitoring equipment is not able to detect a complete absence, so how do we know it’s completely gone?
- Does the term “substantially removed” allow any latitude?
- What impact might apply to ozone sensitive products (sensitive below the limit of detection)?

What is Ozone's Real Half Life?

- Search the internet and you'll find 20 minutes
- That's not accurate in all cases
- Most water contains TOC that consumes ozone
- Which leads to everyone thinking that ozone has a shorter half life
- In Low TOC water, ozone's half life might be closer to 60-80 minutes



Thank You !!

QUESTIONS?