



Cipla achieves accurate pH balance in API production with Walchem controllers

pH is a critical parameter in Active Pharmaceutical Ingredient (API) processes. It is important to maintain the required pH level not only because it is a regulatory need, but also because it ensures consistent quality of the product. Maintaining the correct pH balance reduces the risk of product failure during the manufacturing process.

Background

Cipla Limited is an Indian multinational pharmaceutical and biotechnology company, headquartered in Mumbai, India. A pioneer in API manufacturing in India for over 5 decades, Cipla currently manufactures more than 200 generic and complex APIs. Cipla has a network of modern API manufacturing facilities; all approved by the US FDA and other major international regulatory agencies.

Challenge

API is the substance or substances that are biologically active within the drug and is the specific component responsible for the desired effect in the body. Hence, maintaining pH value between 07 and 10 is very crucial. Cipla used the conventional process for pH control that involves a manual sampling technique. Here the technician manually samples ingredients from the reactor and measures their pH value in the laboratory. Based on the test results, the technician has to add acid or alkali manually in to the API reactor. This process is repeated till the pH reaches the desired level.

Since the process is manual and needs to be repeated frequently, some of the issues faced are:

- Accuracy is not guaranteed
- More chances of product failure
- Employee safety is compromised (as manual handling of hazardous acid/alkali is involved)
- Time consuming

Solution

Having understood the problems faced by Cipla, A.T.E. offered the perfect solution – the Walchem automated online pH monitoring controller along with dosing skid.

The Walchem controller is automated. It records online the pH reading with the help of an integrated sensor. The controller then compares the recorded pH value against the pre-set value and gives a pulse proportional command to the skid-mounted dosing pump to dose acid or alkali until the pH value reaches the pre-set value. The controller continuously tracks the pH value and automatically repeats the process to maintain the desired pH value.

Result

With the Walchem automated dosing system in place, Cipla was able to overcome the issues with the manual sampling technique and also realise the following benefits:

- a. Saving in time
- b. Maintains pH accurately
- c. Ensures employee safety
- d. Reduces acid and alkali consumption

Mr Sandip Dhumal, Section Head – Engg Dept., Cipla, says “We found A.T.E to be a very reliable flow technology solution provider. We are very happy for the solution provided in process analytical technology with the Walchem automated pH controller and dosing skid, which helped to maintain the true pH value of the API. We are going to replicate this solution in other units of Cipla.”

