



PHARMA DEVILS

QUALITY CONTROL DEPARTMENT

**ANALYTICAL METHOD VALIDATION REPORT FOR DETERMINATION OF HYDROCORTISONE IN THE
CLEANING SAMPLES BY UV SPECTROPHOTOMETER**

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1.0 SUMMARY:

Analytical method validation study for determination of Hydrocortisone in the cleaning samples by UV Spectrophotometer was executed in accordance with the approved protocol.

a) Precision Study:

Precision of the analytical method was carried out to ensure the suitability of the method.

The statistical evaluation shows % RSD of absorbance was 1.009%, which is well within the acceptance limit of 2.0%.

b) Accuracy Study:

The accuracy study was carried out by adding known concentration of standard sample.

% recovery was found from 99.827% to 100.784% which is well within the acceptance limit of 90.0% - 110.0%.

c) Linearity & Range:

The Linearity & Range of the method was studied for standard solution in the concentration range of 0.1 ppm, 0.25 ppm, 0.5 ppm, 1.0 ppm, 2.5 ppm, 5.0 ppm, 8.0 ppm, 10.0 ppm and 12.0 ppm.

The correlation coefficient [r] value is 0.999 (Limit: Not less than 0.995)



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d) Limit of Detection (LOD):

Limit of Detection is found to be 0.4 ppm.

e) Limit of Quantitation (LOQ):

Limit of Quantitation is found to be 1.0 ppm.

Precision of LOQ concentration (1.0 ppm): The statistical evaluation shows % RSD of absorbance was 11.362%, which is well within the acceptance limit of 33.0%.

The statistical evaluation parameters (i.e. Precision, Accuracy, Linearity & Range, Limit of Detection, Limit of Quantitation) shows the analytical method is valid for its intended use of determination of Hydrocortisone in the cleaning samples by UV Spectrophotometer upto 1.0 ppm.

2.0 CONCLUSION:

All the analytical parameters studied for the method are well within the acceptance limit set for the method. Therefore, the analytical method of determination of Hydrocortisone content in the cleaning samples is considered as a validated method for its intended purpose.

3.0 REPORT APPROVAL:

	Compiled By	Reviewed By	Approved By
Signature			
Date			
Name			
	Quality Control	Quality Control	Head – Quality