Malladi Drugs & Pharmaceuticals Ltd.

An Overview

MALLADI

Background

- Founded in 1980 - First company in India to manufacture pharmaceutical actives Ephedrine & Pseudoephedrine through a fermentation process
- Awarded the prestigious PC Ray award for indigenous technology development
- Recognized by Govt. of India for development work & given the award "R&D Efforts in Industry"
- Manufacturing facilities – 3 plants in 2 locations in India
- Employees – Over 800
- Revenue – US $ 60 million; Customers in over 50 countries
- Full Regulatory compliance – Inspected by all major regulatory agencies and large pharma companies
- Professionally managed - Corporate Governance Sustainable growth
- Committed to health, Safety & Sustainability

Research & Process Development

Malladi has a process development laboratory in the outskirts of Chennai. The lab is well equipped and has 40 chemists working on synthesis and analytical development. The facility is built suitable for quick expansion.

Synthesis Laboratory:

32 Fume hoods expandable to multi floor operation

Analytical:

HPLC – UV, ELSD, PDA , auto LC MS

GC with Headspace, auto UV IR, auto-titrator

Scale Up

2 kilo labs

5 L to 20 L Glass Reactor

All glass reaction set up

Separators

High Pressure Reactor 2000 psi

Supercritical CO_2 Extractions

Malladi – Research & Process Development

- Newly built state of the art - Process Development lab in Chennai
- Over 70 chemists
- Synthetic Organic, Analytical chemistry
- Process development work for API , Advanced Intermediates and Cosmetic Ingredients
- Development & Synthesis of compounds – support for customers in preclinical stage
- R&D recognized by universities for Doctoral programs

Chiral chemistry

Acylation

Iodination

Friedel-Crafts Alkylation

Grignard Reaction

Benzoylation

Mannich Reaction

Bromination

Esterification

Eshweiler-Clarke Methylation

N-Alkylation

Tosylation

Oxidation

Sodium Borohydride reduction

Nitrosation

Hydrogenations

Cryogenic Reactions (-70 to -80° C)

Flourinations

Benzoin Condensation

Malladi - Manufacturing

- US FDA Inspected API manufacturing facility
- Manufacturing sites – Ranipet (2), Tirupathi
- Australian TGA & ANSM, France approved
- EDQM approved for Dossier compliance and GMP compliance
- ISO 9001: 2008
- Excellent waste treatment systems – zero effluent discharge

Sustainability at Malladi

Employee welfare	•Healthy and Safer working condition for employees • Self development/skill development training for employees • Career planning/development programs for employees • Appraisal with emphasis on sustainability principles
Environment Management	• Waste Management • Water conservation (Reduce, recycle , reuse) • Reduce energy consumption through innovative technologies • Greener Manufacturing • Increase use of renewable energies
Social Responsibility	•Fair Business Practices • Reaching out to the society with welfare schemes
Sustainable Procurement	•Educating supply chain on the principles of sustainability • Integration of social & environmental factors in vendor evaluation

