



A Multivariate Strategy for Tablet Manufacturing Optimization

Eutimio G. FERNÁNDEZ ^{1,2} *, Mirna FERNÁNDEZ ³, Hoang Minh HOANG ³, Irela PÉREZ ³,
Dayneris GUERRA ⁴, Adalberto IZQUIERDO ⁴, Rodolfo VALDÉS ⁵, & Mena Cayetana RAMOS ⁶

¹ *Inorganic Chemistry Department. Center for Engineering and Chemical Researches.
F Street, # 115 be/ Ave 5th and Calzada. Havana City, 10400, Cuba*

² *Radiopharmacy Center, Nuclear and Energy Research Institute, Av. Lineu Prestes, 2242,
Cidade Universitaria, Butantã, Sao Paulo, 05508-000, Brazil*

³ *Institute of Pharmacy and Food, University of Havana. Street 23 No. 21425 be/ 214 and 222,
La Coronela, La Lisa. Havana City, Cuba*

⁴ *Novatec Laboratories. Ave 25, # 216A03 be/ 216A and 222. Atabey, Playa. Havana City, Cuba.*

⁵ *Department of Monoclonal Antibody Production, Center for Genetic Engineering and Biotechnology
(CIGB), P.O. Box 6162, Ave 31 be/158 and 190, Playa, 10600 Havana, Cuba.*

⁶ *“Salvador Allende” Hospital. Calzada del Cerro #1551. Havana City, Cuba.*

SUMMARY. The objective of this work was to develop a multivariate strategy to optimize tablet manufacturing employing mephenesin as model drug. The process variables for granulation step were binders and lubricants types, while the mixture variables included the proportions of binders and lubricants. To reduce the experimentation and tablet characterization in the compression step, a principal component analysis was performed. Tableting process was studied according to a three level factorial design. The factors were the scores in first principal component of granulation variables and hardness of the tablets. The properties of tablets were mainly influenced for the scores of granules. The optimum formulation, achieved using the desirability function, was the formulation with PVP K 90 as binder (4.25 %) and talc as lubricant (1.25 %). The multivariate strategy provides an effective tool for tablet manufacturing optimization when the high experimentation costs are prohibitive or the granulation process is influenced by many factors.

KEY WORDS: Crossed experimental design, Mephenesin, Multivariate strategy, Principal component analysis, Tablet manufacturing.

* Author to whom correspondence should be addressed. *E-mail:* eutimiocu@yahoo.com