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STUDY OF KEY-JO CLAY AS A MOISTURE SCAVENGING AGENT

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INTRODUCTION

This study was conducted to evaluate the moisture scavenging properties of Key-Jo clay by determining the moisture content of the clay at a constant temperature under varying relative humidity. Experimental results were then validated by comparison with published data for some commonly used pharmaceutical excipients--corn starch, magnesium trisilicate, casein, magnesium carbonate and the desiccant, anhydrous calcium chloride (1,2).

METHODS

Equilibrium moisture content for pharmaceutical excipients may be determined by equilibrating samples in an atmosphere of known relative humidity at constant temperature by observing weight loss or gain. In this study a modification of Strickland's (1) method was used to obtain reliable, reproducible results and to monitor the relative humidity throughout the experimental observation period.

Large (250 mm ID) Pyrex glass vacuum desiccators were used as relative humidity chambers. Relative humidity values of 0, 20, 40, 60, 80, 90 and 100% were obtained by use of one liter sulfuric acid-water solutions of appropriate concentration (3) in the bottom of each desiccator. The vacuum port of each desiccator lid was modified to accommodate probes from a recording psychrometer designed to measure temperature and relative humidity.

Determination of Moisture Sorption-Desorption Equilibrium Moisture Content

Sorption

After determining the moisture content of each of the six untreated, undried powders, powder samples of each were placed in an electric drying oven and dried for three days at 110 ± 2 degrees. Three-gram dried samples, accurately weighed, were placed in the 0% relative humidity chamber and allowed to equilibrate for 10 ± 2 days. Samples were then weighed as quickly as possible and transferred to the next higher percent relative humidity chamber. This procedure was repeated until sorption data were obtained at 0, 20, 40, 60, 80, and 90 percent relative humidity for each of the powder samples.

Desorption

At the completion of the sorption study for a given sample, the procedure was reversed and samples were equilibrated successively in the descending order through each of the relative humidity chambers until equilibrium conditions were obtained and the weight loss recorded.

DISCUSSION

Moisture content data for corn starch, magnesium trisilicate, magnesium carbonate and casein as determined from this study agree well with data reported by Strickland (1) for these same excipients. Because magnesium trisilicate and corn starch are

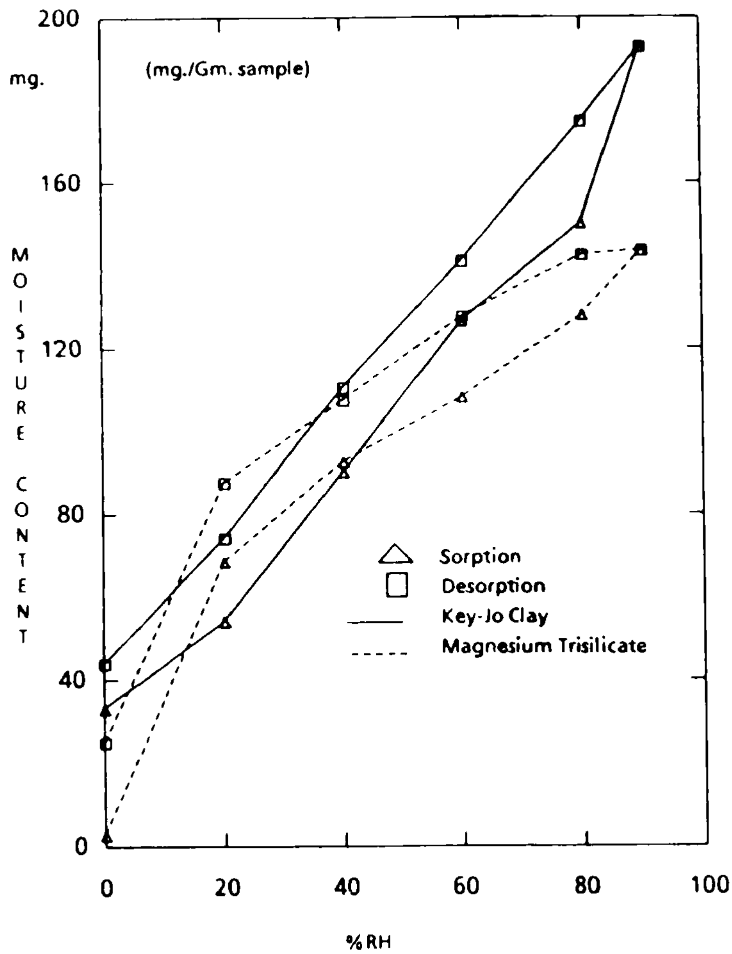

FIGURE 1. Moisture Sorption and Desorption, Magnesium Trisilicate, Key-Jo Clay 30-40 Mesh

