

# **CHAPTER-6**

## **FORMULATION DESIGN AND PREPARATION OF TRANSDERMAL PATCHES**

### **6.1 Introduction:**

In matrix diffusion type of dosage form, the drug reservoir is formed by homogeneously dispersing the drug into a hydrophilic or lipophilic polymer matrix and the medicated polymer matrix is then molded onto an impermeable backing having a specific surface area and controlled thickness<sup>1,2</sup>. The simplicity and ease of preparation makes matrix diffusion type as the unique and convenient transdermal drug delivery system. Moreover the polymer matrix in which the drug is uniformly dispersed acts as the continuous source of the drug upon topical administration<sup>3</sup>. Unlike the reservoir type of transdermal patches, matrix type transdermal patches do not depend on the release rate controlling membrane. The porous membrane which is responsible for allowance of the drug from the patch reservoir to the skin layers may sometime hindrance the system by choking the pores by dispersed particles. Whereas matrix type patches ensure uninterrupted drug release from the drug-polymer matrix source.

### **6.2 Preparation of backing membrane<sup>4</sup>:**

The backing membrane was prepared by solvent evaporation method. A weighed amount of polyvinyl alcohol (4 % w/w of PVA) was added to a requisite volume of warm distilled water. A homogeneous solution was made by constant stirring and intermittent heating at 60°C on a magnetic stirrer for about five minutes. Care was taken to prevent the entrapment of air bubbles in to the solution during stirring. The homogeneous solution was then poured into both side open glass moulds (2 ml in each mould). Moulds were of uniform specific diameter and height (2.8 cm and 4 cm respectively) and were previously wrapped by aluminum foil at one side. The moulds were then kept in dryer at 60°C ± 2°C for 6 hours to get uniform, smooth, transparent backing membrane.

### **6.3 Incorporation of drug loaded polymer matrix onto the backing membrane<sup>4,5,6,7</sup>:**

Matrix type transdermal patches containing propranolol hydrochloride were prepared using different ratios of ethyl cellulose (EC), polyvinyl pyrrolidone (PVP) (Table 6.1) and ethyl cellulose, hydroxypropyl methyl cellulose (HPMC) (Table 6.2) combination by solvent

evaporation technique in cylindrical glass moulds opened from both end. The bottom of the mould was wrapped with aluminum foil on which the backing membrane was cast earlier. The two polymers in each combination were weighed in requisite ratio and were then dissolved in ethanol. The ratios of the polymers were varied for all the formulations keeping the total weight fixed at 500 mg. Dibutyl phthalate 30 % w/w of polymer composition was added as plasticizer. Propranolol hydrochloride at a concentration of 20 % w/w of polymer was added and stirred with a mechanical stirrer for 15 minutes to get a homogeneous dispersion. The dispersion (2 ml) was cast on the prepared PVA backing membrane in each mould. The rate of evaporation was controlled by inverting a funnel over the mould and dried at 40°C for 6 hours. After drying, all the patches were removed from the moulds and were kept in desiccator for further study.

**Table 6.1: Formulation of propranolol hydrochloride transdermal patches containing ethyl cellulose and polyvinyl pyrrolidone:**

Sl. No.	Formulation code	Ratio of polymers (EC:PVP)	Drug (mg)	Dibutyl phthalate (% w/w of polymer)	Total weight of polymers (EC and PVP) (mg)	Ethanol (ml)
1.	TTs1	1:2	100	30	500	10
2.	TTs2	1:4	100	30	500	10
3.	TTs3	1:6	100	30	500	10
4.	TTs4	1:8	100	30	500	10
5.	TTs5	1:10	100	30	500	10
6.	TTs6	10:1	100	30	500	10
7.	TTs7	8:1	100	30	500	10
8.	TTs8	6:1	100	30	500	10
9.	TTs9	4:1	100	30	500	10
10.	TTs10	2:1	100	30	500	10

**Table 6.2: Formulation of propranolol hydrochloride transdermal patches containing ethyl cellulose and hydroxypropyl methyl cellulose:**

<b>Sl. No.</b>	<b>Formulation code</b>	<b>Ratio of polymers (EC:HPMC)</b>	<b>Drug (mg)</b>	<b>Dibutyl phthalate (% w/w of polymer)</b>	<b>Total weight of polymers (EC and HPMC) (mg)</b>	<b>Ethanol (ml)</b>
1.	TDS1	1:2	100	30	500	10
2.	TDS2	1:4	100	30	500	10
3.	TDS3	1:6	100	30	500	10
4.	TDS4	1:8	100	30	500	10
5.	TDS5	1:10	100	30	500	10
6.	TDS6	10:1	100	30	500	10
7.	TDS7	8:1	100	30	500	10
8.	TDS8	6:1	100	30	500	10
9.	TDS9	4:1	100	30	500	10
10.	TDS10	2:1	100	30	500	10

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