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AEROSOL: A REVIEW OF RECENT DEVELOPEMENT

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ABSTRACT
Aerosol science is a rapidly evolving and cross-disciplinary area that has significant impacts on human health, climate change, and various technologies. Aerosols, which are minute particles that float in the air, come from a variety of natural and human-made sources and affect global processes such as radiative transfer and cloud formation. This review consolidates the latest progress in important areas of aerosol research, emphasizing notable improvements in measurement methods, modeling, and technologies tailored for specific applications. A colloidal system of tiny solid particles or liquid droplets suspended in a gas is called an aerosol. This assignment offers a thorough analysis of aerosols, including their basic characteristics, many sources, and important effects on the environment and human health. The differences between anthropogenic (such as smoke, industrial pollution) and natural (such as dust, sea spray) aerosols are discussed, along with their origins. The physics and chemistry of aerosol generation, movement, and removal from the atmosphere are among the main subjects covered. The project also explores the deep ramifications of atmospheric aerosols, including their function in respiratory health and air quality as well as their direct and indirect consequences on climate change. Pharmaceutical aerosols' therapeutic uses in inhalation medication administration are illustrated in a special section.

KEYWORDS: *Pharmaceutical Aerosol, Components of Aerosol, Inhalers, Types, Quality Control.*

INTRODUCTION
An aerosol container is a pressurized package that holds medicine mixed with a gas that is either compressed or turned into liquid. This gas helps push the medicine out of the container in the form of a spray, foam, or stream.

Benefits of Using Aerosols
- The medicine is protected from oxygen and moisture, which helps keep it stable.
- The medicine can be applied directly to the area that needs treatment.
- The medicine works quickly when given this way.
- It avoids being broken down in the stomach.
- It skips the liver's first-pass metabolism, so more of the drug reaches the bloodstream.
- It can be used for both whole-body (systemic) and local treatments.
- It's easy to use.
- The drug stays sterile (free from germs), and contamination is prevented.

The way the aerosol works depends on several parts: the valve, the container, the actuator (which is the part you press), and the propellant.
There are two main parts in an aerosol:
1. **Product concentrate** – This contains the active medicine.
2. **Propellant** – This is a gas with a high pressure at 40°C (105°F). It creates the pressure needed to push the medicine out in the form you want (like mist, foam, or spray). Sometimes, the propellant also helps dissolve the medicine or carry it..

PROPELLANT
The pressure created by the propellant inside the container makes the valve open, which then pushes the medicine out as a spray (tiny droplets) or foam.

Types of Propellant
Depending on the route of administration and use, the propellant can be classified as given in **Table1**

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Table 1: Types of Propellant

Application	Name of propellant
For oral and inhalation	**Fluorinated hydrocarbons** Di-chloro di-fluro methane (propellant 12) Trichloromonoflouromethane (propellant 11) Di-chloro tetra-fluro ethane (propellant 114)
Topical preparation	Propane, Butane, Isobutane
Compound gases	Nitrogen, Carbon dioxide, Nitrous oxide

Chlorofluorocarbon (CFC) Propellants
Propellants are chosen based on some important qualities: they should not react with other substances (chemically inactive), should not be poisonous, and should not catch fire or explode easily. Because of these qualities, certain chlorofluorocarbon (CFC) gases like P-11, P-12, and P-114 were used in aerosol products for many years.

However, their use has now decreased because they harm the ozone layer. Even so, small amounts are still used in medicines for asthma and COPD because they are not very toxic or flammable.
Newer propellants like P-134a and P-227 have now been developed to replace P-12 in aerosol medicines.

Principle of releasing out of product concentrates from container:
In a sealed aerosol container, the liquefied propellant (or a mix of propellants) stays in balance with the medicine mixture. Some of the propellant turns into gas and fills the space at the top of the container. Because the liquid and gas are in balance, the pressure inside the container stays steady. That's why it's called a *pressurized aerosol container*.

The force created by the gas is called *vapor pressure* and is measured in **psig**. This pressure depends on the type of propellant used. When you press the valve, the pressure inside pushes the medicine up through a tube and out of the container. Once the spray reaches the air (where the pressure is lower), the propellant quickly turns into gas and disappears, leaving behind dry medicine particles.