Malladi –APIs

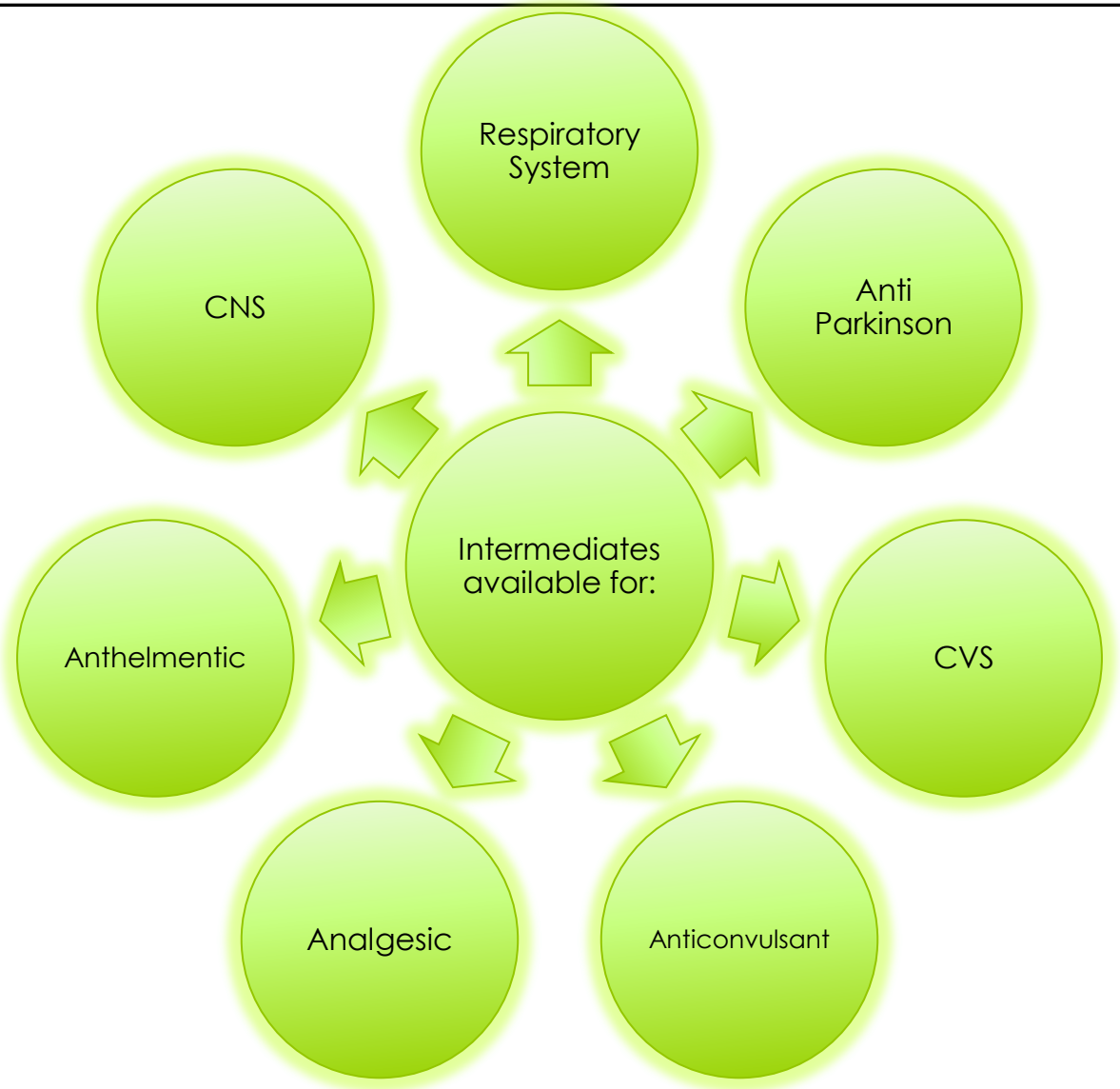
APIs

- Ephedrine/ Pseudoephedrine salts
- Phenylephrine & Salts
- Triprolidine Hcl
- Fexofenadine Hcl
- Dextromethorphan Hbr
- Epinephrine,Norephedrine
- Selegiline,
- Alprazolam,Lorazepam,Methylphenidate,
- Metaraminol Bitartarate
- Butamirate Citrate
- Phenobarbital

