



# STEAM QUALITY – WHAT’S ALL THE FUSS ABOUT?

**Whenever we carry out audits of sterile products manufacturers we invariably ask questions regarding approaches to steam sterilisation, which leads inexorably to discussions on steam quality.**

If we are auditing a manufacturer outside the European Union (or, more precisely, outside the United Kingdom and Ireland) and we ask how the quality of steam used for sterilisation purposes is confirmed, we almost always get an answer something like this ...

“We regularly sample condensed steam and analyse it for compliance with water for injection standards.”

Whilst such a sampling and testing procedure can confirm the **purity** of the steam, it fails to answer questions regarding the quality of the steam for sterilisation purposes. To do this, it is necessary to assess certain other physicochemical attributes: namely...

- > superheat
- > dryness fraction
- > non-condensable gas content

In this article we will try to answer the two most important questions concerning steam quality...

- > why is steam quality so important to achieving effective sterilisation?
- > if it is so important, why don't the regulators demand regular steam quality testing?

## WHY IS STEAM QUALITY SO IMPORTANT?

To answer this question, we must first understand how steam under pressure kills microorganisms, and this requires an understanding of the thermodynamic properties of steam.

Cast your mind back to your schooldays and the first time you placed a bunsen burner under a beaker of

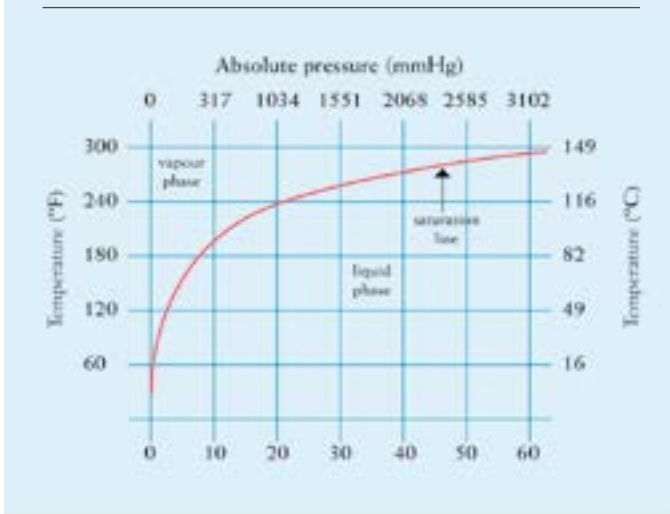
water and measured the water temperature with a thermometer. As the bunsen burner imparted heat (energy) to the beaker of water, so the temperature rose until the water reached boiling point. Then what happened? The bunsen burner continued to put energy into the water, but the temperature remained the same (100°C if you were at sea level). So what was happening to all this energy, if the temperature was no longer rising? The answer is that the energy was bringing about a **phase change** in the water; it was converting it from a liquid (water) to a gas (steam).

The energy required to raise the temperature of 1 gram of water by 1°C is 1 calorie (4.2 kilojoules). By contrast, the energy required to convert 1 gram of water into 1 gram of steam without any increase in temperature is 540 calories (2268 kilojoules).



Figure 1.

Relationship between temperature and pressure for steam saturation



This energy is known as the **latent heat of vaporisation**.

Thus, steam contains two types of heat...

- > **sensible heat**, which you can measure with a thermometer
- > **latent heat**, associated with the phase change

When steam comes into contact with a cool object it condenses, releasing the latent heat of vaporisation and the sensible heat associated with the drop in temperature. Hence, steam under pressure at 1.1 barg has a temperature of 121°C. When it meets a cool object, for example an item of equipment in an autoclave, and condenses and cools to 120°C, it gives up 1 calorie of sensible heat and 540 calories of latent heat. It is the energy associated with the latent heat which is largely responsible for the killing effect of steam.

But this energy release and subsequent killing effect only occurs if the steam is on the point of condensing – it is what we call **dry, saturated steam** or **phase boundary steam**.

Steam above the phase boundary line (see Figure 1) is **superheated**. It is not on the point of condensing and so will not give up its latent heat of vapourisation on contact with a cooler object until the temperature

drops to that of the phase boundary – which may never happen during the sterilisation phase of an autoclave cycle. Thus, superheated steam is a very ineffective sterilising medium.

Common causes of superheated steam are...

- > additional external heating, for example by an autoclave jacket which is hotter than the chamber
- > rapid expansion of steam from a narrow distribution pipe into a large autoclave chamber – so-called adiabatic expansion

Although steam will not exist below the phase boundary line, steam containing droplets of water will be wet, which will both reduce its efficiency as a sterilising medium and may also result in wet loads.

Common causes of wet steam include...

- > failure to remove entrained water droplets in the steam generator
- > inadequate condensate removal from the steam distribution system – infrequent or inappropriately placed condensate valves

Finally, if steam contains significant quantities of **non-condensable gases** (air or other gases which don't condense into water when steam is cooled) then these gases can accumulate within equipment to be sterilised and insulate against the sterilising effects of steam by stopping steam from coming into direct contact with a non-sterile surface and releasing its latent energy.

Common causes of non-condensable gases include...

- > poor steam generator design or performance
- > ingress of air into steam distribution systems via faulty pipework or faulty valves

From all the above, it should be clear that, for steam to be an effective sterilising medium, it should be...

- > saturated, and not superheated
- > not too wet
- > free of significant levels of non-condensable gases



## IF STEAM QUALITY IS SO IMPORTANT, WHY DON'T THE REGULATORS TAKE A GREATER INTEREST IN IT?

This is a difficult question to answer. Perhaps it is due to lack of education. Perhaps it is due to an understandable desire to place emphasis on microbiological confirmation of sterilisation efficiency (via bioindicators) rather than on less direct, physical measures.

However, at least two European regulatory authorities do demand steam quality testing. They are the UK's MHRA and Ireland's IMB. Both make reference to two important sources of guidance relating to testing and acceptance criteria...

- > Health Technical Memorandum 2010, "Sterilization"
- > European Standard EN 285: Sterilization – Steam Sterilizers

Failure to conduct steam quality tests or to comply with the acceptance criteria contained within these documents is considered to be a serious GMP failure by these regulatory agencies.

It is our firm belief that companies should regularly test their steam for superheat, dryness fraction and non-condensable gases, not because the regulators demand it, but because it is a central component of a Quality Assurance system for our steam sterilisation procedures. So just because your regulatory agency doesn't demand it, it doesn't mean that you shouldn't do it.

For more information, contact [pharmamail@nsf.org](mailto:pharmamail@nsf.org) or visit [www.nsfpharmabiotech.org](http://www.nsfpharmabiotech.org)

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