

## We only just Scraped through last Summer!



### Contents

#### Page 2

- The Best System at any Cost
  - Evaporative Cooling Explained
- Cooling Process Comparisons

#### Page 3

- Does Evaporative Cooling Work in the UK?

#### Page 4

- Evaporative Cooling & Humidity

#### Page 5

- Recent Installations
- Temperature Mapping & Monitoring via an automated network

#### Page 6

- MHRA Requirements at a glance
- Keeping it on the MKT

## Introduction to the Pharmacool Integrated System

*"Pharmacool is the only solution on the market that comes with a full compliance guarantee, giving you complete piece of mind."*

Procool has developed its Pharmacool system as a modern, cost effective and compliant solution to reduce storage temperatures when required.

Evaporative cooling, which is at the heart of every Pharmacool design, uses fresh air and a natural cooling process called evaporative cooling to control warehouse temperatures, using the lowest possible amount of energy.

Pharmacool is the industry's first truly integrated system for warehouse temperature control, specifically developed for the Pharmaceutical Industry. Our unique guarantee is made possible by incorporating all aspects of temperature control from heating to cooling and initial mapping to ongoing recording.

Where appropriate, the Pharmacool

solution combines four main component parts:-

- Evaporative Coolers and new or existing heating systems
- Ventilation and duct work
- Temperature Control & Mapping
- Report Generation

Each Pharmacool system is designed to suit the nature of your individual building, from small 740m stockrooms through to large 10,000+m warehouses. All systems offer the same guarantee, low cost installation and low operating costs.

The MHRA 'Orange Guide', revised in February 2007, lays out the requirements for Pharmaceutical manufacturers and distributors. It's through a thorough understanding of these that Procool is able to bring you cost effective temperature control, at a

fraction of the operating cost of other solutions.

The Pharmacool solution is brought to you by Procool; one of the countries leading specialists in Warehouse cooling.

### The Pharmacool Guarantee

Unlike most manufacturers and installers of warehouse cooling systems, at Procool we design our systems to remain compliant with MHRA temperature storage requirements whatever the weather throws at you.

The result is a unique guarantee, stating that conditions within your warehouse will remain compliant, even under the sort of freak conditions we sometimes experience in the UK



# The Best System at Any Cost

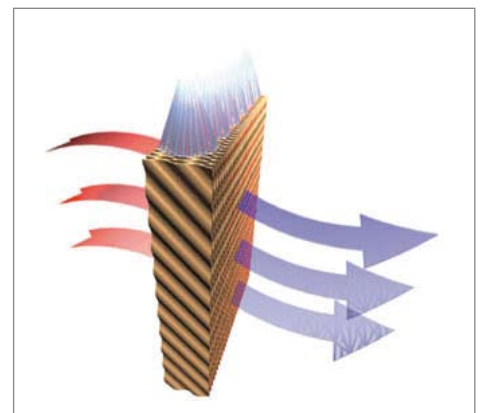
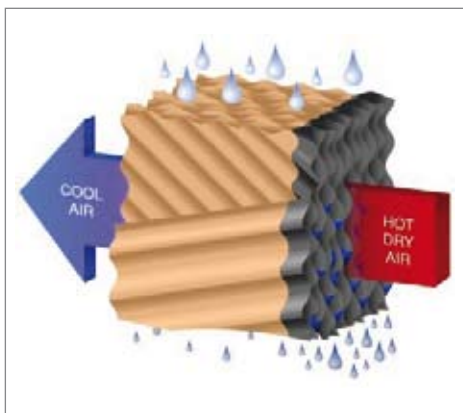
## – Evaporative cooling explained

Pharmacool systems employ a natural process called evaporative cooling to reduce temperatures when required. Evaporative cooling works by drawing hot fresh air over a set of wet extended surface pads. As water is evaporated into the airstream, energy is removed from the air in the form of heat, thus cooling it. As

it gets hotter, the effect increases and so more cooling is achieved.

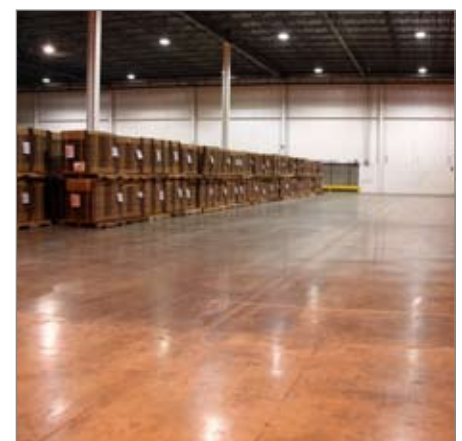
Because typically a Pharmacool system will cost 40% to 70% less to install than a traditional air conditioning system, it can be tempting to think that evaporative cooling is a compromise, but this couldn't

be further from the truth. Properly designed, evaporative cooling out-performs air conditioning regardless of cost. Therefore, when you have critical applications that need cooling, even under unexpected or extreme conditions where conventional systems fail, Pharmacool clearly is the best choice on the market.



