

activity and stability from being compromised by annealing. We will discuss this in detail in a later section.

We stated in the previous paragraph that glycine was completely crystallized out as a result of annealing. The evidence was the eutectic melting of glycine shown in Figure 2. Another way to verify the crystallization of glycine is to conduct an X-ray powder diffraction study on the freeze-dried cake. Figure 3 is a diffractogram of the lyophilized crystalline matrix formulation. Figure 4 shows a diffractogram of a lyophilized glycine-only formulation. Comparing

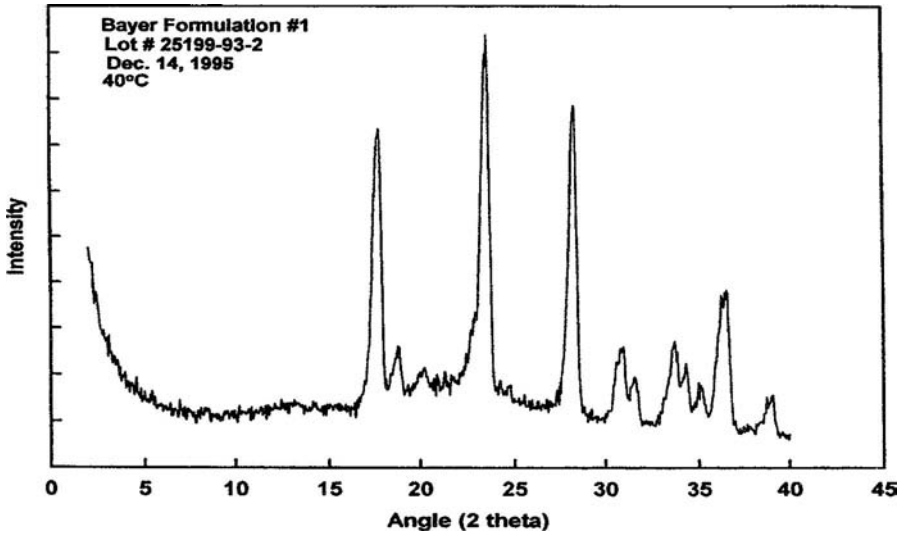


FIGURE 3 X-ray diffractogram of the crystalline matrix formulation.

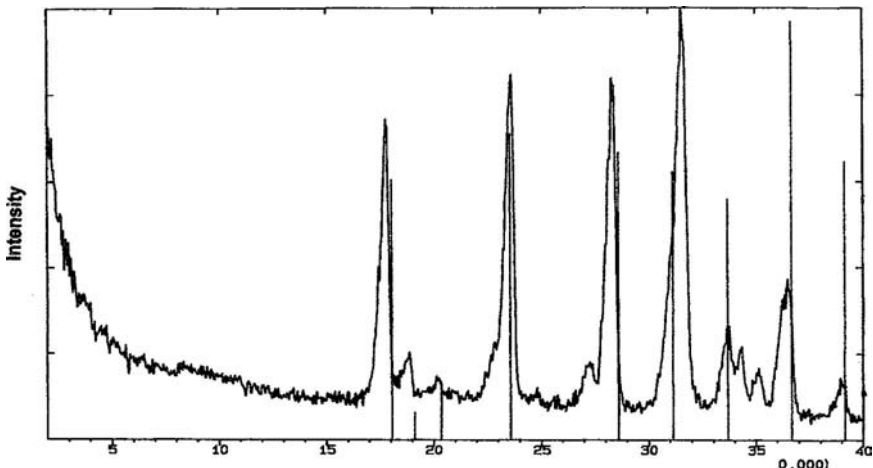


FIGURE 4 X-ray diffractogram of glycine.