

## White Spots on Tablets—Compliance Case Study #8

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A case study involving unexpected white spots on a previously problem-free blue tablet product is described. Initial speculation was that the white-spot problem was either grease spots or microbial growth. FD&C Blue #2 was the colorant in the tablet formulation. Chemical change (chemical reduction in alkaline pH) of the blue dye was determined to be the source of the white spots. Manufacturing personnel indicated that there was potential for incorrectly assembled milling equipment causing materials to not be milled. Comparative testing of control tablets and experimental tablets under...

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