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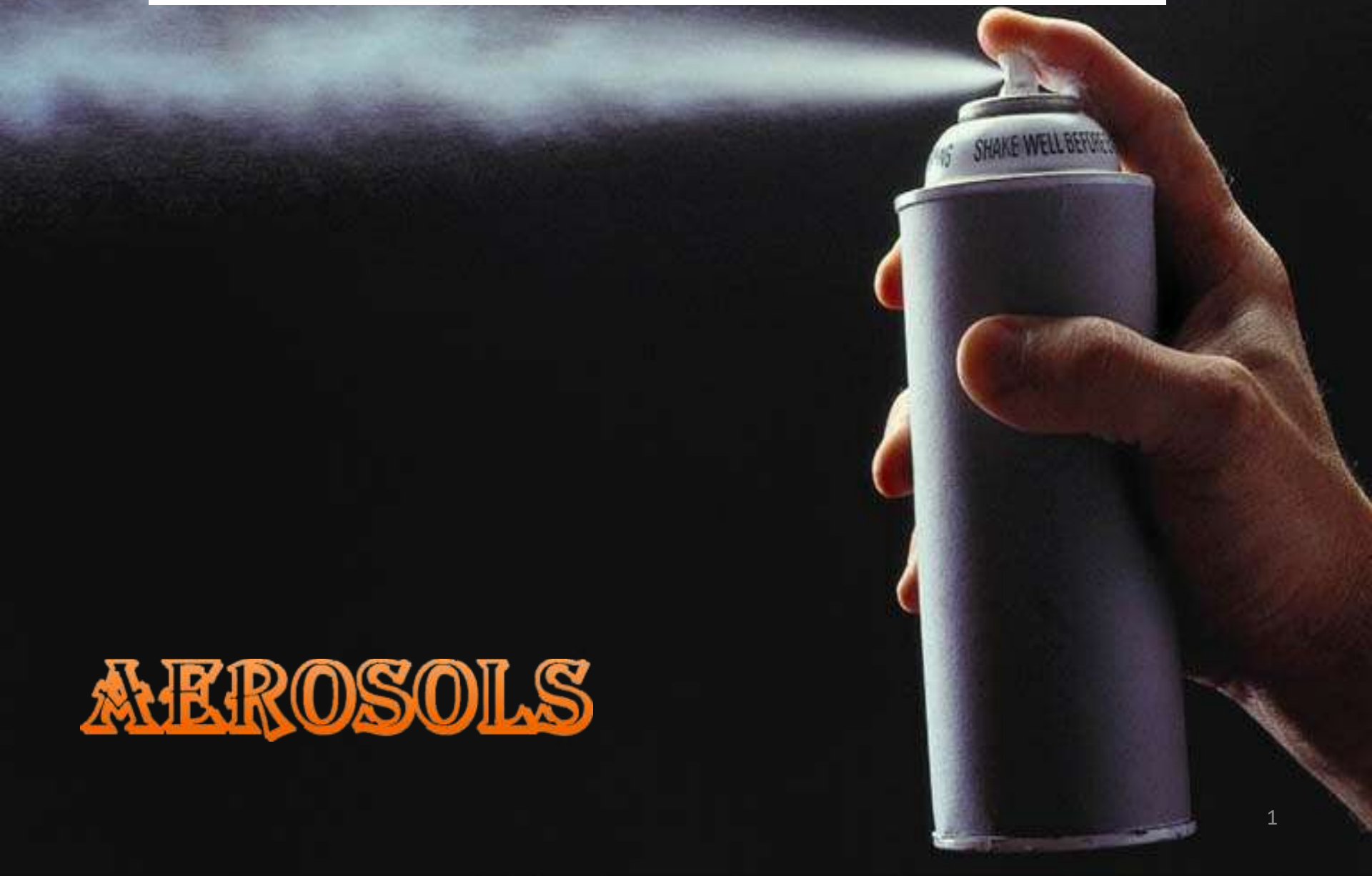


AEROSOLS

INTRODUCTION

•Aerosol or Pressurized package is defined as ―A system that depends on the power of a compressed gas or liquefied gas to expel the contents from the container.‖

•Pharmaceutical Aerosol is defined as aerosol product containing active ingredients dissolved ,suspended or emulsified in a propellant or a mixture of solvent and propellant and intended for oral or topical administration or for administration into the eye, nose ,ear, rectum and vagina.