New API Launches

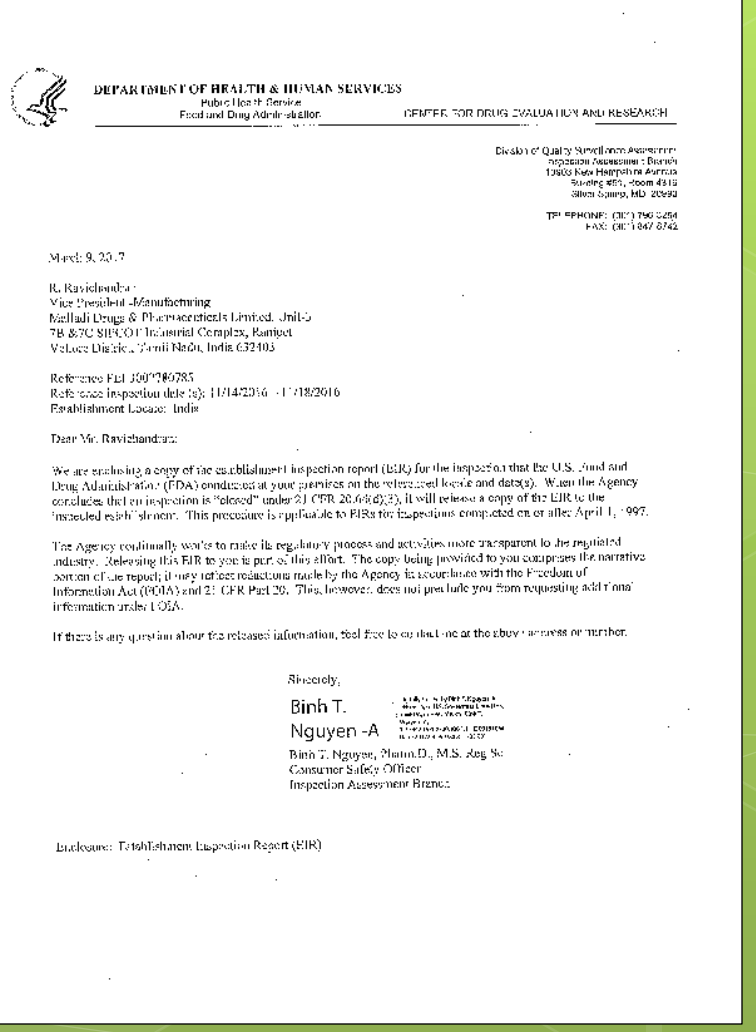
- Butorphenol
- Leviteracetam
- Mephentermine
- Tranexamic Acid
- Docusate Sodium

Malladi-Intermediates



Malladi – Quality Systems

- In House Method Development, Validations of Methods & Processes
- EDMF Filing, DMFs in NEES and eCTD formats
- 7 Successful US FDA Inspections; last successful inspection September 2012
- Ranipet Plant audited by EDQM and ANSM for EU GMP compliance
- Several DMFs filed with the US FDA & Other Regulatory agencies
- 2 Certificates of Suitability from EDQM
- 2 CEP's filed
- Ranipet plant inspected & approved by several customers and large pharmas like Pfizer, GSK, Novartis, Sanofi Aventis, Proctor & Gamble etc for GMP compliance



DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service
Food and Drug Administration
CENTER FOR DRUG EVALUATION AND RESEARCH

March 9, 2017

R. Ravichandran
Vice President -Manufacturing
Malladi Drugs & Pharmaceuticals Limited, Unit-5
7B &7C SIPCOT Industrial Complex, Ranipet
Vellore District, Tamil Nadu, India 632403

Reference FEI 3007286785
Reference Inspection date(s): 11/14/2016 - 11/18/2016
Establishment Locale: India

Dear Mr. Ravichandran:

We are enclosing a copy of the establishment inspection report (EIR) for the inspection that the U.S. Food and Drug Administration (FDA) conducted at your premises on the referenced locale and date(s). When the Agency concludes that an inspection is "closed" under 21 CFR 20.64(d)(3), it will release a copy of the EIR to the inspected establishment. This procedure is applicable to EIRs for inspections completed on or after April 1, 1997.

The Agency continually works to make its regulatory process and activities more transparent to the regulated industry. Releasing this EIR to you is part of this effort. The copy being provided to you comprises the narrative portion of the report; it may reflect redactions made by the Agency in accordance with the Freedom of Information Act (FOIA) and 21 CFR Part 20. This, however, does not preclude you from requesting additional information under FOIA.

If there is any question about the released information, feel free to call me at the above address or number.

