Symbiotica

Speciality Ingredients Sdn. Bhd.

Malaysia

Symbiotica

Speciality Ingredients Sdn. Bhd.

Malaysia

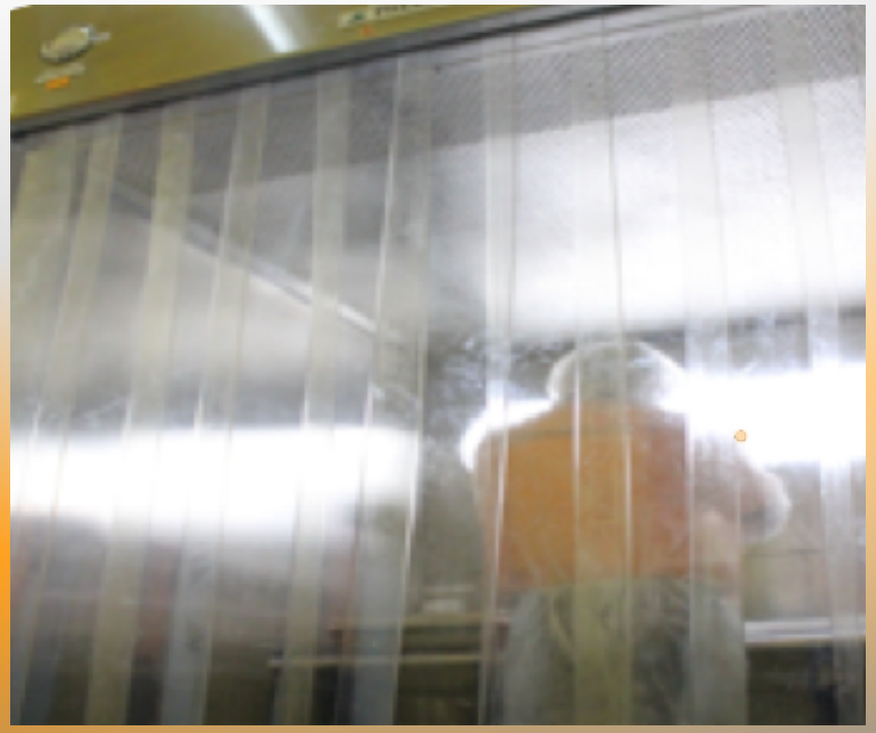
Established since 2001

Manufacturing Facility in Kulim, Kedah

First Regionally Owned Manufacturer of APIs in Malaysia and ASEAN

Symbiotica
Speciality Ingredients Sdn. Bhd.
Malaysia

Core Activity



Research Development & Manufacture of
Active Pharmaceutical Ingredients

Symbiotica
Speciality Ingredients Sdn. Bhd.
Malaysia

Accreditation, Certification and Filings

PIC/S - ICH Q7A GMP CERTIFICATION - NPRA, MALAYSIA

US FDA - INSPECTED AND ACCEPTED FACILITY

COFEPRIS, MEXICO - GMP CERTIFICATION

EDQM CERTIFICATE OF SUITABILITY - 8 PRODUCTS, 2 UNDER EVALUATION

US DMF - 8 FILED, 10 MORE BEING FILED

REPHINE, UK PHARMASSES GMP

MNC - APPROVED SUPPLIERS TO GSK, SANOFI, TAKEDA, MYLAN, STADA, TEVA

ISO 9001:2008 CERTIFICATION - BUREAU VERITAS CERTIFICATION

The Beginnings

Symbiotica
Speciality Ingredients Sdn. Bhd.
Malaysia

2000 - 01 :	- Period of Establishment. - Development. - Commercialisation (1 kg Batches).
2002 - 03 :	- Pioneer status. - Scale up (5 kgs Batches).
2004 - 06 :	- Expansion & upgrading works (Grade D Cleanroom of class 100 K). - GMP certification - ICHQ7A-PIC/S and WHO. - ISO Certification. - First CEP application.
2007 - 09 :	- Export Excellence Award (MITI - MATRADE). - Enterprise 50 awards - 6th Position (SME corp - Delloite Malaysia). - First CEP awarded from EDQM - for Dexamethasone Sodium Phosphate. - More CEP applications - for additional produtcs began.
2010 - 12 :	- First Major expansion on existing site by addition of adjacent buildings, raising of work space height - Scale up (20 kgs batches). - A separate facility for non-steroidal API was set up on the same site. - Three major MNC supply audits and commercial contracts. - US market developmental efforts - filing of US DMFs. - Awarding of more CEPs.
2013 - 17 :	- First US FDA inspection took place by mid 2014 which was successful & entry into the USA market - Cofepris GMP certified. - New site of 15.14 acres was acquired at the nearby Kulim High Tech Park & additional industrial buildings in Taman Industri Waja for the future growth strategy. - Additional CEP filings and DMF compilations made.