• In 1942 - First aerosol was developed. (insecticide)

•In1950 - Pharmaceutical aerosol for topical administration was developed.

•In 1955 - Aerosol for the local activity in the respiratory tract was developed (Epinephrine).

ADVANTAGES OF AEROSOLS

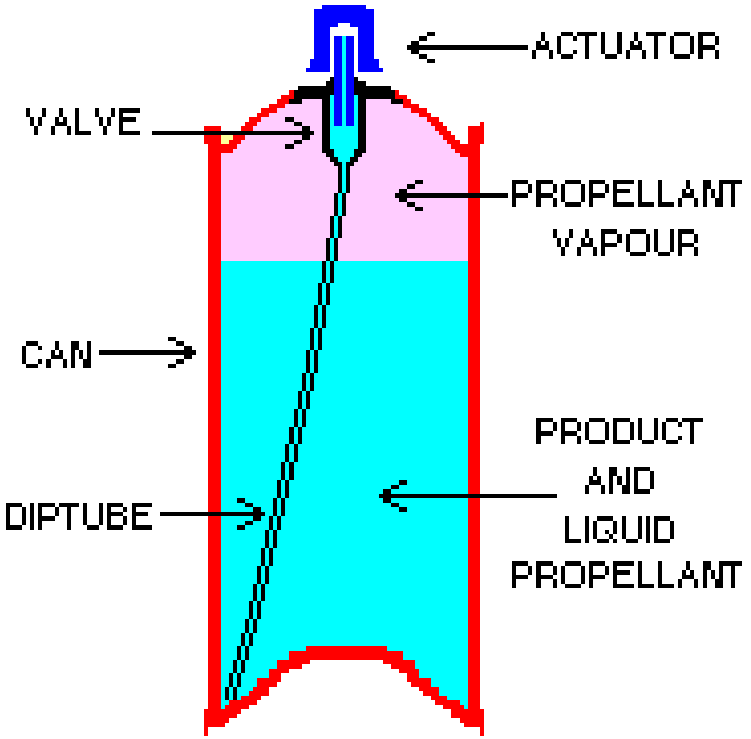
- A dose can be removed with out contamination of materials.
- Stability is enhanced for these substances adversely affected by oxygen and or moisture.
- When sterility is an important factor, it can be maintained while a dose is being dispensed.
- The medication can be delivered directly to the affected area in a desired form. (localized action)
- Irritation produced by the mechanical application of topical medication is reduced or eliminated.
- Ease and convenience of application.
- Application of medication in thin layer .
- Rapid response to the medicament .
- Bypasses First pass effect.

DISADVANTAGES OF AEROSOLS

- Expensive.
- Chlorofluorocarbon propellants cause Ozone layer depletion.
- Inflammability
- Toxicity
- Explosivity

COMPONENTS OF AEROSOLS

- Propellant
- Container
- Valve and actuator
- Product concentrate



PROPELLANTS

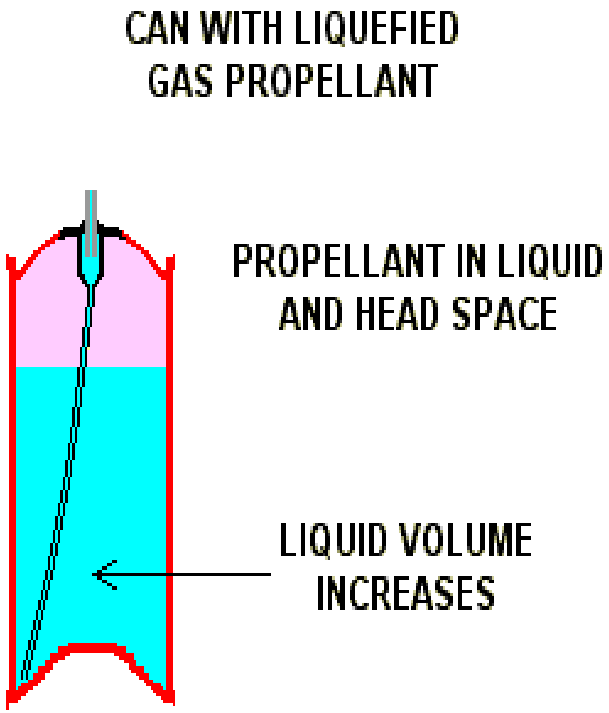
- Responsible for developing proper pressure within the container.
- Provide driving force to expel the product from the container.

