3.2.P.3.1 Manufacturer(s)

This section contains information about the manufacture of the drug product, Clobetasol Propionate Foam, 0.05%.

1.0 Drug Product Manufacturer (Manufacturing, Packaging and Labeling)

Clobetasol Propionate Foam is manufactured, packaged, and tested according to cGMP by Pharmasol Corporation in Easton, MA; NJ Laboratories in New Brunswick, NJ; and MPL Laboratories in Sparta, NJ. All firms involved in the manufacturing, packaging, and testing of the finished drug product are listed in Table 1. The compliance certifications of each firm are provided herein.

Table 1. Sites and Contacts

Establishment	Contact Information	Responsibility
Pharmasol Corporation 1 Norfolk Avenue Easton, MA 02375, USA DUNS# 065144289 FEI# 1250001 cGMP and Debarment	Bill Washington V.P. Quality & Regulatory Affairs Tel: 508-238-8501 X 308 Fax: 508-238-0105 bwashington@pharmasol.com	• Responsible for the manufacture of both exhibit batches and commercial batches. • Manufacturing and packaging, labeling, testing and release of finished product. • Release of drug substance, excipients, and packaging components. • Stability storage and testing for all packaging configuration. • Storage for finished drug product
New Jersey Laboratories 1110 Somerset Street New Brunswick, NJ 08901, USA DUNS# 063155238 FEI# 2219935 cGMP and Debarment	Sandra E. Lee Tel: 732-249-0148 Fax: 732-249-0243 sandy@njlabs.com	• Drug Substance Testing for Specific Optical Rotation, Residue on Ignition
MPL Laboratories 12 Wilson Drive Sparta, NJ 07871, USA DUNS# 080265475 FEI# 2246393 cGMP and Debarment	Patricia O. Griffin Tel: 973-300-9715 Fax: 973-300-9830 patty@marypaullabs.com	Finished product samples and stability samples • Microbial Testing

2.0 U.S. Applicant

Table 2. Sites and Contacts

Establishment	Contact Information	Responsibility
Aucta Pharmaceuticals, Inc. 71 Suttons Lane Piscataway, NJ 08854, USA cGMP Statement	Tina Lee Executive Director, Regulatory Affairs Tel: 732-640-0030 Fax: 732-307-9830 reg.affairs@auctapharma.com	• Applicant

3.0 Outside Contract Testing Facilities

The outsourced laboratories involved in comparative in vitro studies of test vs. reference. Based on the instructions for Form FDA 356h, establishment information on bioequivalence testing sites is not required in Form 356h.

Table 3. *In Vitro* Study Center

Establishment	Contact Information	Responsibility
Pharmasol Corporation 1 Norfolk Avenue Easton, MA 02375, USA DUNS# 065144289 FEI# 1250001 cGMP and Debarment	Samir Paliwal V.P. Quality & Regulatory Affairs Tel: 508-238-8501 X 308 Fax: 508-238-0105 spaliwal@pharmasol.com Lynn Murray Director of Quality Tel: 508-238-8501 X 248 Fax: 508-238-0105 lmurray@pharmasol.com	Responsible for in vitro studies of Test vs. RLD: • Microscopic Birefringence Analysis • Time to Break Analysis • Weight per volume of uncollapsed foam.