

Proposal for Standardizing Operation Procedures in a Laboratory that Produces Pharmaceutical Formulations [†]

Adriana Ana Lía Ordoñez ^{1,2,*}, Ana Laura Retamar ²

¹ Pharmaceutical Technology, Faculty of Biochemistry, Chemistry, and Pharmacy, UNT. Tucumán, Argentina; anadryordonez@gmail.com (A.O.); analauraretamar@gmail.com (A.R.)

² Pharmaceutical Technology, Academic Department of Exact, Physical, and Natural Sciences, UNLaR. La Rioja, Argentina; anadryordonez@gmail.com (A.L.R.)

* Correspondence: anadryordonez@gmail.com (A.L.R.);

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Abstract: The Pharmaceutical Laboratory of the National University of La Rioja is devoted to producing officially approved pharmaceutical formulations. Currently, however, no protocols have been established to efficiently guarantee that Good Manufacturing Practices (GMP) are followed, which is vitally important for ensuring good pharmaceutical quality. Since the laboratory constitutes both a production area and an academic learning setting for undergraduate and graduate Pharmacy Degree students, the supervision of all the activities and processes must secure that the manufactured drugs are characterized by their identity, purity, concentration, strength, and safety. This work aims to develop a proposal for designing and setting standard operating procedures (SOP), documents that describe the required methodology for each activity involved in the production and control of formulations, as stipulated by current regulations. This theoretical-prospective proposal covered three stages: literature review, the recording of all the activities carried out, and the preparation of all the required SOP documents. This work guaranteed the uniformity, reproducibility, and consistency of the processes, and the quality and safety of the formulations, by means of documents that pinpointed activities, roles, and responsibilities to be undertaken to achieve this specific purpose.

Keywords: manufacturing operation procedures; good manufacturing practices; drugs.

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Conflicts of Interest

The authors declare no conflict of interest.