TYPES OF PROPELLANTS

(a) Liquefied gases Propellants
(b) Compressed gases Propellants

LIQUEFIED GAS PROPELLANTS

- Liquefied propellants are gases that exist as liquids under pressure.
- Because the aerosol is under pressure propellant exists mainly as a liquid, but it will also be in the head space as a gas.
- The product is used up as the valve is opened, some of the liquid propellant turns to gas and keeps the head space full of gas.
- In this way the pressure in the can remains essentially constant and the spray performance is maintained throughout the life of the aerosol.



CHLORO FLUORO CARBONS

- Propellant of choice for oral and inhalation .

Advantages

- Chemical inertness
- Lack of toxicity
- Non flammability.
- Lack of explosiveness.

Disadvantages

- High cost
- It depletes the ozone layer

Examples: Trichloromonofluoromethane - Propellant 11
Dichlorodifluoromethane - Propellant 12
Dichlorotetrafluoroethane - Propellant 114

HYDROCARBONS

- Can be used for water based aerosols and topical use.

Advantages

- Inexpensive
- Excellent solvents
- It does not cause ozone depletion

Disadvantages

- Inflammable
- Unknown toxicity produced

Ex: Propane - Propellant A-108
Isobutane - Propellant A-31
Butane - Propellant A-17

HYDROFLUORO CARBONS AND HYDRO CHLORO FLUORO CARBONS

•These compounds break down in the atmosphere at faster rate than CFCs.

• Lower ozone destroying effect.

Advantages

- Low inhalation toxicity
- High chemical stability
- High purity
- Not ozone depleting

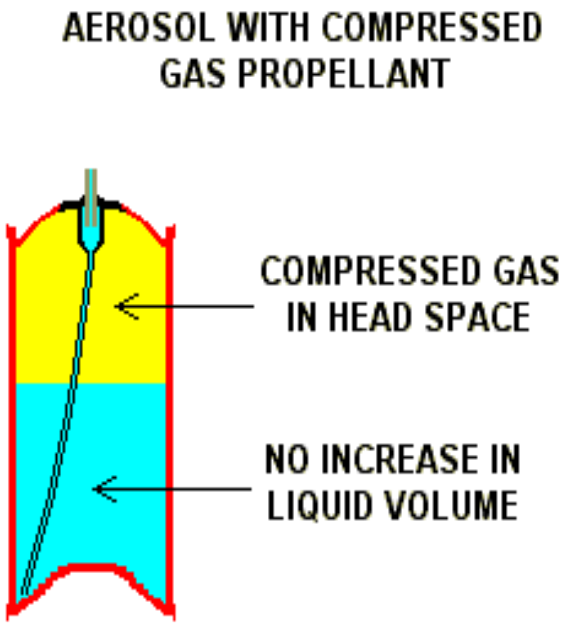
Disadvantages

- Poor solvent
- High cost

Examples: Heptafluoro propane (HFA-227)
Tetrafluoroethane (HFA-134a)
Difluoroethane - Propellant 152a
Chlorodifluoromethane - Propellant 22
Chlorodifluoroethane - Propellant 142 b

COMPRESSED GAS PROPELLANTS

- Compressed gas propellants occupy the head space above the liquid in the can.
- When the aerosol valve is opened the gas 'pushes' the liquid out of the can.
- The amount of gas in the headspace remains the same but it has more space, and as a result the pressure will drop during the life of the can.
- Spray performance is maintained however by careful choice of the aerosol valve and actuator.