representative of inorganic and organic type excipients used in tablet formulation and their sorption-desorption curves approximate those found for Key-Jo clay, these two substances were selected for comparison with Key-Jo clay in this study. Figure 1 shows a comparison of moisture sorption and desorption of Key-Jo clay with magnesium trisilicate. Figure 2 presents the comparison of Key-Jo clay with corn starch in moisture sorption and desorption studies.

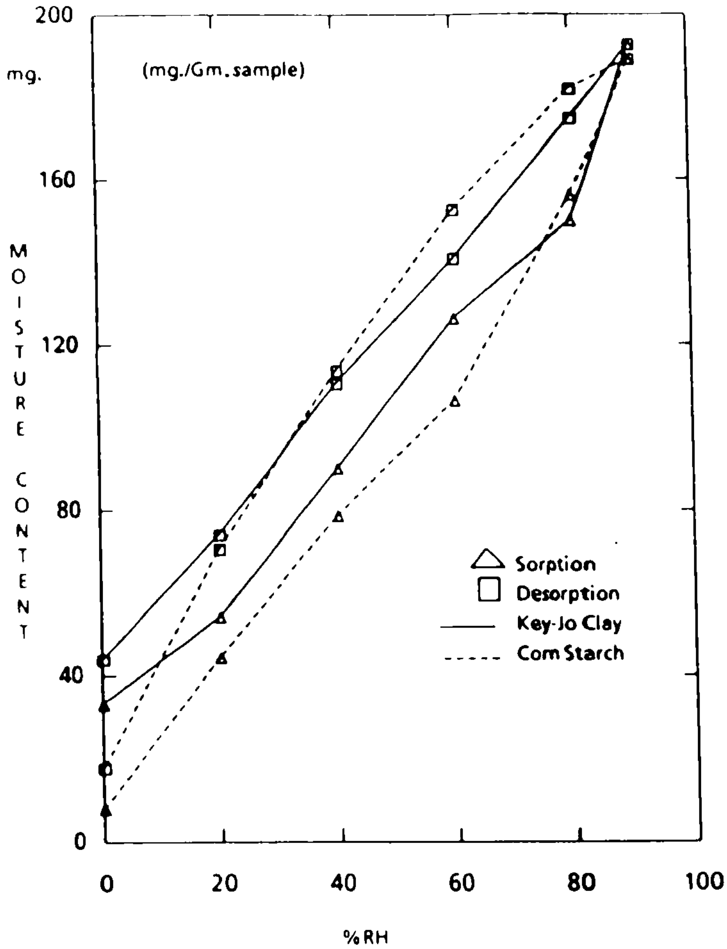

FIGURE 2. Moisture Sorption and Desorption, Corn Starch, Key-Jo Clay 30-40 Mesh

RESULTS

Comparison of the moisture sorption-desorption characteristics of Key-Jo clay with those for corn starch and magnesium trisilicate suggests that Key-Jo clay has good potential for use as a moisture scavenging agent in tablet formulation. In the 60-80% relative humidity range, Key-Jo clay sorbs more moisture and desorbs less moisture than either corn starch or magnesium trisilicate. Corn starch was shown to cake at 80% relative humidity while Key-Jo clay remained unchanged, even at relative humidities up to 100% for a period up to four days. When compared to corn starch, in particular, Key-Jo clay may be used in greater weight percent compositions (4) and demonstrates the ability to scavenge larger amounts of moisture within a given tablet.

FOOTNOTES

1. Strickland, Jr., W. A., J. of Pharm. Sci., 51, 310-314, 1962.

2. Scott, M. W., Liberman, H. A. and Chow, F. S., J. Pharm. Sci. 52, 994-998, 1963.

3. Weast, Robert C., "Handbook of Chemistry & Physics," 6th ed., CRC Press, Inc., Boca Raton, Florida, E-42, 1986.

4. Roe, T. S. and Chang, K. Y., Drug Dev. & Ind. Pharm., 12 (11-13), 1567-1585, 1986.