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| Effective Date: <u>1/7/01</u> | Physicians Formula Inc./Pierre Fabre Inc. Standard Operating Procedure | Document Number: SOP PROD-01 |
| Supersedes Date: <u>10/24/00</u> | Title: Operation and Maintenance of the TF-2 Filling Line | Revision Number: 1 Page 1 of 3 |

Approvals:

| Department: | Name: | Date: |
|--------------------------------------|--------------------|-----------------|
| Manager, Quality Control | <i>[Signature]</i> | <u>1/4/2001</u> |
| Director, Research & Development /QA | <i>[Signature]</i> | <u>1/4/2001</u> |
| Vice President of Operations | <i>[Signature]</i> | <u>1/7/01</u> |

1.0 Purpose

- 1.1 To define the steps needed for proper operation and maintenance of the TF-2 filling line

2.0 Scope

- 2.1 Covers the TF-2 filling machine ID# TF2-1

3.0 Introduction

- 3.1 The TF2 Filling Line utilizes a rotary TGM Meccanica filler, model S400. Product containers are loaded into their matching alignment pucks, which are placed into the machine pockets for filling. The filler is designed to fill various volumes of products packaged in tubes, small bottles and vials. When filling tubes, an orienting station orients the tube correctly by matching an I-mark using an optical sensor. After the filling station, the tube end is melted using a hot air nozzle – hot air melts the inside of the tube, and cold water circulation keeps the exterior of the tube cool. A crimping mechanism is then used to seal the tube end and emboss a product code. The tube then passes through a jet of ambient air to aid set-up. A trimming station then cuts the tube end flush and the filled tube is then ejected onto a moving conveyor. When filling bottles, and vials, the tube sealing tooling is removed and a wiper depressor is installed as needed.

4.0 Responsibilities

- 4.1 It is the responsibility of the TF-2 operators to follow the SOP. It is the responsibility of the facility Manager and plant Manager to assure that the SOP is followed at all times.

5.0 Procedure

5.1 Operation

5.1.1 Instructions for Filling Vials.

- 5.1.1.1 Set up the line, product and components according to Standard Operating Procedure PROD-00.