Examples: Carbon dioxide, Nitrous oxide and Nitrogen

CONTAINERS

They must be able to withstand pressures as high as 140 to 180 psig (pounds per sq. inch gauge) at 130 ° F.

AEROSOL CONTAINERS

A . Metals

1. Tinplated steel
2. Aluminum
3. Stainless steel

B. Glass

1. Uncoated glass
2. Plastic coated glass

TIN PLATED STEEL CONTAINERS

- It consist of a sheet of steel plate, this sheet is coated with tin by electrolytic process .
- The coated sheet is cut into three pieces (top , bottom and body) .
- The top, bottom are attached to body by soldering .
- When required it is coated with organic material usually oleoresin, phenolic , vinyl or epoxy coating .
- Welding eliminates soldering process, Saves considerable manufacturing time and decreases the product/container interaction.
- Recent developments in welding include Soudronic system and Conoweld system.

ALUMINIUM CONTAINERS

- Used for inhalation and topical aerosols .
- Manufactured by impact extrusion process.
- Light in weight, less fragile, Less incompatibility due to its seamless nature.
- Greater resistance to corrosion .
- Pure water and pure ethanol cause corrosion to Al containers.
- Added resistance can be obtained by coating inside of the container with organic coating like phenolic , vinyl or epoxy and polyamide resins.

STAINLESS STEEL CONTAINERS

- Used for inhalation aerosols

Advantage :

- Extremely Strong.
- Resistant to many materials.
- No need for internal coating.

Disadvantage :

- Costly

GLASS CONTAINERS

•These containers are preferred because of its Aesthetic value and absence of incompatibilities.

•These containers are limited to the products having a lower pressure (33 psig) and lower percentage of the propellant.

•Used for topical and MDI aerosols.

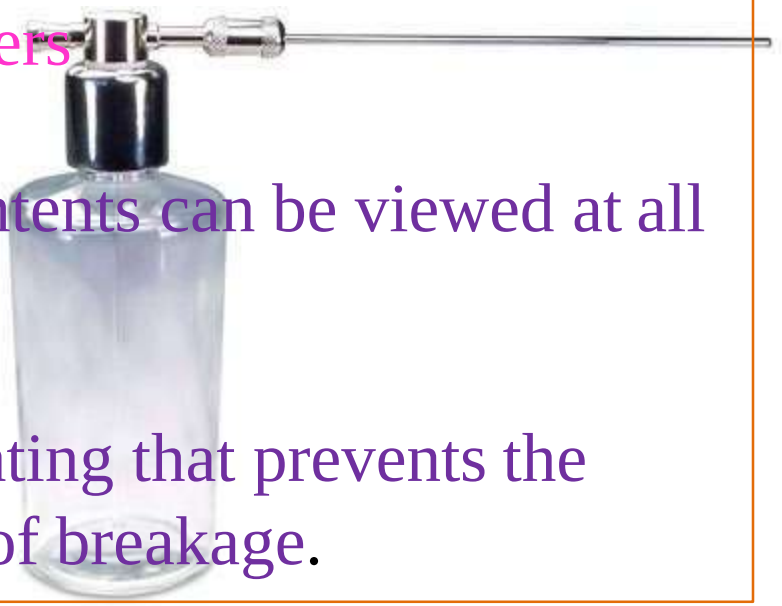
Two types of glass aerosol containers

i) Uncoated glass container:

•Less cost and high clarity and contents can be viewed at all times.

ii) Plastic coated glass containers:

•These are protected by plastic coating that prevents the glass from shattering in the event of breakage.



