



Inhaler Development and Filling

Inhaler development

- ▶ It is introduced as a device into the market after 7-10 years of continuous effort.
- ▶ Many years are spent for the development and formulation of the drug, device designing & development and clinical testing including performance testing, formulation stability and regulatory approval among others.
- ▶ Many changes including FDA's guidelines for parametric testing have been witnessed in the device development process since 2002. For e.g., ISO 20072 is intended for device design verification and not for drug product quality assessment
- ▶ Inhaler filling service contributes a maximum of only 15-25% of the total cost involved in the inhaler development process

Emerging Trends in the industry:

- ▶ Increasing regulatory requirements and the transition to CFC free pMDIs led to the development of valves to meet HFA propellants and dosing uniformity.
- ▶ The transition to HFA propellants has also led to the development of pMDI actuators with improved delivery efficiency.
- ▶ Several companies are introducing new valves for pressurized metered dose inhalers, which have many benefits over conventional valves.
- ▶ Major service providers are upgrading their manufacturing sites with new filling equipment to enhance their inhaler filling service capabilities. For example, Harro Hoffiger Omnidose filling unit enables powder filling in 1-300 mg DPIs.
- ▶ A pharmaceutical and healthcare group is developing a unique inhalation drug delivery platform using high density aerosol (HDA) technology. The device is expected to be as efficient as the drugs which are taken orally.

Inhaler Filling Techniques:

For Dry Powder Inhalers

Auger Filling:

- ▶ This mechanism uses an auger, which is rotated for a predetermined number of revolutions in a conical hopper to discharge the required volume of product.
- ▶ The main benefit of these machines is their ability to control dust during the filling operation and therefore used extensively for powders.

Drum Filling:

- ▶ The drum filler with vacuum is suitable for powder with poor flow properties.

- ▶ With this mechanism, the filling can be done in the dosing range of 1-50 mg.

Dosator Filling:

- ▶ For processing compactable powder with reproducible fill volume, the dosator filling mechanism is used.
- ▶ The dosing range lies between 1-600 mg.
- ▶ High speed filling is possible for disk and capsule dry powder inhalers.

For Pressurized Metered Dose Inhalers

Cold Filling:

- ▶ The entire formulation is added to canisters in a single step process.
- ▶ The valves do not require any special design to withstand pressure filling.

Pressure Filling:

- ▶ The formulation performance does not need to be assessed and developed to meet processing requirements at -60°C.
- ▶ Both formulation and filling can be conducted at ambient temperature.

International Compliance and Standards

Approval from Regulatory Bodies:

- ▶ Manufacturing sites of service providers are expected to be accredited by different regulatory bodies like the FDA and EU.
- ▶ International accreditations include WHO, MHRA, ANMAT (Argentina) and INVIMA (Colombia).

Compliance to GMP, cGMP Standards

- ▶ The standards address various issues like safety, equipment verification, and process validation in manufacturing sites of service providers.
- ▶ These standards also ensure that service providers provide them with the latest technologies that comply with regulations.

Certifications from Various Organisations:

- ▶ ISO sets international industrial standards required by service providers for various services that are being provided.
- ▶ Service providers are also expected to maintain clean room conditions, which provide specifications for number of particles present in the air for a clean room manufacturing environment.

Conclusion:

The need for inhalers is increasing with a large number of patients suffering from Asthma and COPD around the globe. The transition from CFC to environment friendly HFA propellants is a major development along with the other new inhaler development and filling techniques. The major pharmaceutical companies are looking at Asia for procuring the inhaler filling services, and the Asian population is also being introduced to a wide range of treatments for Asthma and COPD.

Sources: In-Pharmatechnologist, Health-Informant, Pharma Tech, Pharma Asia, Outsourcing-pharma, Pharmapro, Pharmaceuticalonline, thepharmaletter

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