

EXPRESS PHARMA

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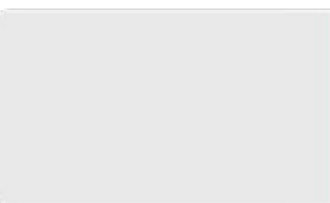


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VALUE ADD

ClearView by Electrolab: A cost-effective solution

Aditya Marfatia, Director, Electrolab and Neelam Sayed, Application Scientist Electrolab, give an insight on ClearView by Electrolab, which utilises the innovative and proven UV technology to reduce frequent water bath cleaning by maintaining a clean dissolution water bath for extended period of time



Aditya Marfatia, Director, Electrolab



Neelam Sayed, Application Scientist, Electrolab

DISSOLUTION TESTS are commonly conducted on a dosage form to evaluate the time taken for its active ingredient to release into the body and help predict how the drug performs inside the body. The dissolution test is an important quality control tool and also enables to establish bioavailability and bioequivalence. As the dissolution procedure is an important test to evaluate safety, predict efficacy and stability with respect to manufacturing and storage conditions, regulatory bodies are more stringent about GMP compliance with reference to the dissolution test. Over the past few years, many pharmaceuticals companies have faced drug recalls and have also been issued with form 483, warning letters etc. from regulatory bodies due to problems associated with dissolution

testing. Several observations recorded have either due to failed dissolution specifications, improperly calibrated or poorly maintained dissolution equipment.

An observation in form 483 issued to a pharma company in April 2017, has cited the improper maintenance of the dissolution water bath, along with other dissolution related issues. The observation states "..... Your analyst recorded the water in water bath for dissolution tester as clear. I observed the water in the water bath was not clear as required in your written procedure for operation and calibration of the dissolution tester. I also observed unidentified whitish **** floating in the water bath. Your QC supervisor reviewed the instrument set-up and approved the analyst to proceed

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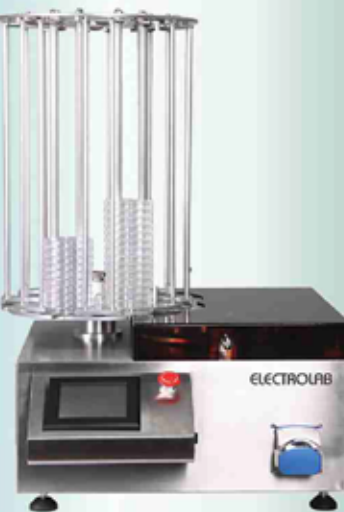
Increase Efficiency



Reduce Error



Rugged Construction



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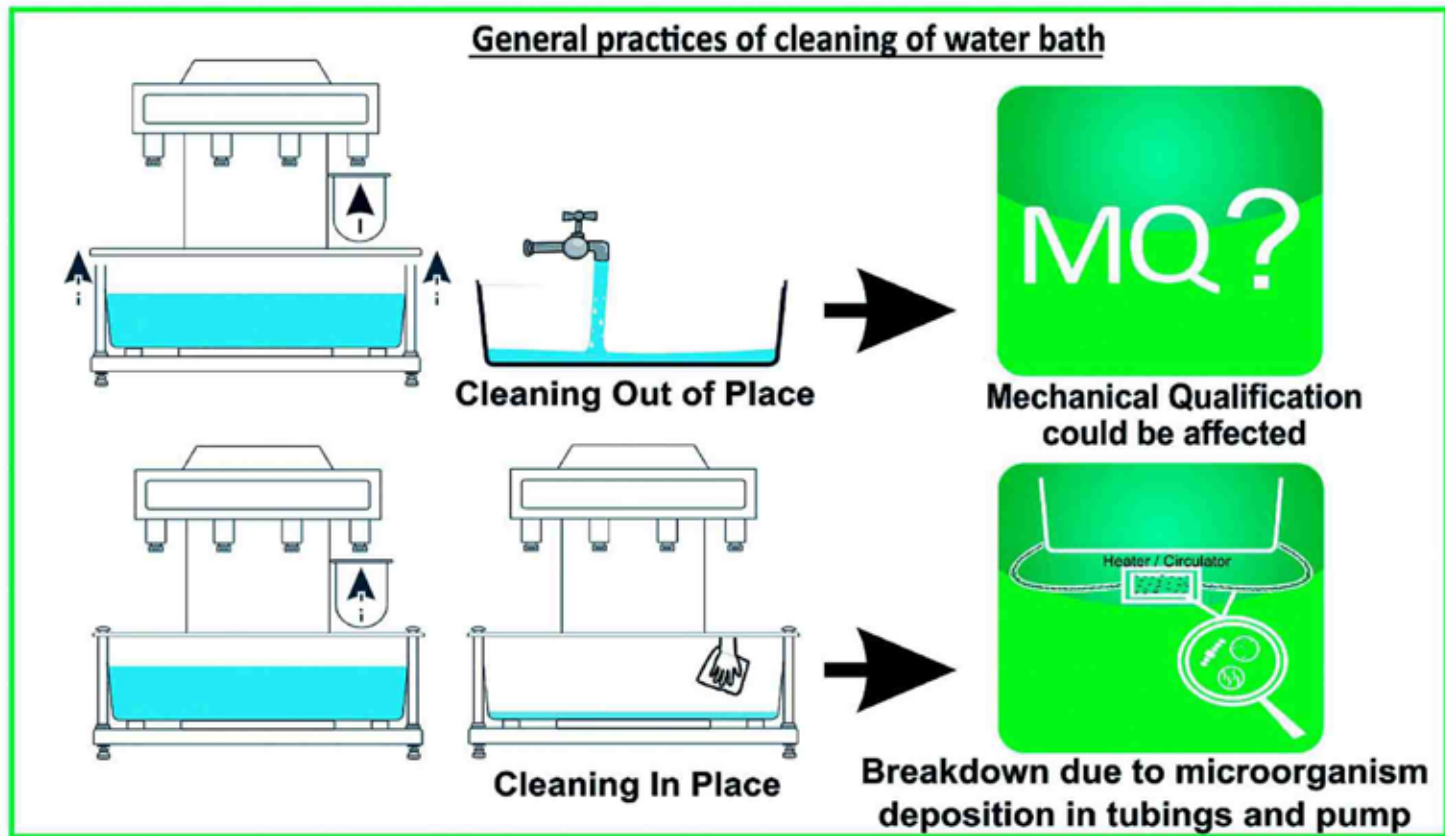
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with the testing without documenting the unclear water in the water bath."