Symbiotica Today

Symbiotica
Speciality Ingredients Sdn. Bhd.
Malaysia

Turnover of USD 17 Million approx.

Manufacturing nearly 40 APIs in batch sizes of
1 kg - 100 kgs.

85 % of revenue contributed by exports, one of the largest exporters from the Malaysian Pharmaceutical Industry.

Market presence in over 50 countries worldwide : Asia-pacific, Middle east, Russia, Balkans, Africa, Maghreb, Western EU, Eastern EU, North America, Central America, Latin America etc.

GMP certified as per the ICH Q7 A guidelines by NPRA, Malaysia, a PIC/S member country, qualified to provide written confirmation as per new EC directive.

Successfully inspected and accepted by the US FDA in July 2014.

Cofepris GMP certified.

Audited regularly by MNCs, EU clients, Independent EU audit agencies & other overseas clients.

Hold 8 CEPs & filed 8 US DMFs.

Winner of 2 awards – EXPORT EXCELLENCE from MITI & ENTERPRISE 50 from SME Corp.

Regular participant in International Pharma fairs.

Team of 80 people.

Symbiotica
Speciality Ingredients Sdn. Bhd.
Malaysia

Philosophy

Believe in Symbiosis,
Function with Specialization & Synergy,
Deliver Ingredients with Quality,
Serve with Excellence,
Live with passion !

Make the world
Happy, Healthy & lively,
as a Life Sciences Company.

Symbiotica
Speciality Ingredients Sdn. Bhd.
Malaysia

Core Competence

Quality

Trust
Service
Flexibility
Reliability
Competitiveness

Quality Department

Symbiotica
Speciality Ingredients Sdn. Bhd.
Malaysia

Quality Assurance

Quality Control

Validation

Regulatory Affairs

Symbiotica
Speciality Ingredients Sdn. Bhd.
Malaysia

Quality Management System

Pharmaceutical Inspection Cooperation Scheme
(PIC/S) / ICH Q7A

Certified by

National Pharmaceutical Regulatory Agency
Malaysia

ISO 9001: 2008

Certified by

Bureau Veritas Quality International

QMS managed and implemented through a 5 Step Plan

- Internal Audit
- Certification Audit
- Client Audits/ Vendor Audits
- Local Regulatory Audits
- International Regulatory Audit

Quality Assurance

Symbiotica
Speciality Ingredients Sdn. Bhd.
Malaysia

Responsible for Quality Management system and batch release

Ensures Compliance towards ICH Q7A GMP & ISO 9001:2008

Conducts Training & retraining to ensure that personnel follow SoPs

Effects Surveillance audits to enforce QMS & GMP

Carries out Annual Internal Audits & Management Review

Documentation preparation, implementation, review and control.

Designs & implements procedures related to validation involving process, cleaning procedures, equipment qualification, utility qualification.

Regulatory document management in terms of preparation, submission, registration, review of Drug Master Files as well as responding to regulatory queries from regulatory authorities and customers.

Approval, filing and review of change controls, deviations, CAPAs, etc.

Management of Annual Product Review, Customer Complaints & Investigation when necessary.

Issuance & Review of Batch Manufacturing Records.