Hydrocarbons Propellants
Hydrocarbon propellants are good for use because they are safe for the environment, have low toxicity, and don't react easily with other substances. They are often used in water-based aerosols because they don't break down in water (since they don't have chlorine). Since hydrocarbons don't mix with water, they float on top.

Hydrocarbons create the pressure needed to push the medicine out of the container.
The downside is that hydrocarbon propellants can catch fire or explode. To make them safer, different types of propellants are mixed together, and special valves called vapor tap valves are used to reduce the risk of fire.

Compressed Gas Propellants
Compressed gases like nitrogen, nitrogen dioxide, and carbon dioxide are used as propellants to release products as fine sprays, foams, or semi-solid forms. These sprays are quite wet, and the foams they create are less stable compared to those made with liquefied gas propellants.

Unlike aerosols with liquefied gas, there is no liquid propellant inside. Instead, the compressed gas is stored in the empty space at the top of the container, and its pressure pushes the product out. Because of this, a higher gas pressure is needed.
These types of aerosols are often used for food products, dental creams, hair products, and ointments.

CONTAINERS
Aerosol containers are usually made from glass, metals (like tin-plated steel, aluminum, and stainless steel), or plastics. The material used must be strong enough to handle high pressure. These containers need to safely hold pressures between 140 and 180 pounds per square inch (psig) at 130°F. Besides strength, the cost and how well the material works with the medicine inside are also important to think about. The pressure limitation of aerosol container is as given in **Table 2.**

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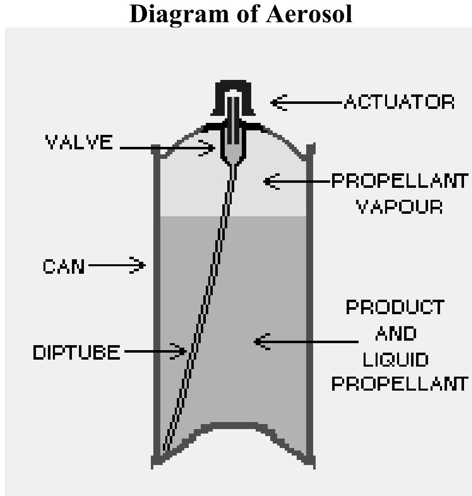
Table 2: Pressure Limitations of Aerosol Container

Container material	Maximum pressure (psig)	Temperature (^{0}F)
Tin -plated steel	180	130
Uncoated glass	< 18	70
Coated glass	< 25	70
Aluminum	180	130
Stainless Steel	180	130
Plastic	< 25	70

Diagram of Aerosol



Glass

Glass is sometimes used for aerosol containers, but because it can break easily, it's only used when the pressure is low (less than 25 psig) and there is a small amount of propellant (less than 15%).

To keep glass containers from breaking under pressure, they are covered with two layers of plastic coating. Two types of coatings used are epoxy and vinyl resins. Vinyl coatings can't handle high heat like steam at about 200°F, but epoxy coatings can.
These coatings work well for water-based products that are slightly acidic (low pH).

Metals

Tinplated Steel

Tin-plated steel containers are light and cheap to make. Both sides of the tin container are covered with thin steel sheets to protect the inside from rust and to stop the tin from reacting with the medicine inside. These containers are coated with materials like oleoresin, phenolic, vinyl, or epoxy. Tin-plated steel containers are often used for sprays applied to the skin (topical aerosols).

Aluminium

The aluminium containers are light weight and are less prone to corrosion than other metals. Aluminium is used in most metered dose inhalers (MDIs) and many topical aerosols. Epoxy, vinyl, or phenolic resins coatings are done on aluminium containers to reduce the interaction between the aluminium and the formulation. The seamless aerosol containers manufactured by an impact extrusion process have greater safety against leakage, incompatibility, and corrosion. The container themselves available in sizes ranging from 10 ml to over 1,000ml.

