

# Samples of Comparison for Visual Binary Testing of p-Chloroaniline as Impurity in Substance Chlorhexidine Digluconate

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*For the visual detection of the impurity - p-chloroaniline (p-CA) at the level of its limiting content in the substance chlorhexidine digluconate (CH), it was suggested to use the screening methodology - binary testing using a single sample of comparison. Two indicator reactions were selected: the reaction in a solution of diazotized p-CA with N-naphthylethylenediamine (sample of comparison 1) and the chemisorption reaction of diazotized p-CA with polyurethane foam (sample of comparison 2). For establishing the concentration of p-CA in the samples of comparison a statistical approach that previously had used for estimating the limit of detection for visual test methods, was applied. Estimated value of the threshold concentration of p-CA less than the normalized level on the value which providing the risk of false-negative test result not more than 5%. Accuracy of the visual binary testing of p-CA in the chlorhexidine digluconate substance was confirmed by spectrophotometric, chromatographic methods and diffuse reflection spectroscopy.*

**Keywords:** p-chloroaniline, chlorhexidine, normalized concentration, spectrophotometry, visual binary testing