Sincerely,

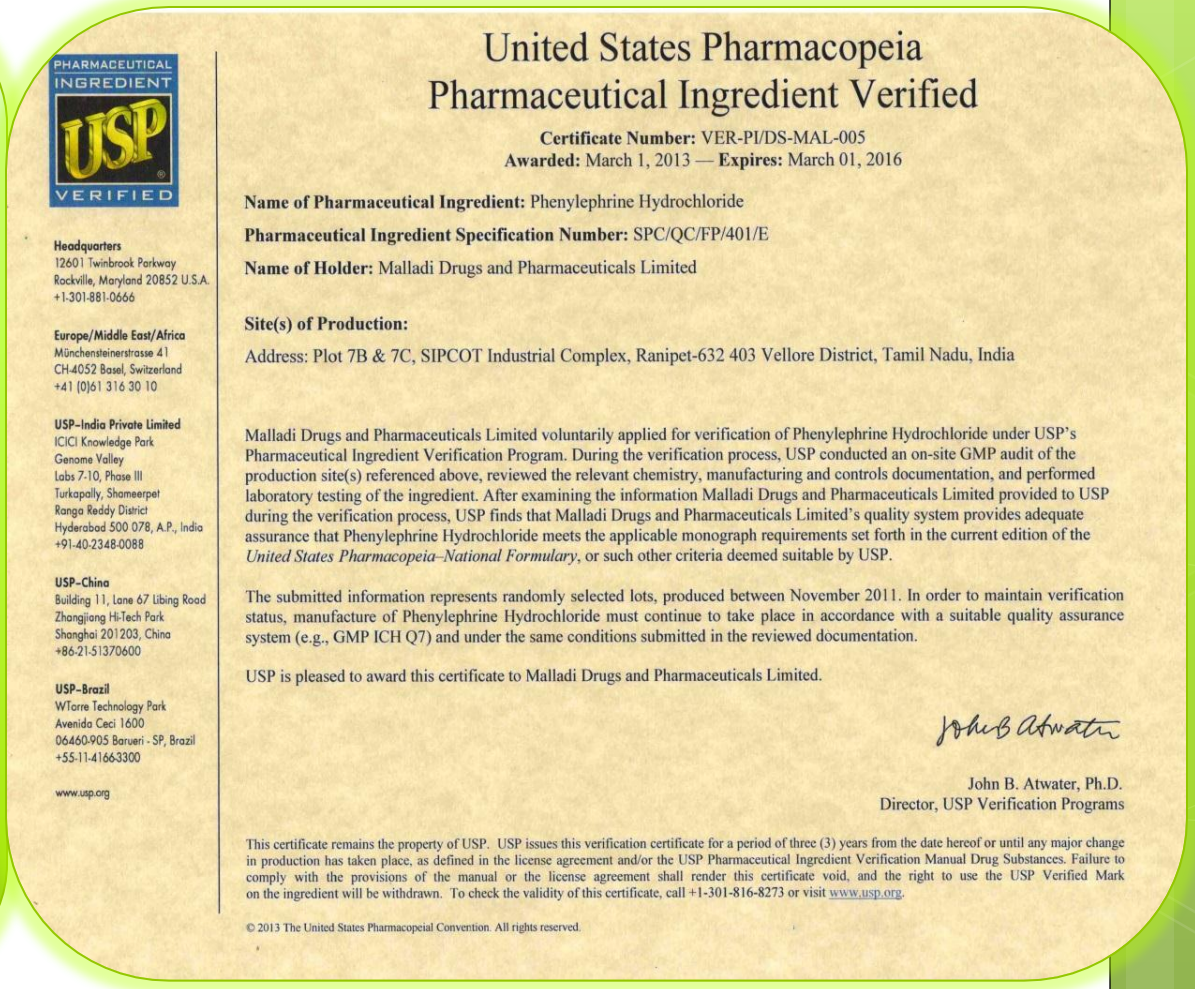
Binh T. Nguyen -A

Binh T. Nguyen, Pharm.D., M.S. Reg Sc
Consumer Safety Officer
Inspection Assessment Branch

Enclosure: Establishment Inspection Report (EIR)

Malladi – Quality Systems

- Pseudoephedrine hydrochloride , Phenylephrine hydrochloride and & Phenylephrine bitartrate have been verified by the United States Pharmacopeia
- Malladi is the only company to have this verification for these ingredients
- This allows Malladi to have the USP logo on the label and the Certificate of Analysis



