KMS Health Center Pvt. Ltd.

ISO certified (ISO 9001:2008; ISO 13485:2003; ISOIEC 17025:2005)

Vision & Mission statements

Vision

To be a value driven among top 5 international health care research organization in the field of pharmaceutical industry

Mission

- Collaboration with industries and academia
- Continuous training in the field of science
- Innovative R&D

About Us

KMS was established in 2011 by Dr Ganesan, an first generation entrepreneur. Founded to make affordable generic medicines to all reach of people across the globe, KMS formulation development is not limited to a specific geography.

Scientist from all segments and region work at KMS to make harmony in the working environment.

KMS is committed to comply with customer requirement. Company will sustain organizational excellence through quality product, visionary leadership, employee participation. KMS always have innovative efforts and effective implementation of quality management system.

KMS is registered with department of scientific and inductrial research, Government of India, from the year 2017.

Our company always strive to meet the global regulatory requirement in terms of quality.

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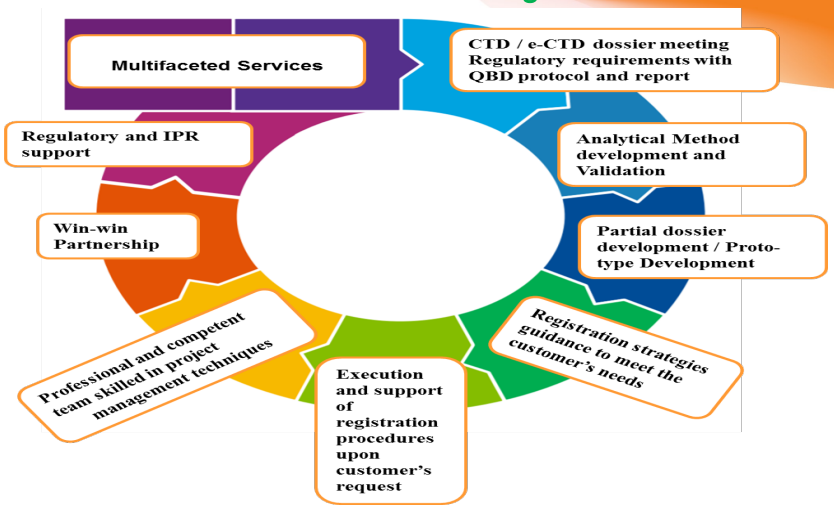
Service Offerings



- KMS offers drug product formulation development expertise with an extensive understanding of commercial pharmaceutical manufacturing processes
- Solving complex development challenges and of new ,existing products and technology transfer
- Total commitment to Quality and Quality By Design from lab to ANDA

Our Team

Dr. M. Ganesan, Ph.D -Director

- Dr.M.Ganesan is the founder and Managing Director of **KMS health Center Pvt ltd.** He began his career as Trainee chemist in 1990 and became an entrepreneur after working 15 years in the corporate. He set-up his own research and development center in 2005. He is a Doctor of Philosophy in Applied Sciences from College of Engineering, Anna University, Chennai.

- **Dr. M.Ganesan**, first generation entrepreneur, has a multi-role experience in Pharmaceutical field.

- Dr. M.Ganesan is a true visionary. He has a professionally dedicated team of more than 350 scientists, who are involved in the world of innovative healthcare & life sciences. He has a team of highly skilled scientist. He transformed his vision and experiences to the reality of achieving the common goal **to serve the humanity**.

- Dr. M.Ganesan is a well-known personality in Pharmaceutical and Biotechnology Industry. He had established a numerous clinical research laboratories across India, those meet GLP and GCP global regulatory requirements

Our Team

- **K. Eswaran – Director**
- He holds a post graduate degree in Master of Science, specialized in Chemistry with 16+ years experience in Analytical Department. He started his career as Quality chemist in Quality Control Department of Micro Labs Pvt Ltd at Bangalore.

- He is heading Analytical Development Team as Director and responsible for the continuous tracking and execution of the projects within the set timelines with uncompromised quality documentation to various regulatory agencies as per the requirement.

- He has played various roles and responsibilities in Bio Analytical Department which gives him an insight of complete operation. He has been involved in more than 200 BA/BE studies as a Bio Analytical investigator and developed/validated various new Bio Analytical method for more than 200 molecules including challenging molecules like Hormonal drugs, Endogenous compounds etc. He is one of the key person to set up a new Bio Analytical lab for Group CRO.

- He had successfully involved in various regulatory audit conducted by USFDA, French (AFSSAPS), Brazil (ANVISA), WHO and accord approval for all the studies and systems at Group CRO.

