Pharmaceutical aerosols

INHALATION DOSAGE FORMS:

in this inhalers are used

inhalers: A device for delivering an aerosolised medicine to the respiratory system of a patient.

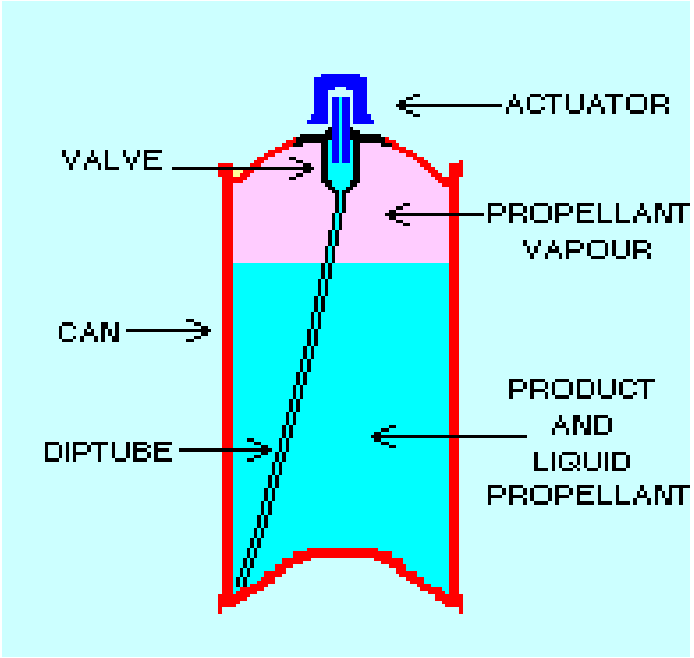
PHARMACEUTICAL AEROSOLS:

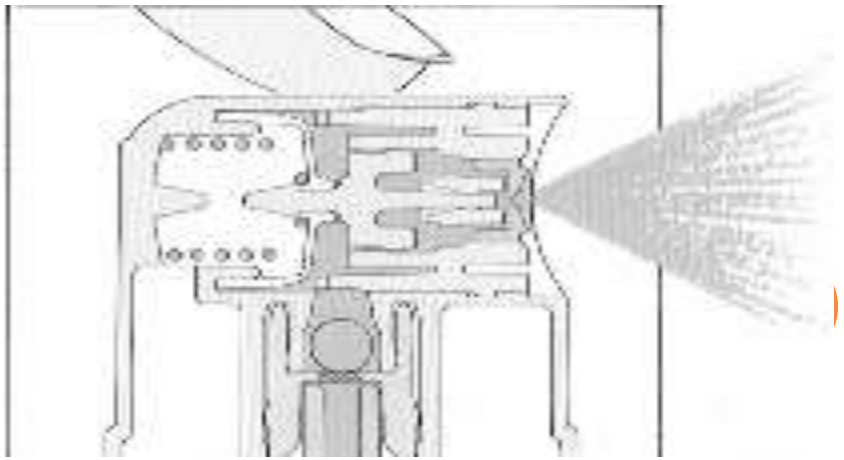
Involves Packaging of therapeutic active ingredients in a pressurized system.

In this compressed or liquefied gas expel the contents from containers.
Ex: Ventolin ® inhaler

COMPONENTS OF AEROSOLS :

- Propellant
- Container
- Valve and actuator
- Product concentrate





Formulation of pharmaceutical aerosols

Contains two essential components

- Product concentrate
- Propellant

Product concentrate

Product concentrate contains ingredients or mixture of active ingredients and other such as solvents, antioxidants and surfactants.

Propellant

May be single or blend of various propellants

❖ Blends of propellant used in a pharmaceutical formulation to achieve desired solubility characteristics or various surfactants are mixed to give the proper HLB value for emulsion system.

❖ To give the desired vapor pressure, solubility & particle size.

PROPELLANT:

It is responsible for developing the power pressure with in the container and also expel the product when the valve is opened and in the atomization or foam production of the product.

For oral and inhalation eg.

Fluorinated hydrocarbons

Dichlorodifluromethane (propellent 12)

Dichlorotetrafluromethane (propellent 114)

Topical preparation

Propane

Butane

Isobutane

Compound gases

Nitrogen

Carbon di oxide

Nitrous oxide

- The vapor pressure of prpellants mixture can be calculated according to Daltons law:
- $P = p_a + p_b$
- From Roalts law:
- $P\ a = [n_a \div (n_a + n_b)] \times p_a\ o$
- n=moles of propellant
- $p_a\ o$ vapor pressure of pure propellant
- Gauge pressure = psia-14.7

Types of systems

- **Solution system** (two-phase system) of vapor and liquid phase.

May contain co-solvents. 5% (foam)- 95% (inhalation).