The temperature of water inside the dissolution water bath acts as a perfect incubator for promoting growth of single celled organisms like algae, fungi, bacteria etc. The constantly stirring water introduces a good supply of oxygen that further promotes the propagation of these organisms. This propagation later gets deposited in the water bath tubing and pump and significantly affects the circulating system by reducing the flow rate and thus causes a great impact on temperature regulation. The heating efficiency of the system may also be hampered, as the response from the temperature sensor is delayed due to the formation of biofilm over the temperature sensor. The microbial growth deposited on water bath wall, tubing, pump and other contact parts may lead to breakdown resulting in lower throughput. In order to extend the life of the dissolution tester and enable continuous use for many years, it is essential that the water bath is cleaned thoroughly at regular intervals. Cleaning of water bath is a tedious aspect of using dissolution technology and usually lab performs this maintenance every week.

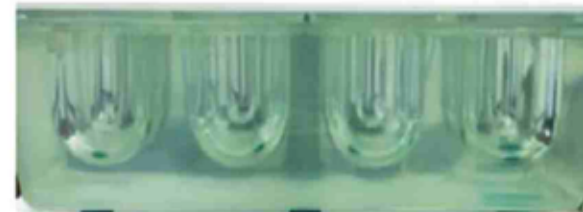
In addition to these general practices depicted above, chemical agents such as algaecides, Bronopol, Deconex, Cetyl Pyridinium Bromide etc. are sometimes added to water bath to eradicate microorganisms and to maintain clean water bath for longer period of time. But such chemical agents offer limited effectiveness as they may be organism specific and may not be able to inhibit the propagation of other organisms commonly found in untreated water. Going beyond the conventional bath dissolution tester, bathless dissolution testers are also available; where vessels are heated by a heating jacket instead of a water bath. These systems eliminate frequent water bath cleaning and all other associated maintenance.

In order to prevail over the above concerns, Electrolab has introduced ClearView, a cost-effective solution that can be



Schematic representation of general practices of cleaning of water bath with their probable drawbacks

ClearView™ (ECV-08): Retrofittable to most brands of dissolution testers.



Within weeks of routine use



After several months of integration with ClearView™

Data on file

easily retrofitted to most brands of conventional 8 and 14 station dissolution testers (USP Dissolution Apparatus 1-7) and disintegration testers. ClearView utilises the innovative and proven Ultraviolet (UV) technology that significantly reduces frequent water bath cleaning by maintaining a clean dissolution water bath for extended period of time. ClearView is a non-chemical, rugged water sterilisation system with a smaller footprint

that incorporates an UV steriliser into the water bath's circulating system. The steriliser contains an UV lamp that safely emits germicidal rays that disrupts or alters the DNA or RNA of single celled organisms that are commonly found in untreated water. Although, the UV light alters the DNA or RNA of these microorganisms but; it does not otherwise alter the water being treated or cause any damage to the water bath, tubing, pump etc. Being

fully enclosed, ClearView does not cause any harm to human beings nor does it have any impact on the dosage form being tested. Although, the efficiency of ClearView depends on the source water bioburden, but deconex 12 BASIC in combination with ClearView can be used to enhance the efficiency of the system.

Integration of ClearView not only enhances the visual observation of the dissolution process but also significantly reduces

breakdown, cost of consumables like high purity water, water bath, tubing, pump etc. and also reduces the labour time involved in water bath cleaning and maintenance.

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