Our Team

Mr.Kumar Shanmugam, Associate Vice President

- He holds a postgraduate degree in Master of Pharmacy, specialized in Pharmaceutics, graduated from Birla Institute of Technology.
- Started career as formulation development scientist in Torrent Research Centre and has diverse experience in various formulation which include solid orals, powder for oral solution/suspension, liquid orals, injectables, semisolids
- Had worked in various companies in India, which include Ranbaxy research Labs, Mylan Labs, Dr. Reddy's Lab and, Orchid Healthcare and Par formulations.
- He is well versed with designing formulation strategies, which are stable, bioequivalent and non infringing to any patents.
- Is keen on developing quality product meeting all regulatory requirements. Well versed with the current guidance and regulatory requirement for USA and EU market.
- Has has 18 years experience in Formulation Development and Technology transfer. He has a rich experience in formulating complex molecules to overcome stability, BE challenges. Formulations developed are predominantly were for registration with USA and EU markets.
- He also has a rich experience in scaling up formulations from lab scale to pilot and pilot to commercial scale manufacturing.
- He was key member in the international audits like FDA and MHRA audits.

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Our Team

Formulation development team

- **Mr. Guru Balaji.S, M.Pharma (Pharmaceutics),P.G.D.P.L(Patent).,** Sr. Manager., having 15 years of experience in drug product development **i.e.** 505(j),505(b)2,ANDS, EU and other global markets.
- Expertise in development of patent noninfringing immediate/modified/controlled (IR/ER/DR) release formulations, product life cycle management.
- Skilled in product development of low soluble drugs, trouble shooting and technology transfer to different country site.
- Previously associated in formulation R&D with Cipla, Dr.Reddys, Daewoong Pharma(Global R&D ,Seoul), Nectar lifesciences and Strides Shasun Pharma.
- Formulation development team has 10 formulation scientists. The team has an average of 6 years' experience in developing different kinds of dosage forms for US, EU and other countries requiring CTD
- The team works with a holistic approach combining the properties of drug substance, inactive with a suitable manufacturing process to develop a drug product

Formulation development team

- **Dr. Sivakumar, PhD, Manager.**
- Having 10 years of experience in injectable Drug Product development for Regulated markets.
- Previously associated with Zydus Research Centre, Invictus Oncology, Hetero Drugs, and Mylan Labs in Product Development.
- Expertise in handling simple and complex injectable dosage forms.
- Hands on experience on developing and scale up and trouble shooting experiences.
- Have handled regulatory submission batches and responses to regulatory queries. .
- Good experience in identification of niche molecules for injectables development in the portfolio of the company.
- Devise strategies to formulate non infringing strategies to make formulation.
- Expert in writing product development report and allied sections of section 3.2.P of dossier.

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Our Team

Analytical Development Team

- **Mr.P.Jeyakumar, M.Sc. (Chemistry) Sr.Manager**, around 14 years of relevant experience in USFDA and MHRA approved reputed pharmaceutical companies (Handled Analytical Method Validation, Analytical Method development, stability and GLP teams).
- Previously associated with R&D at Eywa pharma ,Kemwell biopharma,Aizant drug research solutions, Shasun ,Strides and Cipla.
- Analytical development team has 20 analytical scientists and 3 team leaders. The team has an average of 3-12 years' experience in developing different kinds of dosage forms for US and EU market and separate lab for analytical method validation approved by USFDA.
- Skilled in method development of low soluble drugs, trouble shooting and analytical technology transfer to different country site.
- Expertise in analytical method validation as per ICH /USP guidelines.
- Expertise in development stability studies as per ICH guidelines
- Expertise in formulation analytical method development with a background of pharmaceutical and science. Experienced in generic product development with ANDA's.
- Handled various regulatory observations like USFDA,MHRA, TGA and WHO audit and resolved.