Stainless Steel

As it is strong and resistant to corrosion; no coating is required. Also it can withstand high pressure. The drawback is expensiveness which restricts its sizes to small sized containers.

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Plastic
Plastics let air and vapors, like oxygen, pass through easily. This can cause the medicine inside to react or break down. Polyethylene terephthalate (PET) containers are sometimes used for products that are not medicines.

VALVES
A valve releases the medicine in the right form and controls how much medicine comes out of the container. The valve must be strong enough to handle the pressure inside and should not rust. There are two main types of valves: continuous spray valves and metering valves.

Actuator
The actuator is the button you press to open and close the valve. It also helps aim the spray where you want it to go. The actuator has small holes of different sizes and shapes, and a special space called the expansion chamber. These parts control how much medicine and propellant come out, the design of the spray, and how the medicine is released as a spray or foam. This is especially important for inhalers, where the size of the medicine particles needs to be just right.

Stem
The actuator is supported by the stem and the formulation is delivered in the proper form to the chamber of the actuator by the stem. It is made up of Nylon, Delrin, Brass and Stainlesssteel.

Gasket
The stem and valve are held firmly in place by a gasket, which stops the medicine from leaking. The gasket is made of special rubber called Buna N or Neoprene.

Spring
The spring holds the gasket in place and helps keep the valve closed when you stop pressing the button to release the medicine..

Mounting Cup or Ferrule
The mounting cup, also called a ferrule, is usually made of aluminum. It holds the valve in place and attaches it to the aerosol container. Since the bottom of the mounting cup touches the medicine inside, it needs to be safe to use with the medicine to avoid any reaction. Sometimes, it is coated with a protective layer like vinyl to stop it from reacting with the medicine and to prevent the aluminum from rusting.

Housing or Valve body
The housing or valve body is found just below the mounting cup. It's made of materials like Nylon or Delrin. Its job is to connect the dip tube, stem, and actuator. The size of the small opening (called the orifice) controls how fast the medicine comes out and in what form (like spray or foam).

Dip Tube
The dip tube is made of plastic (polyethylene or polypropylene) and goes from the valve body down into the medicine inside the container. Its job is to carry the medicine up to the valve. The size of the dip tube depends on how thick (viscous) the medicine is and how fast it should come out. Thicker medicines need a wider tube. For thin liquids, the tube's inside width is about 0.12 to 0.125 inches. For thicker liquids, it can be as wide as 0.195 inches.

TYPES OF INHALERS
Depending on the physical state of the dispersed phase and continuous medium, inhaled drug delivery system is classified into three principlecategories
1. Pressurised metered dose inhalers (pMDIS)
2. Dry powder inhalers (DPIs)
3. Nebulisers

Pressurised Metered Dose Inhaler (pMDIs)
The pressurised metered dose inhalers (pMDIs) as shown in Figure 5; are composed of a canister, and actuator, and Pressurized Metered Dose Inhalers (pMDIs):
- The pMDI canister contains the medicine, a liquefied gas propellant, and a stabilizer.
- The medicine can be mixed or dissolved in the propellant.

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- When you press the inhaler, the valve opens and sprays a fixed amount of medicine with the propellant out of the canister. This is called **cavitation**.
- The propellant quickly turns from liquid to gas, leaving tiny dry drug particles to be inhaled into the lungs.

Problems with pMDIs

1. Until the 1990s, they used CFC gases which damaged the ozone layer. These were replaced with hydrofluorocarbons (HFCs), but HFCs contribute to global warming.
2. The spray comes out fast and can get stuck in the throat instead of reaching the lungs.
3. Chemicals from the inhaler parts can mix with the medicine, causing it to break down.
4. Using the inhaler requires good timing between pressing it and breathing in.
5. Medicine often deposits in the throat instead of the lungs.
6. Dry Powder Inhalers (DPIs) were developed later to fix many of these problems.

Dry Powder Inhalers (DPIs)

Advantages of DPIs over pMDIs:

- DPIs don't need the user to coordinate pressing and breathing because they work when you inhale.
- They don't cause chemical breakdown from device parts.
- Drug delivery is usually better.
- DPIs are more stable, efficient, and easier to use.