## Process Comparison

Evaporative Cooling	Air Conditioning
<ul style="list-style-type: none"> <li>As outside temperature increases, evaporative cooling increases in capacity / effectiveness / performance</li> <li>At temperatures well above design parameters, evaporative cooling keeps working</li> <li>As doors are opened and/or left open, evaporative cooling maintains control and keeps working</li> <li>Evaporative coolers have only a few moving parts, all of which can be replaced easily in minutes if they fail</li> <li>Evaporative cooling systems use fresh air to deliver free cooling when it's cooler outside, saving energy, wear on components and money</li> <li>Evaporative cooling can be used to cool just small parts of a large open building (Spot cooling)</li> <li>Properly designed evaporative cooling systems maintain a natural moisture level without excessive humidity</li> </ul>	<ul style="list-style-type: none"> <li>As outside temperature increases, air conditioning decreases in capacity / effectiveness / performance</li> <li>At temperatures well above design parameters, air conditioning fails completely</li> <li>As doors are opened and/or left open, air conditioning loses control and possibly fails completely</li> <li>Air conditioners have many moving parts, most of which take hours to replace and need specialist equipment and labour</li> <li>Air conditioning re-circulates internal air, and may need to run even when it's cooler outside</li> <li>Air conditioning does not work well in parts of a large space, unless physical partitions are installed</li> <li>Air conditioning dries the air, increasing static build up and decreasing comfort levels</li> </ul>





# Does Evaporative Cooling work in Pharmaceutical Warehouses in the UK?

In response to the rapid acceptance and growth of evaporative cooling in recent years, some air conditioning companies have attempted to argue that it doesn't work. Below we correct some of the misinformation that abounds.

Unedited copies of some of our competitor's articles are available from Procool, with a more detailed response.

*"Fact" number one: Evaporative coolers can cool by no more than 8 to 10 deg C.*

The figure of 8 to 10 deg C is based on a 30 deg C, 50% RH day (typical air conditioning industry design conditions). It is NOT true that only 8 to 10 deg C is available at other conditions. For example, at 36 deg C and 25% RH, you'd get 14 deg C of cooling.

*"Fact" number two: The fact that it's hotter inside than outside without cooling is a bad thing for evaporative coolers.*

If the warehouse is 5 deg C warmer than outside, it follows that simply replacing the indoor air with outdoor air (without cooling it) will reduce the inside temperature by 5 deg C. If that air is allowed to stay in the room it will of course increase in temperature over time, but with evaporative cooling we don't allow that to happen.

Add cooling into the equation, and the result is compliant temperatures even in

extreme conditions.

*"Fact" number three: On hot days you'll get no cooling because it'll be too humid.*

Take a look at the article opposite for more detail, but the truth is that high humidity and high temperatures do not coincide in the UK.

*"Fact" number four: Evaporative cooling systems use single units delivering air in one spot and so can't achieve good air distribution.*

This is a little like saying a poorly designed evaporative cooling system won't work as well as a well designed air conditioning system, which is obviously true! The principles of good air distribution are as crucial and as easy to apply for both systems, though evaporative cooling starts with an advantage as it circulates far more air and mixes things up better.

*"Fact" number five (contradicts fact number four!): Evaporative cooling systems use multiple units on the roof, risking leaks from roof penetrations and from water distribution systems.*

We can issue weatherproofing guarantees of up to 10 years if required, water pipes are never run through the warehouse and roof mounting is far from the only option anyway.

Using multiple units means that if one

fails, the vast majority of the system is still working and very little cooling is lost.

*"Fact" number six: Evaporative cooling systems are difficult and expensive to maintain.*

Annual maintenance costs are very similar to those for air conditioning and the work doesn't have to be carried out by specialist refrigeration engineers.

*"Fact" number seven: Evaporative coolers give you legionnaires disease.*

Dr Tom Makin, who co-authored the official HSE guidelines into the control of Legionella, has now confirmed that evaporative coolers are inherently safe. A copy of his report is available on request.

There are in excess of 30,000,000 evaporative coolers installed worldwide, yet there's been not one case of legionnaires disease as a result.

*"Fact" number eight: There's only one example of evaporative cooling being used for pharmaceutical storage, which is in the South of France where conditions are very different.*

The French example is far from the only one available, but is a good one because it demonstrates what happens not only under "normal" UK conditions, but also at the exceptional conditions we might experience as global warming takes hold.

# Evaporative Cooling & Humidity

The subject of humidity and evaporative coolers crops up frequently, and there are generally two opposing concerns:

- Will my coolers perform less well if it's very humid outside?