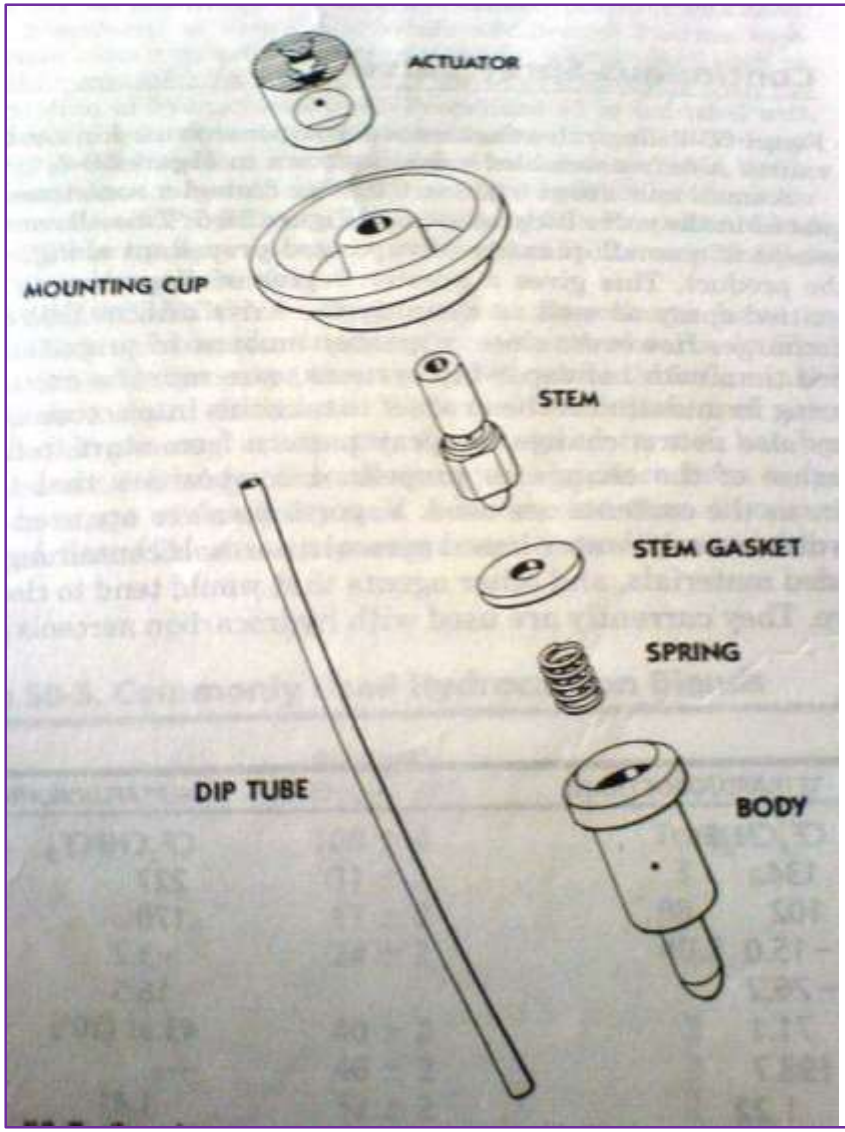
VALVES

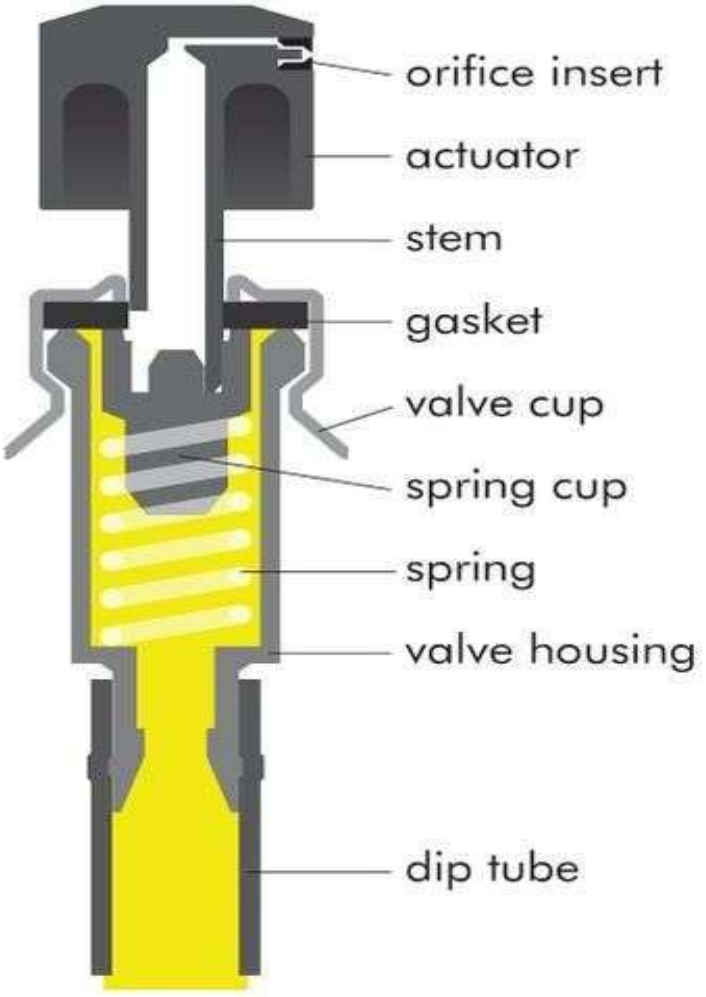
- Easy to open and close .
- Capable of delivering the content in the desired form such as spray, foam, solid stream etc.
- It can deliver a given amount of medicament .

