

# **PROCESS VALIDATION OF RONCOLD PLUS TABLET**

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## **ABSTRACT**

The aim of this work was to study process validation of Roncold Plus tablet. Initially Twenty batches data were taken for Retrospective validation to confirm that the parameters lie within established specifications. Thereafter three consecutive process validation batches of same size, method, equipment and validation criteria were taken and subjected to concurrent validation. The critical parameters involved in sifting, granulation, drying and blending were identified and evaluated as per validation master plan. All the instruments were calibrated as per standard operating procedures. % Assay in Granulation was optimum in 20 minutes as % Standard deviation was between 0.16 to 0.80. Drying time of 30 minutes was suitable for obtaining moisture content within 1.11 to 1.37 %. Blend uniformity was optimum in 25 minutes as % Standard deviation was between 0.24 to 0.82. Compression speed was optimum at 18 RPM as % Standard deviation of Average weight was 0.40, Hardness was between 0.25 to 0.29, Thickness was between 0.0042 to 0.0048, Friability was 0.07 and Assay

was between 0.26 to 0.71. The outcome indicated that data obtained by process validation of three batches provides high degree of assurance that manufacturing process of Roncold Plus Tablet produces product meeting its predetermined specifications and quality attributes.

**Key words:** Roncold Plus, Process Validation, Retrospective Validation, Concurrent Validation