The straight answer to this is yes, they will, as evaporative coolers work best when it's hot and dry! The question is, how does that fit with what we need in the UK? The UK has a temperate climate, which means we don't get huge extremes of either temperature (as in an arid climate), or of humidity (a tropical climate).

The diagram below shows relative humidity (RH) vs. outside temperature, recorded in the UK over a three year period, with each dot being a single recorded incidence. It shows very clearly that as temperature increases, humidity falls, so that while we might get to 90% RH

at 20 deg C, we only ever reach 50% when it's as hot as 30 deg C, and that the drop in humidity continues as we approach extreme temperatures.

This all means that the hotter it gets outside, the drier it gets, and the better the evaporative cooler performs. At 20 deg C and 90% RH, an evaporative cooler will only achieve around 1 deg C of cooling, but that's OK because it's already cool. At 25 deg C and 70% RH, we can cool through 3.5 deg C, resulting in 21.5 deg C, while at 30 deg C and 50% we get down to 22 deg C, all of which are acceptable temperatures.

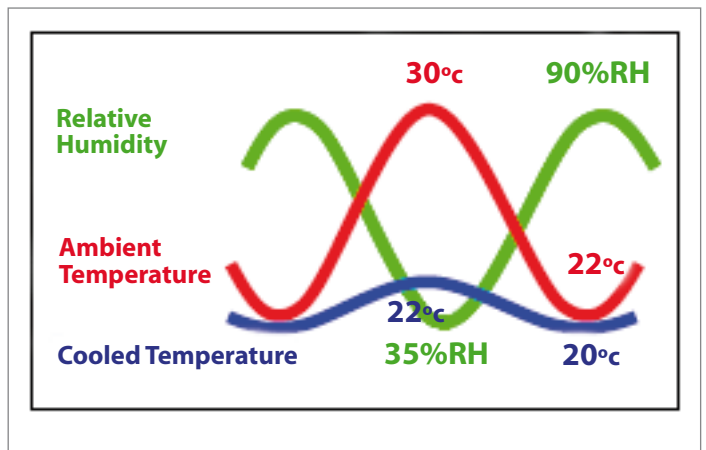
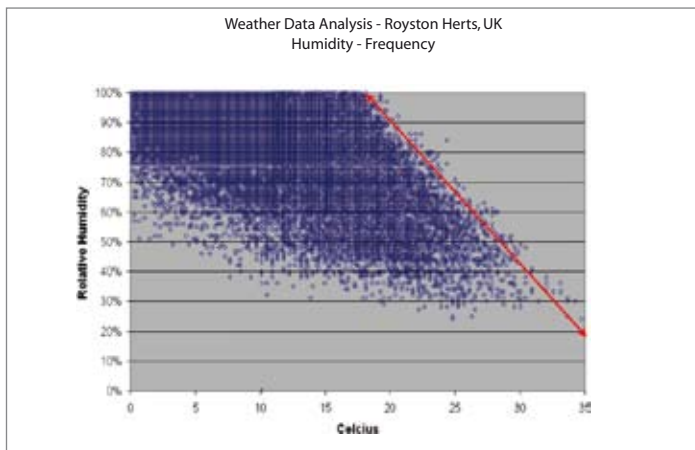
- Will the evaporative coolers create high humidity in the warehouse?

Most people's experience of evaporative coolers is with mobile units of the type you might hire. Such coolers very rarely

see 100% fresh air, and so end up re-circulating some of the air they've already cooled. As they do that they add moisture on top of moisture, and do end up humidifying the room, and also failing to cool – the worst of all worlds.

Permanently installed coolers are different animals altogether. They operate using 100% fresh air at all times, and form part of a balanced ventilation system. One of the best ways to reduce humidity in a large space is to ventilate it, and that is achieved using an evaporative cooling system. Moisture is then added back in by the cooling effect, but the result is humidity levels no higher than you'd expect to see naturally on a cooler day anyway, typically around 50 to 55%.

The net effect is that an evaporative cooling system will create conditions on a hot day that feel fresh and "springlike", without excess humidity.



# Recent Installations

Here's a roundup of some of the most recent companies to recognise the benefits of Procool's Pharmacool systems:

## Westfield Medical:

Westfield produce sterilization packaging for the UK and overseas, and when their existing ventilation system failed to maintain the required temperatures, Procool were able to help. While not obliged to meet the MHRA temperature requirements, the need for cleanliness while keeping staff comfortable is obvious.

## Durbin plc:

Durbin's 2 year old air conditioning system failed to maintain MHRA compliant temperatures, and was very expensive to run, so was replaced with a fully automatic Pharmacool system using an interest free Energy Efficiency Loan from the Carbon Trust.

## Wren Laboratories:

Wren's DTECTA probiotic products have been a huge success, and when they needed cooling to support their Andover warehouse they turned to Procool for the most cost effective solution available.