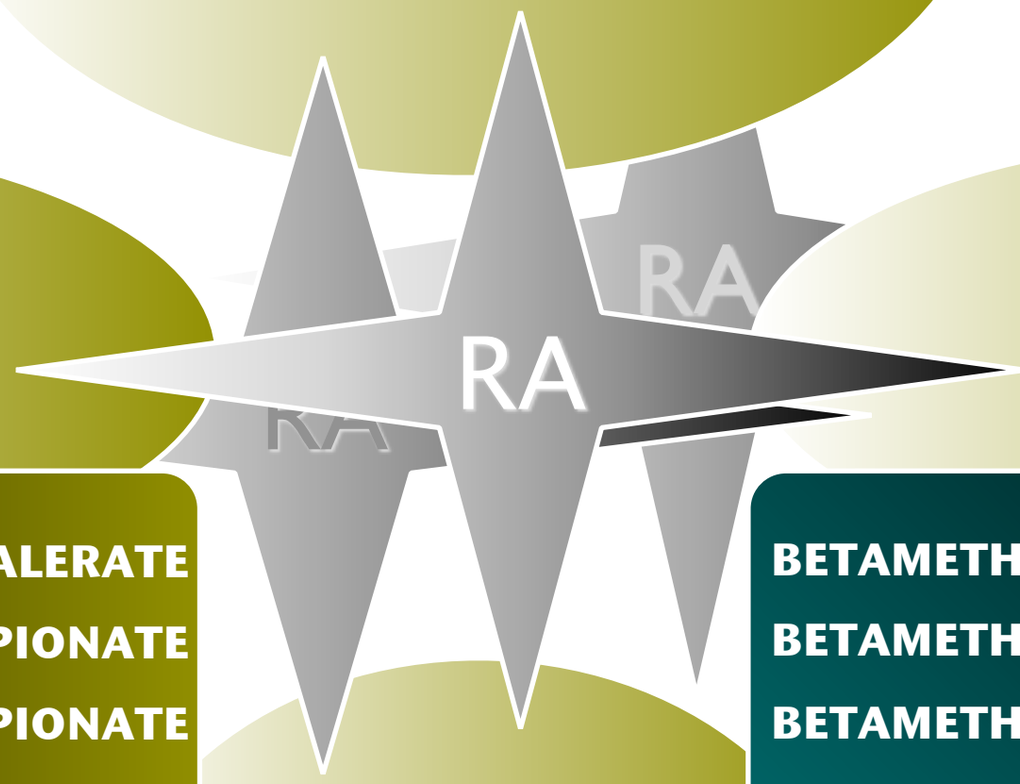
Preparation and maintenance of Master Protocol such as SoP list & Validation Protocol

Management of Vendor Qualification.

Regulatory Affairs

Symbiotica
Speciality Ingredients Sdn. Bhd.
Malaysia

Filing of
Drug Master files
Common Technical Documents
Technical Packs



US DMFs

BETAMETHASONE VALERATE
BETAMETHASONE DIPROPIONATE
CLOBETASOL PROPIONATE
DEXAMETHASONE SODIUM PHOSPHATE
HALOBETASOL PROPIONATE
HYDROCORTISONE VALERATE
MOMETASONE FUROATE
EXEMESTANE

Registration with authorities, Answering of queries of authorities & customers

CEP/COS

BETAMETHASONE VALERATE
BETAMETHASONE DIPROPIONATE
BETAMETHASONE SODIUM PHOSPHATE
CLOBETASOL PROPIONATE
DEXAMETHASONE SODIUM PHOSPHATE
MOMETASONE FUROATE
PREDNISOLONE ACETATE
TIBOLONE

APPLIED :
EXEMESTANE
TESTOSTERONE PROPIONATE

Manufacturing Site - Current

Symbiotica
Speciality Ingredients Sdn. Bhd.
Malaysia

Steroidal Block

10 Mts/Annum

Multiproduct Site

Kulim, Kedah, Malaysia

Non-Steroidal Block

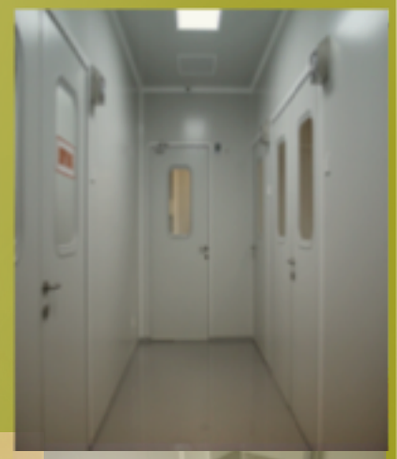
20 Mts/Annum

Manufacturing activity

Symbiotica
Speciality Ingredients Sdn. Bhd.
Malaysia

Facility is spread over 27,000 sqft (2,500 m2) land area with 2 separate manufacturing blocks for Steroidal and Non-Steroidal APIs. Centralized warehouse is located inside a separate building.

Raw materials are subjected to quarantine, sampling & QC release prior to dispensing in separate and dedicated Down-Flow Booths prior to transfer for
production.



Production involves various chemical synthetic steps involving reaction, distillation, extraction, separation etc., which are carried out in the Crude Chemical area. This area is equipped with Reactions Vessels made of Stainless Steel, Mild-Steel-Glass-Lined, Full-Glass, etc. Condensers, Centrifuges, Neutsche Filters, Sparkler Filter, Tray Dryers, etc.

Final Powder Processing is carried out in a ISO Class 8 Clean-Room involving Drying, Milling, Micronization, Blending, Packing etc. Equipments used in this area are Tray Dryers, Vacuum Tray Dryers, Rotary Cone Vacuum Dryers, Blenders, Mills and Micronizers. Packing is carried out only after final QA batch release. In-Process Quality Control ensures adherence to standard procedures for consistent Quality under GMP compliance

Plant utilities involve Huber Temperature Control Systems, Chillers, Nitrogen Generator, Vacuum Pumps, DI water system, Scrubber, Evaporative Ventilation Systems, Exhausts, Air-Handling Units etc.

