The objective of this study was to evaluate the feasibility of BASF's wettable high
molecular weight povidone (Kollidon® VR 30, VR 50, VR 90, and Kollicoat® IR 35 Mr) and low
molecular weight povidone (Kollidon® VA64) for the preparation of drug delivery systems
in a film format. The technology is an elegant, fast disintegrating (dissolving) film that is
compatible and readily dissolved in aqueous media. Typically, films are marketed to
consumers in the form of dissolving strips of Listerine®, Chloraseptic®, Triaminic®, and
multivitamins have been developed that can provide a reduced risk of choking and enhance
patient compliance.1-3 Recently, fast-disintegrating films have been developed to provide
an alternative to conventional tablets for immediate release of medicaments.4-6 The
objective of this study was to develop and evaluate the feasibility of these low
molecular weight povidone formulations as a dissolving strip for a model drug
Ibuprofen. These strips were tested for film forming ability, disintegration time,
tackiness, elongation, film thickness, and drug loading.

MATERIALS AND METHODS
Kollidon® VR 30, VR 50, VR 90, and Kollicoat® IR 35 Mr and Kollidon® VA64 were
used as received. Formulations were obtained from BASF Polymers (Franklin Lakes, NJ).
Solvent was obtained from Fisher Scientific (Pittsburgh, PA). Water was obtained from a
purified water system (MilliQ, Millipore). Talcum powder was obtained from USP grade
talcum powder (Mallinckrodt, St. Louis, MO). Disintegrant was obtained from a
proprietary source. The disintegrant was a non-compressed disintegrant that
provides an extended release profile and is ideal for oral delivery. The model drug,
Ibuprofen, was obtained from BASF Polymers (Franklin Lakes, NJ). Diphenhydramine
hydrochloride was obtained from Fisher Scientific (Pittsburgh, PA). The polymer
compositions were varied as shown in Table 1. Disintegration time was assessed
by marking 1 cm distance at the edge of the film and applying equal
force to all the sides of the film. Disintegration time was measured from the
moment of application of force until the end of the strip reached 1 cm distance. Each
disintegration test was performed in triplicate.

RESULTS
All the polymers were shown to be suitable for the formation of a film. A series of
formulations containing 10-60% of Kollidon® VR 30, VR 50, VR 90, and Kollicoat® IR 35 Mr
were prepared (Table 1, A-C). These formulations showed a melting point in the
range of 100-140°C. The water content was determined by Karl Fischer analysis and
the amount of moisture was found to be less than 100 ppm on a weight basis. A
commercially available non-aqueous adhesive film (3M, St. Paul, MN) was used as a
standard control. The film containing 10% of the polymer was evaluated for thickness and
drug load. The films prepared using the disintegrant showed disintegration time of
50 sec or less. The films containing Kollidon® VA64 polymer showed a clear
increase in disintegration time compared with those containing Kollidon® VR 30, VR 50,
VR 90 or Kollicoat® IR 35 Mr polymers. The increase in disintegration time was
attributed, in addition to the high molecular weight of the polymer, to the hydrophilic
nature of Kollidon® VA64 polymer, which causes a reduction in viscosity of the film
matrix and hence increase in disintegration time. In a few cases during the disintegration
test, the films were observed to be softer at the edges, indicating a possible water uptake
and increase in disintegration time.

Distribution of Films
Figure 5 provides a clear demonstration of the film forming ability of 10% of
Kollidon® VR 30, VR 50, VR 90, and Kollicoat® IR 35 Mr polymers. The films prepared
using Kollidon® VR 30, VR 50, VR 90, or Kollicoat® IR 35 Mr polymers were all
able to disintegrate in 60 sec or less. These films were then evaluated for the
distribution of the model drug, Ibuprofen. The results are shown in Figure 6 and
Table 4. It can be clearly seen that the Kollidon® IR films showed a high
distribution of Ibuprofen compared with the Kollidon® VR 30, VR 50, VR 90, and
Kollicoat® IR 35 Mr films. The films containing Kollidon® IR 35 Mr polymer showed a
high distribution of Ibuprofen in the form of a flat profile; all disintegrated in 60 sec or
less, while the ibuprofen strips were disintegrated 5-times slower at all the dose levels.

DISCUSSION
The results obtained in this study demonstrate that the high molecular weight povidone
polymer can be used in flexible film development. This film can be developed into a
formulation that is appropriate for immediate release of medicaments. The polymers were
developed into films of different thickness using a manual applicator. The films were
pared for film forming ability, disintegration time, and drug distribution. The films
prepared using Kollidon® IR 35 Mr polymer showed a high degree of disintegration
and drug distribution. The results clearly demonstrate that the films are highly
hydrophilic and dissolve readily in 60 sec or less under the identical aqueous
conditions. These results may be due to the hydrophilic nature of the polymer used for
film development. The film containing Kollidon® IR 35 Mr polymer showed a clear
increase in disintegration time compared with those containing Kollidon® VR 30, VR 50,
VR 90 or Kollicoat® IR 35 Mr polymers. The increase in disintegration time was
attributed, in addition to the high molecular weight of the polymer, to the hydrophilic
nature of Kollidon® IR 35 Mr polymer, which causes a reduction in viscosity of the film
matrix and hence increase in disintegration time. In a few cases during the disintegration
test, the films were observed to be softer at the edges, indicating a possible water uptake
and increase in disintegration time.

REFERENCES