4.5. Release Liner

A release liner is a film which contains an anti-adherent coating. The release line's role is to protect the system as long as it is present in the package and is removed immediately before applying the TDDS onto the skin. Release liner has an essential role to play in the stability and safety and functionality of the product. It eliminates leakage and also stops the deterioration of drugs that could have transferred to the adhesive base [14].

4.6. Backing Layer

Backing laminate has the primary function of providing support to the TDDS. Such film's role is to protect the active layer and to preserve the system's integrity. They should be able to prevent the medication from leaving the dosage form overhead. Typical backing membranes contain pigmented layers, an aluminium layer, a plastic film and a heat seal layer [15].

4.7. Other Excipients

Drug reservoir is prepared by using various solvents such as chloroform, methanol, acetone, Iso-propanol and dichloromethane. In addition plasticizers that provide plasticity to the transdermal patch are included, e.g.: di-butyl-pthalate, tri-ethyl citrate, polyethylene glycol and propylene glycol.

The delivery of drugs and its pharmaco-therapeutic effects of a drug are directly related to the adhesion or lack of adhesion of transdermal systems to the skin. The partitioning of the drug between the skin and the transdermal patch and the permeation of the drug across the skin is related to the drug absorption process. When there is accidental detachment of patch or lift of TDDS from the area of skin concerned there is the change in the absorption of the drug in an unpredicted manner, thereby can cause therapeutic failure. The therapeutic drug concentrations may elevate if the patch is applied to the skin which might be subjected to any sort of damage. When compared to younger skin, the geriatric skin has poor moisture content and has a reduced amount of elasticity. The kinetics involved like the wetting rates and visco-elasticity of the adhesive are the additional requirements for adhesion. The visco-elastic flow of the adhesive will relate to the increase in the adhesion after TDDS is applied due to elevated skin temperature. Reduced adhesive contact will reduce the amount of force which is to be functional to remove a TDDS. Low drug concentration and a gradual shedding of the external layers of the stratum corneum will contribute to the same [2, 12].

5. APPROACHES FOR DEVELOPING TDDS

5.1. Membrane Permeation Controlled TDDS

The approach has the drug core totally compressed in a thin compartment made by a metallic plastic laminate which is drug resistant in nature and the rate controlling polymeric membrane covers the drug delivery side which is either porous (microns or non-porous, e.g., ethylene vinyl copolymer, with a distinct drug permeability property. The release of drug molecules is permitted only through the rate controlling membrane (Fig. 4) [16].

5.2. Adhesive Dispersion Type

This is an easier approach than the membrane permeation controlled system. Here the drug core is prepared by dispersing the drug directly in an adhesive polymer, e.g., polyisobutylene or polyacrylate adhesive, followed by spreading the medicated adhesive either by solvent casting or by hot melt method, on the drug-resistant metallic plastic backing which is thin sheet thus produces a thin layer of the drug reservoir. Above the drug reservoir layer, a thin layer of rate-controlling and non-medicated adhesive polymer of constant thickness is applied to obtain an adhesive diffusion-controlled delivery system [8, 17].

Alternatively, this type of transdermal therapeutic system can be customized to have the drug load level

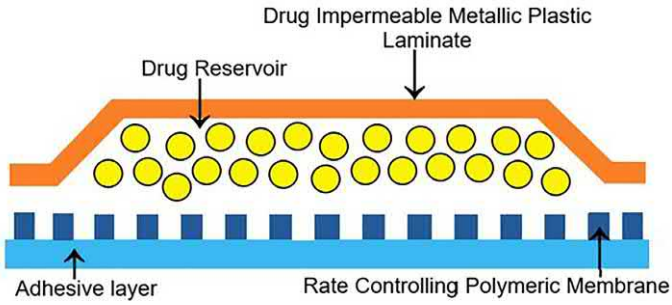

FIG. 4 Membrane permeation controlled TDDS.