Process Validation Of

Cefpodoxime Proxetil Oral Suspension I.P.

By

Joshi Priya Virendra

Enrollment No. 092140804009

Guided by

Dr.(Mrs.) Vandana B. Patel

M.Pharm, Ph.D.

Prof. & PG Director,

A Thesis Submitted to

"Gujarat Technological University"

in partial fulfilment of the requirements for the degree of

"Master of Pharmacy"

in **Pharmaceutical Quality Assurance**

June-2011

Baroda College of Pharmacy

Parul Trust, Limda, Ta. Waghodia, Dist. Vadodara 391760

ABSTRACT

The aim of this work was to study process validation of cefpodoxime proxetil oral suspension I.P. Three initial process validation batches of same size, method, equipment and validation criteria were taken. The critical parameters involved in sifting, mixing, drying and filling were identified and evaluated as per validation master plan. All the instruments were calibrated as per standard operating procedures. Uniformity of blending was optimum in 60 minutes as standard deviation is between ±0.31 to ±0.37. Drying time of 60 min was suitable for obtaining moisture content within 0.3-.06%. The Drug content of reconstituted liquid suspension on day 1 and at day 7 were within the limits of 90% to 110%. The outcome indicated that data obtained by process validation of three batches provides high degree of assurance that manufacturing process of cefpodoxime proxetil oral suspension produces product meeting its predetermined specifications and quality attributes.

Key words: Cefpodoxime Proxetil, Oral Suspension, Process Validation, Uniformity of Blending.