TYPES OF VALVES :

1. Continuous spray valve
2. Metering valves

VALVE ASSEMBLY



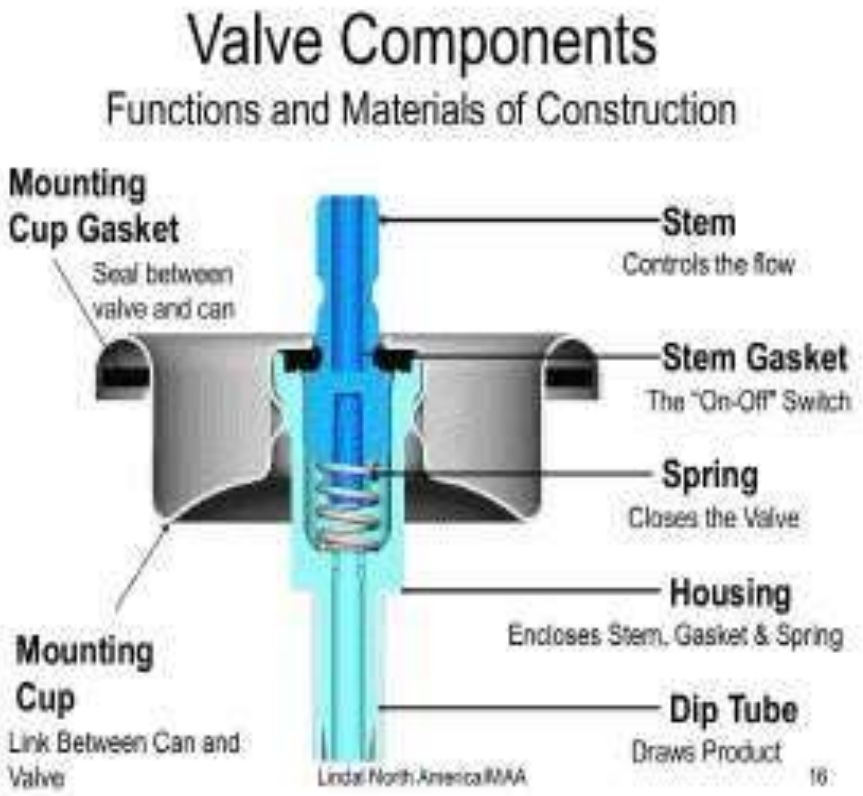


CONTINUOUS SPRAY VALVE

- Used for topical aerosols .

Valves assembly consists :

- Ferrule or mounting cup
- Valve body or housing
- Stem
- Dip tube
- Gasket
- Spring



FERRULE OR MOUNTING CUP :

- Used to attach valve to container.
- Made from Tin plated steel, Al , Brass .
- Under side of the valve cup is coated with single or double epoxy or vinyl resins.

VALVE BODY OR HOUSING :

- Made up of Nylon or Derlin and contains a opening at the point of attachment of dip tube. (0.013 to 0.080 inch)

STEM :

- Made from Nylon or Derlin , brass and stainless steel can also be used. (orifice - 0.013 to 0.030 inch).