How DPIs work

- DPIs use tiny powdered drug particles (less than 5 microns) mixed with bigger sugar particles (like lactose, about 30 microns).
- The small drug particles stick together strongly.
- Adding large sugar particles makes the drug particles less sticky and forms loose clumps.
- When you breathe in, these clumps break apart with the help of mechanical parts inside the inhaler, releasing the small drug particles to reach your lungs.
- The larger sugar particles stay in the device or in your throat.

Types of DPIs

1.Unit-Dose Devices

- These are designed for single doses, which can be reused or thrown away.
- A capsule with powder is placed in the device, opened, and the powder inhaled.
- The empty capsule is discarded after use.
- They are simple and cheap but can't give large doses needed in severe asthma attacks.
- Examples:
    - *Innova*™ has a clear chamber with compressed air that helps release the medicine, independent of how hard you breathe.
    - *Solo*™ is a patient-controlled inhaler with flow control to make sure you get the right dose every time.

2. **Multi-Dose Devices**

- These hold many doses in one device.
- Examples:
    - *Turbuhaler*: First multi-dose DPI, but delivery depends on how strongly you breathe.
    - *Diskhaler*: Uses blister packs with 4 or 8 doses but was not very popular.
    - *Diskus*: Holds 60 doses and only opens the dose just before you breathe in, making delivery consistent and reliable. It's the most popular multi-dose DPI.
    - Others: *GyroHaler®, OmniHaler®, Clickhaler®, Duohaler®* offer features like dual medicines or cost-effectiveness.
    - *PowderHale®* uses a special inactive ingredient to help medicine reach deep into lungs with consistent doses.

Drawbacks of DPIs

How much medicine you get depends on how strongly you breathe in.

- Sometimes doses are not consistent.
- They are more complicated and expensive to make.
- Some medicine may still get stuck in the throat.

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ii) Nebulisers

A nebulizer is a device that turns medicine into a mist so you can breathe it into your lungs. It uses oxygen, compressed air, or ultrasonic waves to break the medicine into tiny droplets called aerosol or mist, which you inhale through a mouthpiece.
The medicine in the nebulizer can be either dissolved in liquid (solution) or mixed in tiny particles (suspension).

Types of Nebulizers

1. **Jet or Ultrasonic Nebulizer**
   Uses pressurized air to push air through the medicine liquid, creating droplets.
2. **Electronic Nebulizer**
   Uses vibrations to create the droplets.

When are Nebulizers Used?

- For quick treatment during sudden breathing problems like asthma attacks or lung infections.
- For patients who find it hard to use other inhalers.

Examples of Nebulizers

- **Omron Microair Nebulizer**
  - Uses electronic vibration to create a fine mist.
  - Delivers medicine fully.
  - Comes with adapters.
  - Very light and portable (only 170 grams).
  - Good for kids with asthma.
  - Saves energy and works for hours on batteries.
  - Easy to clean.
- **DeVilbiss PulmoMate**
  - Good quality and durable.
  - Compact and easy to carry.
- **Pari Trek S**
  - Great for traveling.
  - Comes with a car adapter and portable case.

Benefits of Nebulizers

- No need to time breathing and medicine release together.
- Works well with normal, relaxed breathing.
- Can deliver higher doses of medicine.
- Does not release harmful CFC gases.
- Can be used with extra oxygen if needed.
- Can deliver more than one medicine if compatible.
- Ultrasonic nebulizers are quiet, fast, small, and easy to carry.

Drawbacks of Nebulizers

1. They are expensive.
2. Need a lot of electricity or batteries.
3. Jet nebulizers need pressurized gas.
4. Must be cleaned often.
5. Can get contaminated if not cleaned properly.
6. Some medicines in suspension form don't work well as mist.
7. Jet nebulizers make droplets that are big and vary in size.
8. Ultrasonic nebulizers can heat the medicine, causin

Solution system or two phase system

This system has two phases — liquid and vapor — so it's called a two-phase system. You can use one propellant or a mix of propellants depending on the spray you want.