PHARMACEUTICAL INGREDIENT USP VERIFIED

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www.usp.org

United States Pharmacopeia
Pharmaceutical Ingredient Verified

Certificate Number: VER-PI/DS-MAL-005
Awarded: March 1, 2013 — **Expires:** March 01, 2016

Name of Pharmaceutical Ingredient: Phenylephrine Hydrochloride

Pharmaceutical Ingredient Specification Number: SPC/QC/FP/401/E

Name of Holder: Malladi Drugs and Pharmaceuticals Limited

Site(s) of Production:

Address: Plot 7B & 7C, SIPCOT Industrial Complex, Ranipet-632 403 Vellore District, Tamil Nadu, India

Malladi Drugs and Pharmaceuticals Limited voluntarily applied for verification of Phenylephrine Hydrochloride under USP's Pharmaceutical Ingredient Verification Program. During the verification process, USP conducted an on-site GMP audit of the production site(s) referenced above, reviewed the relevant chemistry, manufacturing and controls documentation, and performed laboratory testing of the ingredient. After examining the information Malladi Drugs and Pharmaceuticals Limited provided to USP during the verification process, USP finds that Malladi Drugs and Pharmaceuticals Limited's quality system provides adequate assurance that Phenylephrine Hydrochloride meets the applicable monograph requirements set forth in the current edition of the *United States Pharmacopeia–National Formulary*, or such other criteria deemed suitable by USP.

The submitted information represents randomly selected lots, produced between November 2011. In order to maintain verification status, manufacture of Phenylephrine Hydrochloride must continue to take place in accordance with a suitable quality assurance system (e.g., GMP ICH Q7) and under the same conditions submitted in the reviewed documentation.

USP is pleased to award this certificate to Malladi Drugs and Pharmaceuticals Limited.

John B. Atwater, Ph.D.
Director, USP Verification Programs

This certificate remains the property of USP. USP issues this verification certificate for a period of three (3) years from the date hereof or until any major change in production has taken place, as defined in the license agreement and/or the USP Pharmaceutical Ingredient Verification Manual Drug Substances. Failure to comply with the provisions of the manual or the license agreement shall render this certificate void, and the right to use the USP Verified Mark on the ingredient will be withdrawn. To check the validity of this certificate, call +1-301-816-8273 or visit www.usp.org.

Contract Services & Manufacturing

- Malladi has been supporting customers in different areas of chemistry
  - ➔ Small volume synthesis of compounds for clinical research
  - ➔ Synthesis & Supply of kilos level quantities for process verification
  - ➔ Cost effective chiral synthesis
  - ➔ Production of tens of kilos to multi ton manufacturing
  - ➔ Development with complete documentation to support filing requirements
  - ➔ Analytical method Development & Validation
  - ➔ Stability studies
- On going projects with large pharma companies

- Malladi has specialization in manufacturing cost effectively
- Trained personnel provide excellent supervision of all manufacturing activities
- Malladi manufactures products for EU & US companies
  - ➔ Process Development / Optimization
  - ➔ Exclusive manufacturing
  - ➔ Confidentiality
- Project Managers for each project activity
- All manufacturing plants and the process development labs of Malladi are ISO certified for quality
- Supply Chain handles all sourcing activities and have a detailed procedure for supplier qualifications
- Contracts are signed and executed through dedicated teams to ensure confidentiality

Advantage > India > Malladi

- India
  - Vibrant economy
  - Growth oriented policies
  - Cost advantage
  - Good regulatory knowledge
  - Approved Facilities
  - Large pool of educated manpower

- Malladi
  - Non Compete business model
  - Product Sustainability
  - Very Good compliance track record
  - Very low focus on generics
  - Focus to work with large pharma as support for “sunset” & “sunrise” projects
  - Experience in Indian and US manufacturing
  - High level of IP integrity & Technical competence
  - Good costing philosophy

Customers

Domestic customers

International customers

MALLADI

THANK YOU