## Chemilines:

15 coolers, heating, energy saving destratification fans, intelligent controls and automatic network based temperature monitoring have been installed at Chemilines state of the art warehouse in Wembley.

# Temperature Monitoring & Mapping via an Automated network



## Temperature Monitoring

The Pharmacool Temperature Monitoring system is specifically designed to allow storage temperatures to be accurately recorded in Pharmaceutical warehouses, either as a stand alone package, or integrated into a temperature control installation.

Accurate monitoring can be difficult or impossible to achieve using traditional min/max thermometers or stand alone data loggers, because of the number of individual measuring points needed to produce a meaningful picture.

Below are a few of the benefits of Pharmacool's Temperature Monitoring system:

- Wired or wireless sensors as appropriate, for maximum flexibility and reliability
- Flexible MHRA specific historical reports
- Real time data display
- Secure data storage
- Temperature alarms (including MKT) by text, e-mail, or even audible alarm
- Secure web browser based interface
- Three levels of automatic data backup
- Can be integrated with cooling and/or heating controls
- Uses industry standard hardware and sensors
- Can be customised to suit specific reporting or other needs, including central multi site reporting

## Temperature Mapping

The Pharmacool Automated Mapping system sends information back to a central hub taking away the inconveniences and issues of manually collecting the data.

Once the data has arrived at the hub a PC automatically stores the information and enables quick and easy generation of

detailed reports for all your compliance needs.

Some of the benefits of The Pharmacool Automated Mapping system are outlined below:

- Measures Temperature and/or humidity
- Logging intervals from one minute to 10 days
- Local cache of 1 week's readings
- Ensures continual compliance
- Easy to set up and re-configure if the use or layout of the warehouse changes
- On-line diagnostics
- Automated data downloading
- Automatic calculation of MKT
- Can be managed remotely
- Information accessed via an internal network, or via the internet
- Remote alarm signalling via e-mail & SMS

"Pharmacool is the only solution on the market that comes with a full MHRA compliance guarantee, giving you complete piece of mind."



**MHRA**  
compliant

# MHRA Requirements At A Glance



In February 2007 the MHRA (Medicines & Healthcare products Regulatory Agency) revised the 'Orange Guide' which is a set of rules and guidelines outlining GMP (General Manufacturing Practice) for Pharmaceutical manufacturers and distributors

Detailed within the guide are the precise conditions required for the storage of drugs at "controlled room temperature", basically those labelled "store below 25°C".

In simple terms, compliance with MHRA regulations requires the following:-

- The MKT remains below 25°C at all times. MKT (Mean Kinetic Temperature) is a complex temperature average that predicts the effect of high and low temperatures on pharmaceutical products over time.

- The instantaneous temperature only exceeds 25°C occasionally. The guidance doesn't define "occasionally", and we do need a definition to be able to design. We've discussed this with the MHRA and agreed a specific set of outside design

conditions that are only exceeded occasionally, and so allow only occasional excursions above 25°C. These design conditions should be applied to any cooling system under consideration, and are available from Procool on request.



- The instantaneous temperature NEVER exceeds 30°C. If it does, then you are non-compliant even if the MKT remains below 25°C. 30°C can easily be exceeded if an air conditioning system fails at high outside temperatures.

- The temperature properties of your building are understood. So storage and temperature control systems can avoid "hotspots," temperature mapping a building is often required so that you can fully understand its thermal properties.

- Temperature conditions are monitored and recorded. Without monitoring it's impossible to demonstrate compliance with the guidelines, and often if a breach is suspected the only safe course of action is to dispose of more stock than would be required otherwise.

Procool's fully integrated Pharmacool Evaporative cooling system will guarantee to meet all of the conditions above – and we are currently the only company in the UK that does!

## Keeping it On the MKT

For the pharmaceutical industry, like the food industry, it could be said that scrutiny over quality needs to be that much greater – and understandably so. The mean kinetic temperature (MKT) requirement places a significant responsibility on all managers of pharmaceutical storage facilities. It is generally accepted as the yardstick by which quality storage is measured, and forms an integral part of the auditing procedures by the Medicines and Healthcare Regulatory Agency (MHRA).

The MKT is defined by the United States Pharmacopoeia (USP) as a: "single calculated temperature at which the total amount of degradation over a particular period is equal to the sum of the individual degradations that would occur at various temperatures".

It is a calculated, fixed temperature parameter, which simulates the effect of temperature variations over a period of time. In particular, it takes into account the likelihood of accelerated product degradation due to high storage temperatures. It is not a simple averaging calculation because it gives greater weighting to higher temperatures in determining the average from a datum.

Whilst high ambient temperatures haven't always been a feature of British summers, recent experience has highlighted the need to plan for preventive action. So what means are available to help control storage conditions to within the MKT? There are three main approaches that can be considered: air conditioning; ventilation; and evaporative cooling.

