Mepivacaine Hydrochloride Polymorphs: a Drug Production Quandary

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The existence of different crystalline forms of Mepivacaine.HCl was revealed by routine quality controls of industrial batches.

Two polymorphic non-solvated modifications were identified and characterized by powder diffraction data: Form II, the commercial one, accepted as a standard, and Form I, the more stable one, obtained by re-crystallization.

Single-crystal structure determinations of ethanol and methanol solvates, respectively Form III (possible precursor of industrial processing) and Form IV, have been carried out [1]. Combined with other data, these have shed light on possible interconversions between some of the above forms. In particular, microcrystalline Form II should be generated by desolvation of Form III in the course of industrial crystallization from ethanol and Form I may then be reached, in suitable conditions, *via* modest structural rearrangements.

[1] Giannelllini V., Bambagiotti-Alberti M., Bartolucci G., Bruni B., Coran S.A., Costantino F., Di Vaira M., *J. Pharm. Biomed. Anal.*, 2005, *submitted*.

Keywords: mepivacaine-hydrochloride, polymorphs, x-ray-diffraction