THERMAL AND MECHANICAL STABILITY STUDIES OF THE HYDRATE FORM OF DICLOFENAC SODIUM (DSH) IN THE SOLID STATE

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Diclofenac sodium can exist in an anhydrous crystalline form (DS) and in various hydrate forms with distinctly different physico-chemical properties. Extensive literature is available for the anhydrous form (DS) [1-4] and in literature a tetrahydrate form [5-9] and a pentahydrate form [10] have been reported. In a recent work the capability of DS to uptake water from the environment giving rise to a new hydrate form with 20% water content (DSH) has been reported. DSH was obtained by exposure by humidity even below 60% (25°C) [11]. Physical stability of DSH by experiments in a desiccator with and without vacuum and on heating was investigated. DSH showed a good stability in a desiccator without vacuum for 68 h, while on vacuum (up to 31 h) it gave rise to an unstable structure (about 5% water content) difficult to isolate. A trihydrate form, DSH3 (15,9% water content) by heating DSH at 40°C for 3 minutes, was obtained. Grinding experiments on DSH powder by Fritsch Pulverisette 2 (mortar grinder) and Fritsch Pulverisette 0 (vibratory micro mill) were performed. Using Pulverisette 2 the dehydration of DSH started after grinding for a few minutes, as expected. The transition into the anhydrous form DS was complete within 80 min. The crystalline structure of DSH was strongly affected also by grinding with Pulverisette 0 for 12 h. This condition induced a slower dehydration of DSH, giving rise to a hydrate form with 13-14% water content and with proper physico-chemical characteristics (FT-IR Spectrum and DSC and TG profiles). Furthermore its X-ray powder diffractometry spectrum is remarkably different from that of the known forms suggesting the existence of another hydrate form of diclofenac sodium.

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