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If you mix a propellant with another one that has a lower vapor pressure than propellant 12, the overall pressure goes down, but the spray droplets become larger. Adding co-solvents (like ethyl acetate, propylene glycol, ethyl alcohol, glycerine, or acetone) also makes larger droplets.

If the drug dissolves in the propellant, you don't need any other solvent. These solution systems are usually used for creams or sprays applied to the skin (topical use).
Examples of common propellant mixes:
- propellant12 / propellant11 (30:70)
- propellant12 / propellant114 (45:55)
- propellant12 / propellant114 (55:45)

Water Based System or Three Phase System

Water-based (three-phase) aerosol systems — simplified
- A water-based aerosol has three parts: **water**, **liquid propellant**, and **propellant vapor** — so it's called a *three-phase* system.
- The propellant does not mix with water, so to help more propellant dissolve into the water you can add:
  - a **co-solvent** like ethanol, and
  - a **surfactant** (0.5–2.0% of the formula).
- Typical propellant amount in these systems is **25–60%**.
- **Nonpolar surfactants** (for example, esters of oleic, palmitic, or stearic acid) are preferred because they work better than polar surfactants.
- Surfactants lower the surface tension between water and propellant so the propellant spreads out more evenly in the water.

Problems
- Adding ethanol helps dissolve the propellant but also **makes the product more flammable**.
- Because there is a lot of water, the spray can be *wet* (liquid droplets).

Newer options
- New valve designs like the **vapour-tap valve** and **aquasol valve** improve performance.
- In the **aquasol system**, drug is dissolved in water (or water + alcohol). The system delivers **vaporized** propellant instead of liquid propellant.
- Vaporized propellant gives **small, dry, fine particles** (a better mist) and is **less flammable**.

Suspension or Dispersion Systems

Suspension or dispersion system is the dispersion of the active ingredients in the propellant or the mixture of propellant by adding surfactants or the suspendingagents.

Foam system

The liquefied propellant is mixed into an emulsion. The main ingredients are a watery or non-watery liquid (vehicle), the propellant, and surfactants (soaps) that help mix them.

Foam Types
- **Aqueous stable foam** — foam made with water that stays foamy for a long time.
- **Nonaqueous stable foam** — foam made without water that also stays foamy.
- **Quick-breaking foam** — foam that collapses quickly after it's sprayed.

Aqueous Stable Foams

Aqueous Stable Foam — Simple Explanation
- This foam uses a small amount of propellant (about **3–4%**).
- The propellant makes a **dry spray**—the liquid dries quickly after spraying.
- If you add more propellant, more of the sprayed material comes out **dry**.
- The propellant sits inside the foam droplets, so only a **small amount** is needed.
- These foams are often used to deliver **steroid antibiotics**.

Non Aqueous Stable Foams

The nonaqueous stable foam contains glycol as the emulsion base and is used as the emulsifying agent.

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Quick Breaking Foams
Here the external phase is propellant. The product will come out as foam which soon merges to form liquid. This type of system can be applied to small area or larger surface. These are used fortopical application. Cationic or anionic or non-ionic surfactants are used in the formulation.

Thermal Foams
The aerosol which is delivered in the form of foam upon the application of heat is called thermal foam. They are used in shavingcreams.

Manufacturing Of Pharmaceutical Aerosols[1,2]
The manufacturing of aerosol consists of three types of apparatus

Cold Filling Apparatus
It consists of an insulated box fitted with copper tubings. The insulated tubings are filled with dry ice or acetone. The copper tubings increase the surface area and cause faster cooling. The hydrocarbon propellant is not to be stored in the copper tubings as it might cause explosion.

Pressure filling apparatus
A pressure-filling machine fills aerosol cans with the right amount of propellant. It uses a measuring tube (metering burette) to control how much propellant goes in.

How it works:
1. The propellant is fed into the can through an inlet valve at the bottom of the valve assembly.
2. A tank of nitrogen (or another compressed gas) is attached to the top of the valve. The nitrogen pressure pushes the propellant through the measuring tube and into the can.
3. Filling stops automatically when the pressure of the propellant flowing in equals the pressure already inside the can.