Facility Layout

Symbiotica
Speciality Ingredients Sdn. Bhd.
Malaysia

519

Centralized Warehouse

518

Non-Steroidal Chemical Area

Non-Steroidal Powder Processing Area

Common Zone

QC-Int

QC-W

517

Steroidal Chemical Area

Steroidal Powder Processing

Manufacturing Sites

Symbiotica
Speciality Ingredients Sdn. Bhd.
Malaysia

Site I : Current

Address	518, Jalan Waja 4, Taman Industri Waja, 09000, Kulim, Kedah
Size	27,000 sft
Certifications	NPRA – ICH Q7A : PIC/S GMP certification (Last inspection – Sep'15)
	US FDA – successfully inspected and accepted (Last inspection – July'14)

Site II : New - Green Field

Address	Lot 4, Industrial Zone Phase 2, Kulim Hi-tech Park, 09000, Kulim, Kedah
Size	15.14 acres (659,498.4 sft)
Certifications	-
	-

Location of the the Sites

Symbiotica
Speciality Ingredients Sdn. Bhd.
Malaysia

Symbiotica - II

Kulim Hitech industrial estate

Targeted date of completion : End 2018

15.14 Acres / 612700 sqm / 659499 sqft

Symbiotica
Speciality Ingredients Sdn. Bhd.
Malaysia

Proposed Activities at the New Green Field Site

Sterile Steroidal API - Crystallized / Lyophilized

Non-steroidal API Block

Additional Steroidal & Hormonal API Blocks

Steroid Intermediate Blocks

Fermentation Block

Phytochemical R&D and Industrial facility

Our Values

Symbiotica
Speciality Ingredients Sdn. Bhd.
Malaysia

Symbiosis

Associate with a spirit of Symbiosis towards mutually beneficial co-existence in all spheres – Internally & Externally

Customization

Customized solutions in terms of tailoring quality, packaging, sterilization, analysis etc to suit customer needs. Impurity profile, Particle size distribution etc are customizable.

Reliability

Very high level of reliability achieved through Prompt responsiveness, Maintenance of ample inventory levels, Secure QMS, Timely deliveries etc.

Trustability

Responsible approach towards servicing of client's regulatory needs, effective & empathetic handling of customer feedbacks, successfully undergoing audits with an open & transparent attitude, etc have contributed towards a very strong factor of trust amongst clientele.

Epilogue

Symbiotica
Speciality Ingredients Sdn. Bhd.
Malaysia

An experiment that Metamorphosed to a rich & great experience.

Challenges of operating an API manufacturing company in Malaysia have been successfully met.

Global reputation as a major player in the steroidal API field and one of the few companies that produces Pinaverium Bromide (Non-steroidal API).

First Asian company to obtain CEP for Dexamethasone Sodium Phosphate – first one to get it after Sanofi and Pfizer.

First Asian company to obtain CEP for Tibolone and the second in the world after an Italian mfr.

Approved supplier to major MNCs – GSK, Sanofi Aventis, Takeda, Mylan, Stada, Teva

Symbiotica
Speciality Ingredients Sdn. Bhd.
Malaysia

STEROIDS

- BECLOMETHASONE DIPROPIONATE *
- BETAMETAMETHASONE ACETATE
- BETAMETHASONE DIPROPIONATE *+
- BETAMETHASONE SODIUM PHOSPHATE *
- BETAMETHASONE VALERATE *+
- BUDESONIDE
- CLOBETASOL PROPIONATE *+
- CLOBETASONE BUTYRATE
- CLOSTEBOL ACETATE
- DEFLAZACORT
- DEXAMETHASONE SODIUM PHOSPHATE *+
- DROSPIRENONE
- EXEMESTANE *+
- HALOBETASOL PROPIONATE +
- HYDROCORTISONE BUTYRATE
- HYDROCORTISONE HEMI SUCCINATE *
- HYDROCORTISONE VALERATE +
- METHYL PREDNISOLONE ACEPONATE
- METHYL PREDNISOLONE HEMI SUCCINATE *
- MOMETASONE FUROATE *+
- PREDNICARBATE *
- PREDNISOLONE ACETATE *
- PREDNISOLONE HEMI SUCCINATE
- PREDNISOLONE PIVALATE
- PREDNISOLONE SOD. METASULFOBENZOATE
- PREDNISOLONE SODIUM PHOSPHATE *
- TESTOSTERONE PROPIONATE
- TIBOLONE *

