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ABSTRACT

STABLE PHARMACEUTICAL COMPOSITION OF 3-(HYDROXYMETHYL)-5,5-DIPHENYLHDANTOIN DISODIUM PHOSPHATE ESTER

Described is a stable pharmaceutical composition of 3-(hydroxymethyl)-5,5-diphenylhydantoin disodium phosphate ester, the produg of 5,5-diphenylhydantoin (phenytoin) a commonly used drug for the treatment and management of epilepsy and other types of convulsive states. It has been found that degradation of the produg of the produg to phenytoin can be controlled by controlling the pH of the compositions. Controlling the pH to between 8.3 to 9.4 results in the production of diphenylglycinamide as the primary degradant and minimization of degradation to phentoin. If the pH is maintain at a lower or higher value, then the degradation pattern changes, with earlier than expected product failure.

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