GASKET :

- Made from Buna-N and neoprene rubber.

SPRING :

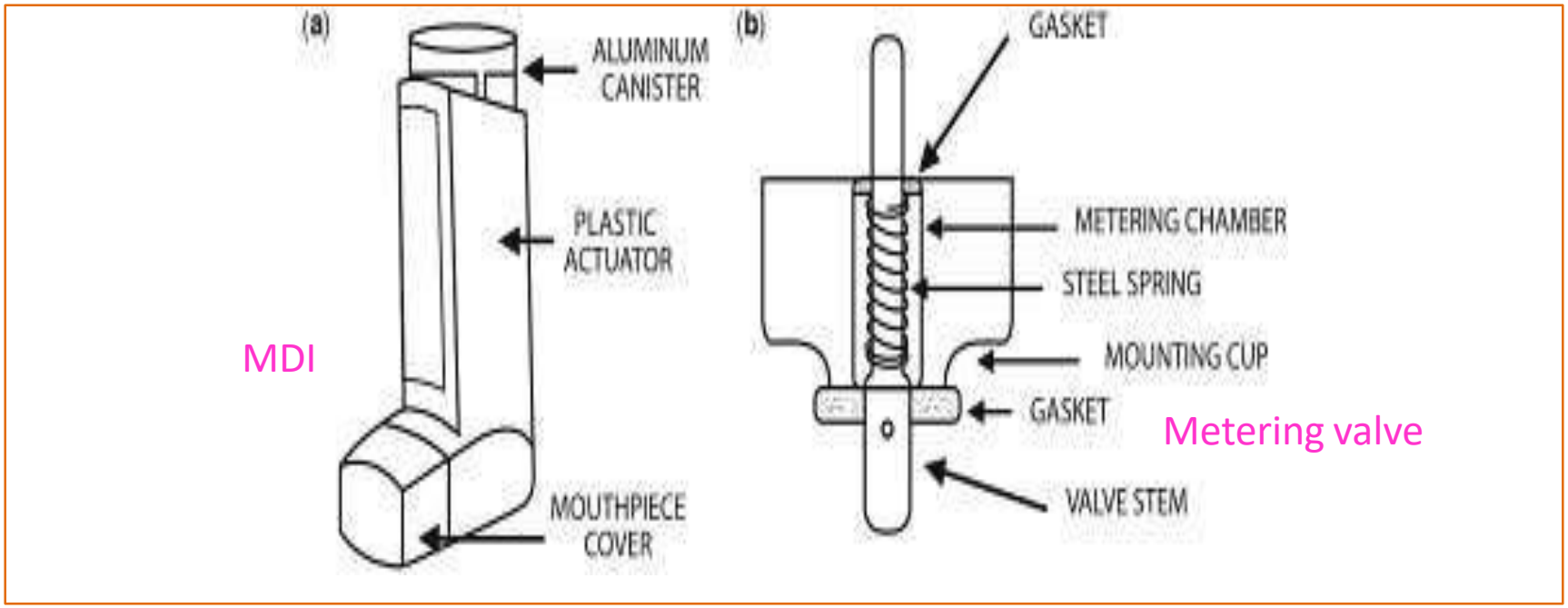
- Made from Stainless steel .
- Used to hold gasket in place.

DIP TUBE :

- Made from Poly ethylene or poly propylene.
- Inner diameter 0.120 – 0.125 inch.
- However for Capillary dip tube inner diameter is 0.050 inch and for highly viscous products it is 0.195 inch.

METERING VALVES

- Used for dispensing of potent medication.
- Operates on the principle of a chamber whose size determines the amount of medication dispensed.
- Approximately 50 to 150 mg ±10 % of liquid materials can be dispensed at one time with the use of such valve.



ACTUATORS

•These are specially designed buttons which helps in delivering the drug in desired form i.e., spray, wet stream, foam or solid stream .

TYPES OF ACTUATORS :

- Spray actuators
- Foam actuators
- Solid steam actuators
- Special actuators

SPRAY ACTUATORS:

- It can be used for topical preparation, such as antiseptics, local anesthetics and spray on bandages etc.
- It allows the stream of product concentrate and propellant to pass through various openings and dispense as spray.

