

**PROCESS VALIDATION OF ALUMINIUM HYDROXIDE,
MAGNESIUM HYDROXIDE &
SIMETHICONE ORAL SUSPENSION**

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ABSTRACT

The purpose of research was to study retrospective and concurrent process validation of Aluminium hydroxide, magnesium hydroxide and simethicones oral suspension. Three initial process validation batches of same size, method, equipment and validation criteria were taken. The critical parameters involved in mixing, pH, Viscosity and filling were identified and evaluated as per validation master plan. All the instruments were calibrated as per standard operating procedures. The outcome indicated that data obtained by process validation of three batches provides high degree of assurance that manufacturing process of Aluminium hydroxide, magnesium hydroxide & simethicone oral suspension produces product meeting its predetermined specifications and quality attributes. As well as retrospective validation is done for 20 batches, each batch result was find as per specification and based on this Annul product review(APR) was prepared.

Key words: Aluminium hydroxide, magnesium hydroxide, simethicone, Oral Suspension, Process Validation, Validation Report, specification, Annual product review (APR)

