Viscosity

Viscosity is very much a limiting factor with regard to the ease with which a film coating can be applied. High viscosity (typically that exceeding about 500 mPa s) complicates transfer of the coating liquid from the storage vessel to the spray guns, and subsequent atomization of that coating liquid into fine droplets. Ideally, therefore, polymers applied as solutions in a selected solvent should exhibit relatively low viscosities at the preferred concentration. This will help to facilitate easy, trouble-free spray application of the coating solution, especially in production-scale film-coating equipment.

Permeability

Appropriate permeability (to which the chosen polymer makes a significant contribution) is a key attribute when considering the various functional properties that film coatings are expected to possess. For example, coating permeability is of significant importance when the film coating is intended to:

- mask the unpleasant taste of the active ingredient in the dosage form
- improve stability of the dosage form by limiting exposure to atmospheric vapours and gases, particularly water vapour and oxygen
- modify the rate at which the active ingredient will be released from the dosage form.

These properties vary widely between the various polymers that might be considered for film-coating formulations.

Mechanical properties

In order to perform effectively for the purpose intended, a film coating must exist as a discrete, continuous coating around the surface of the product to be coated, and must be free from defects typically caused by the stresses to which the coating is likely to be exposed during the coating process, during packaging and during the subsequent distribution of the final product.

Consequently, film-coating polymers should possess suitable characteristics with respect to:

- *film strength*, which greatly affects the ability of the coating to resist the mechanical stresses to which it will be exposed during the coating process and during subsequent handling of the coated product
- *film flexibility*, which imparts similar benefits to film strength and minimizes film cracking during handling or subsequent storage
- *film adhesion*, which is necessary to ensure that the coating remains adherent to the surface of the dosage form right up to the point of being taken by the patient.

The generation and minimization of film-coating defects are discussed more fully later in this chapter.

Types of film-coating polymers: immediate-release coatings

Cellulose derivatives

Most cellulosic polymers used in film-coating formulations are substituted ethers of cellulose.

Hydroxypropyl methylcellulose (HPMC) is the most widely used of the cellulosic polymers. Its molecular structure is shown in Figure 32.4. It is readily soluble in aqueous media and forms films that have suitable mechanical properties, and coatings that are relatively easy to apply. Coatings

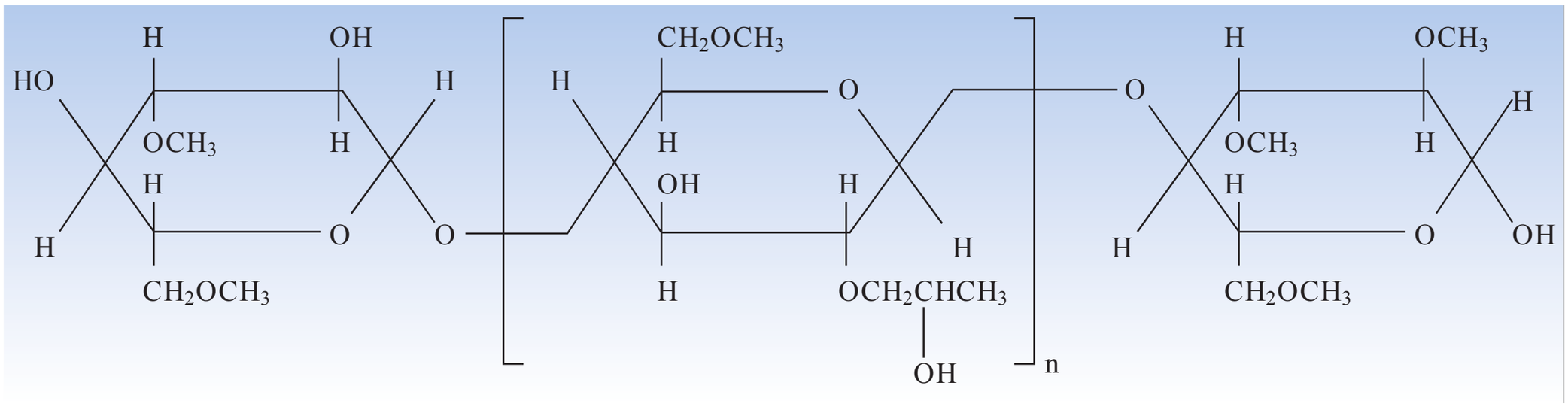

Fig. 32.4 • Hydroxypropyl methylcellulose.