Products with REGULATORY Package

* CEP
+ US DMF
* CEP under application
Others – CTD available

Customizations :

Micronization
Terminal Sterilization :
Gamma radiation @ 10–15 KGY
Dose

Symbiotica
Speciality Ingredients Sdn. Bhd.
Malaysia

STEROIDS

- DIFLORASONE DIACETATE
- DESONIDE
- DEXAMETHASONE DIMETHYL BUTYRATE
- DEXAMETHASONE DIPROPIONATE
- DEXAMETHASONE ISONICOTINATE
- DEXAMETHASONE PALMITATE
- DEXAMETHASONE PHENYL PROPIONATE
- DEXAMETHASONE PIVALATE
- DEXAMETHASONE SOD. METASULFOBENZOATE
- DEXAMETHASONE VALERATE
- FLUMETHASONE PIVALATE
- FLUOCINONIDE
- HYDROCORTISONE ACEPONATE
- HYDROCORTISONE BUTYRATE PROPIONATE
- METHYL PREDNISOLONE ACETATE
- PREDNISOLONE VALERATE ACETATE
- TRIAMCINOLONE ACETONIDE
- TRIAMCINOLONE DIACETATE
- TRIAMCINOLONE HEXAACETONIDE
- TRILOSTANE

Products which can be upgraded to REGULATORY Package against committed projects with potential partners

Customizations :

Micronization
Terminal Sterilization :
Gamma radiation @ 10-15 KGY Dose

Symbiotica
Speciality Ingredients Sdn. Bhd.
Malaysia

NON-STEROIDS

PINAVERIUM BROMIDE

Supported with REGULATORY Package in terms of a CTD format DMF (ASMF, EDMF). Audited by COFEPRIS, Mexico.

Symbiotica
Speciality Ingredients Sdn. Bhd.
Malaysia

US FDA - Products with DMF Numbers

PRODUCT	US DMF NO.
BETAMETHASONE DIPROPIONATE	24486
BETAMETHASONE VALERATE	27210
CLOBETASOL PROPIONATE	24015
DEXAMETHASONE SODIUM PHOSPHATE	24215
EXEMESTANE	25275
HALOBETASOL PROPIONATE	30906
HYDROCORTISONE VALERATE	31423
MOMETASONE FUROATE	26153

US FDA - NDC Listed products

Symbiotica
Speciality Ingredients Sdn. Bhd.
Malaysia

PRODUCT	NDC NO.
Beclomethasone Dipropionate	52128-128-01
Betamethasone Acetate	52128-131-01
Betamethasone valerate	52128-125-01
Betamethsone Dipropionate	52128-123-01
Betamethsone Sodium phosphate	52128-124-01
Clobetasol Propionate	52128-121-01
Deflazacort	52128-135-01
Dexamethasone Sodium phosphate	52128-122-01
Exemestane	52128-134-01
Halobetasol propionate	52128-138-01
Hydrocortisone butryate	52128-130-01
Hydrocortisone valerate	52128-136-01
Methylprednisolone Aceponate	52128-139-01
MethylPrednisolone Acetate	52128-148-01
Mometasone Furoate	52128-126-01
Pinaverium bromide	52128-137-01
Prednicarbate	52128-129-01
Prednisolone Hemi Succinate	52128-149-01
Prednisolone sodium phosphate	52128-127-01
Testosterone Propionate	52128-142-01
Tibolone	52128-146-01
Triamcinolone Acetonide	52128-143-01
Triamcinolone diacetete	52128-145-01
Triamcinolone Hexacetonide	52128-144-01

EDQM - Product/CEP Numbers

Symbiotica
Speciality Ingredients Sdn. Bhd.
Malaysia

PRODUCT	CEP / COS NO.
BETAMETHASONE DIPROPIONATE	R0-CEP 2011-005-Rev 00
BETAMETHASONE SODIUM PHOSPHATE	R0-CEP-2013-326-Rev 00
BETAMETHASONE VALERATE	R1-CEP 2008-215-Rev 00
CLOBETASOL PROPIONATE	R1-CEP 2009-221-Rev 00
DEXAMETHASONE SODIUM PHOSPHATE	R1-CEP 2006-184-Rev 00
MOMETASONE FUROATE	R1-CEP 2009-313-Rev 00
PREDNISOLONE ACETATE	R0-CEP-2014-138-REV 00
TIBOLONE	R1-CEP 2010-294-Rev 00

Symbiotica
Speciality Ingredients Sdn. Bhd.
Malaysia

Thank you