Decrease pressure lead to increase partical size (by addition of less volatile solvent as glycerin and aceton)

Water-based system : relatively large amount of water was added .

Its three –phase system (propellant phase, water phase, and vapor phase).

Surfectant of low water solubility was used(glycol, glycerol).

Suspension or dispersion system: to avoid the usage of co-solvent.

Dispersion of active ingredients in the proprllant by using various surfactant or suspending agents.

Foam system : emulsion and foam aerosols consist of active ingredients, aqueous or non-aqueous vehicle, surfactant, and propellant.

Aqeous stable foam: (active ingredients, oil-wax, o/ w surfactant, water) 95%-96.5% and hydrocarbon propellant (3.5%-5%)

Nonaqueous stable foam: as

Glygol 91-92.5%

Emulsifying agent 4%

hydrocarbon propellant 3.5-5 %

Quick-breaking foam:

In this system, the propellant is in the external phase.

Ethyl alcohol 46-66%

Surfactant 0.5-5 %

Water 28-42 %

hydrocarbon propellant 3-15 %

Manufacturing of Pharmaceutical Aerosols:

METHODS:

A) Pressure filling method:
B) Cold filling method:
C) Compressed gas filling

A) COLD FILLING METHOD:

In this method both the product concentrate and propellent must be cooled to -3.5c to -40c.this temp is necessary to liquefy the propellent gas.this cooling system is mixture of dry ice and acetone After chilled product concentrate quantitatively metered into cold aerosol container,the liquefied gas is added

B) Pressure filling method:

In this method product concentrate is quantitatively placed in aerosol container, valve assembly is inserted and crimped into place and liquefied gas under pressure is metered into the valve system from pressure burette the propellent is allowed to enter the container under vapour pressure when the pressure in the container equals that in the burette, propellent stops flowing.

Additional propellant added by increasing the pressure in the filling apparatus through use of compressed gas

INHALATORS ARE MAINLY THREE TYPES :

1) METERED-DOSE INHALER:

A metered-dose inhaler (MDI) essentially consists of a canister containing a liquid formulation including a propellant; a metering valve for emitting a metered quantity of the formulation with each actuation; and an actuator by which the patient operates the device.

MDIs used in treatment of asthma and chronic obstructive pulmonary disease (COPD).

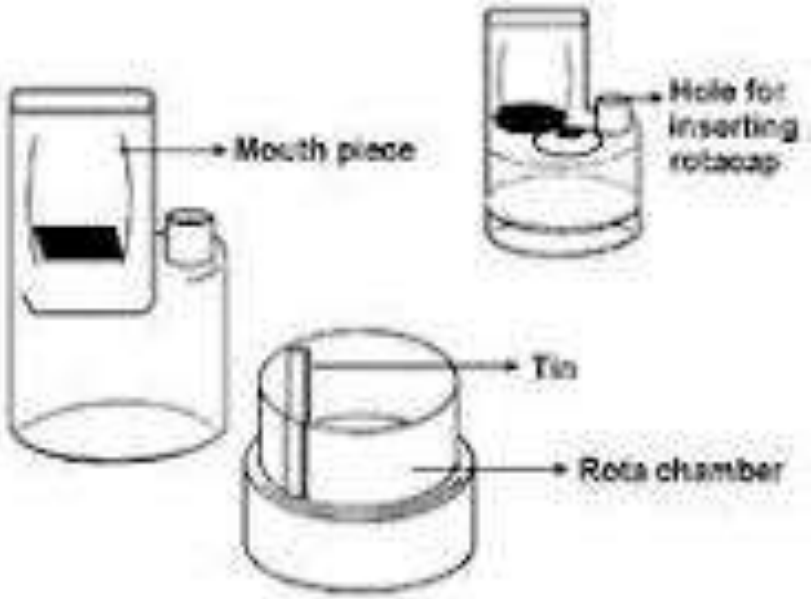
EX: asthalin inhaler composition

Each actuation delivers:
Salbutamol Sulphate IP equivalent to
Salbutamol IP ….100 mcg
Suspended in propellant 134a…

2) DRY POWDER INHALER:

The micronized drug is mixed with carrier such as lactose. it is filled in capsule. the capsule is placed with in a device which pierces the capsule or separates cap and body. the resulted powder is inhaled.

example: Alupent; each dose is delivered through the mouthpiece upon activation of the aerosol valve it is used in the treatment of asthma and other bronchial disorders



3)NEBULISER: An inhaler for dispensing a non-pressurised liquid formulation. Nebulisers are typically used to deliver larger volumes of liquid formulations which cannot be delivered with metered-dose inhalers, or for patients having difficulty using a powder inhaler or metered-dose inhaler.

Various types of nebulisers using different aerosolisation methods are available, such as jet nebulisers, ultrasonic nebu-lisers, and vibrating-mesh nebulisers.

THANK YOU