

HANDBOOK OF  
**ANALYTICAL  
METHOD  
VALIDATION**

FOR PHARMACEUTICALS

A Practical Guide to Verifying drug, biologic,  
chemical & herbal products using HPLC, GC & ICP

- DR. JAGDIP RAJANI -



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**ANALYSIS OF ANALYTICAL METHOD VALIDATION**

ANALYTICAL METHOD VALIDATION IS A CRUCIAL STEP IN THE  
DEVELOPMENT OF A NEW DRUG PRODUCT AND  
IS ESSENTIAL FOR THE PRODUCTION OF  
HIGH-QUALITY DRUGS.

THE VALIDATION OF AN ANALYTICAL METHOD  
IS A PROCESS OF ESTABLISHING THE  
ACCURACY, PRECISION, SENSITIVITY,  
SPECIFICITY, AND RANGE OF A  
METHOD FOR THE ANALYSIS OF  
A PARTICULAR SUBSTANCE.

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ANALYTICAL METHOD VALIDATION FOR PHARMACEUTICALS

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**Wenkui Li, Jie Zhang, Francis L. S. Tse**

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