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Almac Voice

Registered starting material testing - it's not immaterial

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Analytical QC release testing has long been a pivotal step in the manufacture of active pharmaceutical ingredients (API) and drug products, but in recent times this has tracked back into regulatory starting materials (RSM) and key intermediates, where the burden of analytical testing is greater than ever.

As regulatory starting materials have become more complex, often with multiple chiral centres, drug developers are increasingly relying on their manufacturing partners to undertake the thorough analytical testing requirements to enable release of material into GMP manufacture.

Historically a standard specification for a key intermediate would consist of an identity (ID) test with water and solvent content, however there are now multiple considerations for analytical test specifications, some of which are discussed below:

Multiple chiral centres

As has been mentioned above, starting materials with multiple chiral centres are becoming more commonplace therefore analysis needs to be robust in this area.

At Almac's large scale nonGMP manufacturing facility - Arran Chemical Company - we manufacture over forty different regulatory starting materials with an annual output of up to 60 metric tonnes for several of these products. These molecules become more complex over time and often contain one or more chiral centres, bringing chiral HPLC into the release specification and enabling our analysts to enhance their expertise in this area.

Environmental considerations

We are now seeing a trend towards moving manufacture back to the West. This is driven by a number of concerns but, particularly by companies who are looking for greener solutions. These solutions include solvent switches to more environmentally friendly options, but again this impacts the analytical release specification, and therefore requires redevelopment of methods for determination of residual solvents, and often a specialist piece of analytical characterisation to demonstrate that the solvent switch has not affected the final API.

Scrutiny of physical properties

As the industry strives for more efficient manufacture, the physical properties of these key intermediates also come under scrutiny, with particle size and even polymorphic form becoming areas of interest. These parameters affect the solubility of intermediates going into the manufacturing stream as even slight tweaks can potentially have a big impact on the efficiency of the process.

Almac's analytical team has a full suite of capabilities, with extensive experience in structural elucidation, development and valuation of chiral HPLC methods and physicochemical characterisation. Our analytical testing lab in Athlone, Ireland, sits close to our Arran manufacturing facility to support their extensive analytical needs. Additionally, our analytical lab in Craigavon is on the same site as our GMP manufacturing facility where our team are routinely developing and validating release methods.

Get in touch to find out more about our capabilities.

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