

## Documents

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**Evaluation of the inhibitory effects of pharmaceutical excipients toward the efficiency of polymerase chain reaction (Pcr)**  
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### Abstract

Product authentication using a DNA-based technology method, Polymerase Chain Reaction (PCR), is very crucial in determining halal status and preventing any fraud or contamination. Pharmaceutical products contain excipients which are highly processed materials, thus the DNA is present in small fragments and extraction process may render it undetectable. One of the PCR methods that does not require DNA extraction is direct PCR, however the sample itself can cause inhibition. Less studied, the effect of pharmaceutical excipients which may act as PCR inhibitors can potentially lead to PCR amplification disruption. To this aim, various excipients from different functional categories (lactose, corn starch, lanolin, magnesium stearate, titanium dioxide, sodium bicarbonate, gelatin, and polyethylene glycol) were investigated. Each of the excipients were made into different concentration range based on the commonly used concentration in pharmaceuticals. The excipients were tested with porcine DNA by using conventional PCR. The amplification of DNA was then analyzed by using 1.5% gel electrophoresis. The results showed that all concentrations of lactose, corn starch and lanolin did not induce inhibition of DNA amplification, whereas magnesium stearate, titanium dioxide and sodium bicarbonate conversely inhibited the amplification. Gelatin at lower concentrations (0.5% and 1% (w/v)) did not show inhibition however, as the concentration increases to 5% and 10% (w/v), the inhibition was noticed. Similarly, inhibition was not recorded with polyethylene glycol at concentration of 0.5% to 10% (w/v) however, the effect was visible at concentration of 25% (w/v). As a conclusion, pharmaceutical products containing different concentrations of lactose, corn starch, lanolin and low concentrations of gelatin and polyethylene glycol may be used in direct PCR for product authentication without being tampered with. © 2020, Advanced Scientific Research. All rights reserved.

### Author Keywords

Excipient; Inhibition; Polymerase Chain Reaction

### Index Keywords

bicarbonate, excipient, gelatin, lactose, lanolin, macrogol, magnesium stearate, starch, titanium dioxide; agar gel electrophoresis, Article, controlled study, DNA extraction, gene amplification, polymerase chain reaction

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