FOAM ACTUATORS :

- It consist of large orifice which ranges from 0.070—0.125 inch .

SOLID STREAM ACTUATORS :

- These actuators are required for dispensing semi solid products such as ointments .

SPECIAL ACTUATORS :

- These are used for a specific purpose.
- It delivers the medicament to the appropriate site of action such as throat, nose, dental and eyes etc.


SPRAY


ACTUATORS


ACTUATORS


FOAM

METERED DOSE INHALERS

- Used to minimize the number of administration errors.
- To improve the drug delivery of aerosolized particles into the nasal passageways and respiratory tract.

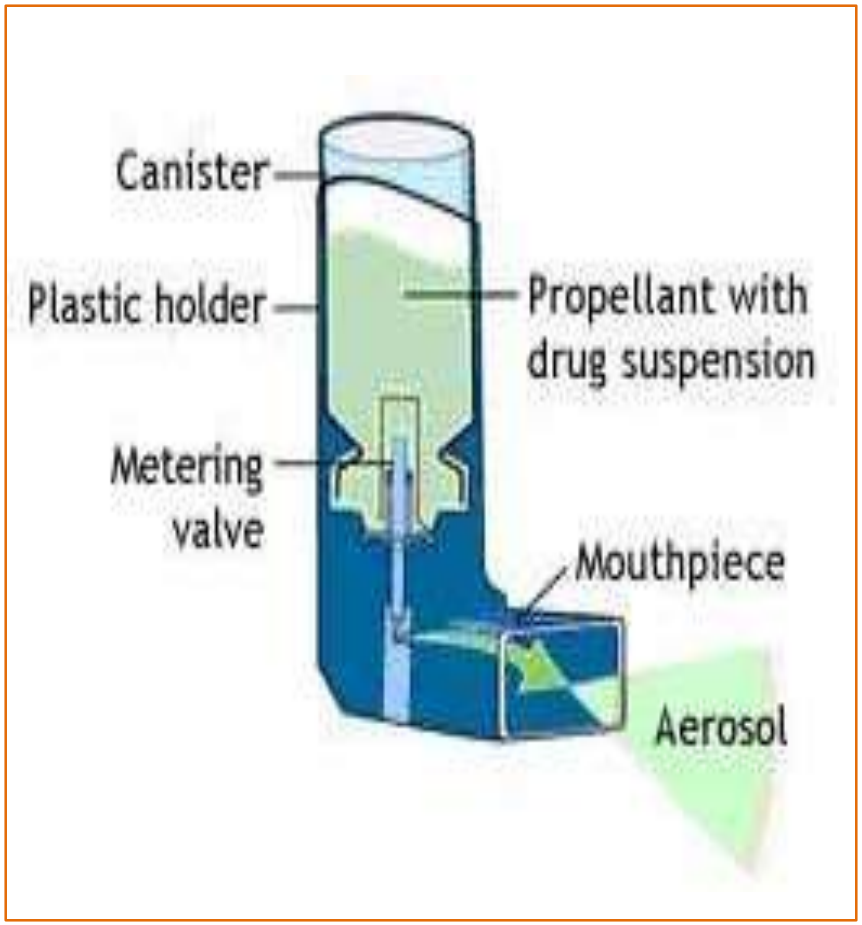
Advantages of MDI:

- It delivers specified amount of dose .
- Portable and compact.
- Quick to use , no contamination of product.
- Dose-dose reproducibility is high.

Disadvantages of MDI :

- Low lung deposition ; high pharyngeal deposition .
- Coordination of MDI actuation and patient inhalation is needed.

Metered Dose Inhalers (MDIs)



MARKETED PHARMACEUTICAL AEROSOL PRODUCTS

Metered Dose inhalers :

BRAND NAME	DRUG	USE
Flovent Diskus	Fluticasone	Asthma
Advair	Fluticasone and Salmeterol	Asthma
Aerobid	Flunisolide	Asthma
Qvar	Beclomethasone	Asthma
Proventil	Albuterol	Bronchospasm