Compressed Gas Filling Apparatus
Filling Aerosols — Simple Explanation
Using Compressed Gas Propellant
- A compressed gas (like nitrogen) is used as the propellant.
- The gas comes in at very high pressure, so a **pressure-reducing valve** lowers it to the correct filling pressure (about **150 psig**).
- The product (the drug mix) is put into the can, the valve is crimped on, and the air inside is removed (vacuum).
- The filling head is placed in the valve and, when the valve is pressed, the compressed gas flows into the can.
- Gas flow stops automatically when the pressure coming in equals the pressure already inside the can.
- If you need more gas to dissolve into the product, gases like **carbon dioxide** or **nitrous oxide** may be used.
- The can is shaken during and after filling so the gas dissolves better in the product.

Two Main Filling Methods
1. Cold Filling
There are two cold filling ways — both use very low temperatures (about **–30 to –40°F**):
- **Method A:** Cool the product, put it into a pre-cooled can, then add the chilled propellant through the valve.
- **Method B:** Cool the product and propellant together, then put that cold mixture into a cooled can.

After filling: the cans are fitted with valves, then tested in a hot water bath (about **130°F**) to check for leaks and strength. Then they're dried, capped, and labelled.
it's good for cans that have metering valves.
But: many products cannot be safely cooled that cold, so cold filling is less common.

2. Pressure Filling
- Product is put into the can at **room temperature** using a metering burette.
- The propellant is added through the valve after crimping.
- Propellant flow stops once pressures equalize.
- Cans are capped and labelled.

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Why pressure filling is preferred
- Emulsions and suspensions can break down if chilled, so pressure filling is safer for those.
- Less moisture — lower contamination risk.
- Faster production and less propellant loss.

Equipment used in Large-Scale Production (Simple List)
- Concentrate filler (fills the product)
- Valve placer (puts valves on cans)
- Purger and vacuum crimper (removes air and crimps valves)
- Pressure filler (adds propellant under pressure)
- Leak test tank (checks for leaks)

Quality control and testing of aerosols & propellants
Propellant (the stuff that pushes the medicine out)
- Every batch is checked against a specification sheet.
- Typical tests:
  - Measure vapour pressure and compare with the specification.
  - Check density when needed.
  - Use gas chromatography to identify which propellant blend it is.
  - Check purity by measuring moisture, halogens (chlorine/fluorine atoms), and non-volatile residue (stuff that doesn't evaporate).

Valves, actuators and dip tubes (the mechanical parts)
- They get both physical and chemical inspection.
- Samples are taken using standard military sampling rules (Mil-STD-105D).
- There's a standard test to check how much each valve delivers and how consistent individual valves are.
  - A test liquid is prepared (three test mixes are used in the original method).
  - Steps (simplified):
    1. Take 25 valves and put them on containers filled with the test liquid.
    2. Put a standard actuator (button) on each valve — the orifice used is 0.02 inch.
    3. Let everything reach room temperature.
    4. Press the actuator for 2 seconds and collect the delivery. Repeat so each valve is actuated twice.
  - Convert weight to volume with:

Volume (µl) = weight (mg) ÷ specific gravity
- **Acceptance rules (from the original method, for 50 deliveries total):**
  - If 4 or more deliveries fall outside the allowed limits → reject the valves.
  - If 3 deliveries are outside → test another 25 valves.
  - After further testing, if more than 1 delivery is outside spec → reject the lot.
  - If two deliveries from the same valve are beyond limits → test another 25 valves; the lot is rejected if more than one delivery is outside spec.
- Limits for delivery accuracy depend on the dose size:
  - For deliveries ≤ 54 µl → allowed variation ±15%
  - For deliveries 55–200 µl → allowed variation ±10%

Containers (Cans, Bottles)
- Check the lining for defects.
- For metal cans, test how well the lining prevents exposed metal (sometimes checked by measuring electrical conductivity).
- Glass containers are checked for cracks, chips, and other flaws.

