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EFFICIENT USE OF DSC IN THE PHARMACEUTICAL QUALITY CONTROLL, FOR EXAMPLE ISOSORBIDE DINITRATE

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Precisely determined thermal analysis can indicate the identity, purity and assay of drugs like isosorbidedinitrate (ISDN) and their mixture ISDN-lactose (4/6) and ISDN-NaCl (1/9).

It is demonstrated with the pure substance ISDN that impurities presented from the synthetic route can be detected.

The size of the crystals of ISDN has no influence on the identity, purity and assay. The ratio of the heat of melting of a mixture of ISDN with either excepient to that of the pure drug was linearly related to the drug content.

Advantages of thermal analysis compared with other methods (HPLC, polariscopic) are presented.

It will be discussed the eutectic points of the main intermediates of ISDN and it is shown the binary phase diagrams with these substances.

The full text of this contribution was not submitted.