Weight checking and leak tests
- Weight checking: put empty tared containers on the line, fill them, remove and reweigh to confirm accurate fill weights. Same method used to check propellant weight.
- Leak test:
  - Measure crimp and valve dimensions to check for correct sealing.
  - Final leak test often done by passing filled containers through a water bath to look for bubbles or leaks.

Spray Testing

- Used to:
  - Clear the dip tube.
  - Check for valve defects.
  - Inspect spray pattern (how the aerosol sprays).

Important Evaluation (Safety and Performance) Tests
Flammability

- Flame projection: spray the product toward an open flame for ~4 seconds and measure how far the flame extends.
- Flash point: the product is cooled very cold, then slowly warmed in a flash-point tester to find the temperature where the vapour ignites.

Physicochemical checks

- Vapor pressure: measured with a puncture device + pressure gauge.
- Density: measured with a hydrometer or pycnometer.
- Moisture: measured with Karl Fischer titration or gas chromatography.
- Propellant identity: gas chromatography or infrared spectrophotometry.

Performance Tests
Valve Discharge Rate

- Weigh a filled aerosol, discharge for a set time, reweigh. The loss in weight ÷ time = discharge rate (g/s).

Spray Pattern
Spray onto specially treated paper (dye/talc) to record the pattern and check uniformity.

Metered-Dose Accuracy

- Either:
  - Collect doses into solvent and assay to measure active ingredient per dose, or
  - Weigh the full container, dispense a set number of doses, reweigh — weight loss ÷ number of doses = average dose. Repeat to check consistency.

Net Contents

- Non-destructive: weigh empty tared cans after filling and compare.
- Destructive: weigh full can, empty it completely, weigh remaining contents — difference equals net contents.

Foam products:

- Foam lifetime varies from a few seconds to an hour+.
- Foam stability tests include visual checks, how long a weight or rod takes to pass through or break the foam, or using a rotational viscometer.

Particle-Size (For Inhaled Aerosols)

- Use cascade impactors or light-scattering methods to determine particle size distribution. Larger particles are captured on earlier stages; smaller ones later.

Biological Testing of Aerosol:
Therapeutic Activity

- For inhaled aerosols: therapeutic effect depends on particle size (smaller particles reach deeper into lungs).
- For topical aerosols: apply to skin and measure how much active ingredient is absorbed.

Toxicity

- Topical: check for skin irritation or chilling effect; measure skin temperature changes with a thermistor probe.
- Inhalation: expose lab animals to the aerosolized product and monitor for harmful effects.

Extractable substances (From Valve Parts)

- Plastics and elastomers (stems, gaskets, housings) can leach chemicals into the formulation, especially because propellants and solvents are organic.
- Choose materials that are compatible with the formulation.

- Test and establish what can be extracted from each valve component, and compare that to what comes out of aged product samples.
- Different analytical methods may be needed to measure individual extractables and total extractables.

Label Warnings — Simplified (Plain Language)
Medicinal aerosols should carry clear warnings. Examples of simple label text:

- "Warning — Avoid inhaling. Avoid spraying into eyes or other mucous membranes."
  If the product is intended to be inhaled, you don't need "Avoid inhaling." If it's for mucous membranes, you don't need "or other mucous membranes.")
- "Warning — Contents under pressure. Do not puncture or burn the container. Do not expose to heat or store above 120°F (49°C). Keep out of reach of children."

If the propellant is a halocarbon or hydrocarbon, additional warnings (when required by regulations) include:

- "Warning — Do not inhale directly; deliberate inhalation of contents can cause death."
- OR "Warning — Use only as directed; deliberate misuse by concentrating and inhaling the contents can be harmful or fatal."

CONCLUSION

Pharmaceutical aerosols are an easy, noninvasive way to deliver medicines through the lungs. This method is one of the best compared to other routes of giving drugs. It is widely used to treat diseases like asthma and chronic obstructive pulmonary disease (COPD).Main advantages include- Direct delivery of the drug to the lungs (site of action),Avoidance of first-pass metabolism (drug is not broken down in the liver first),Quick action of the medicine andFewer side effects on the rest of the body.Because of these benefits, the pulmonary route has great potential for future research and drug development.

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