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KMS partnered companies

SUN PHARMA

Biophore

Shilpa Medicare Limited

eywa pharma

MSN

CHANGZHOU Pharmaceutical Factory Everything For Your Health

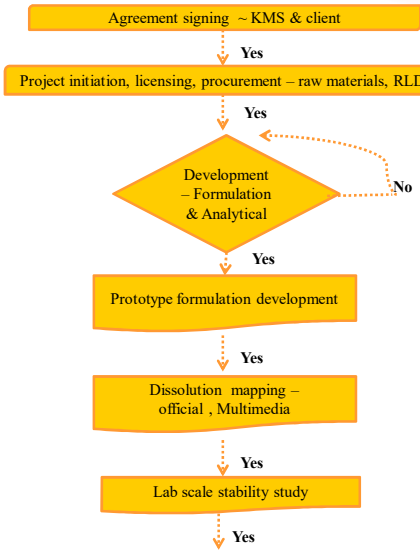
ATNAHS

CELLTRION

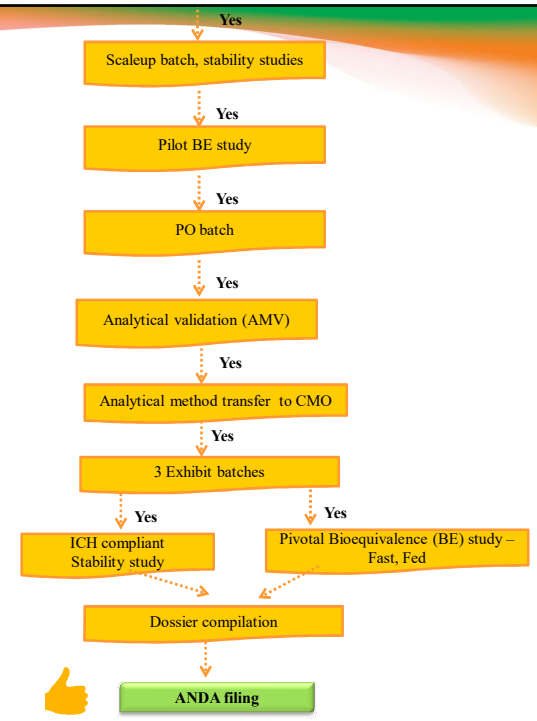
BIONPHARMA

Mankind Serving Life

Case Study project – Flow chart



- flowchart continues



Accomplishments

- Development of innovative value added generic formulation Omega 3 fatty acid soft gelatin capsules with improved bioavailability to control the serum cholesterol level and filed a patent for our proprietary technology of Omega capsules vide PCT filing application WO 2015011724
- EU Dossier submission of Aripiprazole Tablets & Paracetamol film coated tablets
- Deferasirox tablets for oral suspension (DT) approved by FDA.
- US Dossier submission of Oxybutynin Chloride ER Tablets – Almost all queries are addressed and is near to approval.
- US Dossier submitted for Niacin ER tablets in Mar 2019.
- Other products
  - BE (Pivotal) successfully completed for Ezetimibe IR
  - Validation batches completed for Pregabalin capsules
  - Validation batches completed for Deferasirox film coated tablets
  - Validation to be initiated for Posacanazole DR tablets.

Accomplishments

- Development of time release technology based products by adopting novel method such as controlled release by coating technology, Matrix type sustained release technology, MUPS(Multi unit particulate system)– TR, Bioadhesive tablets, Bilayer tablets
- Development of Mesalamine (all strengths) delayed release tablets by colonic drug delivery technology.
- Pilot BE completed for Ibuprofen SR tabs, Ezetimibe + simvastatin tabs, Pregabalin caps, Glipizide tabs, Posaconazole DR tabs, Mesalamine DR tabs 800 mg, Mesalamine DR tabs 1200, Mesalamine DR caps 500 mg
- Product ready for pilot Bio: Doxylamine/Pyridoxine DR tabs and Doxylamine/Pyridoxine ER tabs, Paroxetine ER tabs, Paliperidone ER tabs, Progesterone tabs, Guaifenesin ER tabs, Pregabalin ER tabs, Mesalazine DR tabs 1g, Simvastatin/Ezetimibe, Aprepitant capsules, and Solifenacin tabs.
- Product under development - Esomeprazole DR caps, Vigabatrin Oral Solution , Mirabegron ER tabs, Sucroferric Oxyhydroxide, Empagliflozin tabs, Metformin and Vildagliptin Dexlansoprazole DR caps, Ambrisentan tabs, Saxagliptin tabs, Selexipag tabs, Ramelteon tabs and Disulfiram tablets

Sterile dosage forms

- KMS had initiated sterile formulation development from Jun 2019.
- Formulation laboratory is ready and formulation development trials are intiated
- List of products under development are
  - Voriconazole for Injection 200 mg/vial
  - Esomeprazole for Injection, 20 and 40 mg/vial
  - Azithromycin for Injection, 500 mg/vial
  - Caspofungin Acetate for Injection, 50 and 70 mg/vial
  - Levetiracetam Injection, 500 mg/5mL
  - Paclitaxel Protein bound Nano-particle suspension for Injection, 100 mg/vial
  - Paliperidone Palmitate Extended Release Injectable Suspension, 39 mg, 78 mg, 117 mg, 156 mg, 234 mg
  - Enoxaparin Sodium Injection, prefilled syringes

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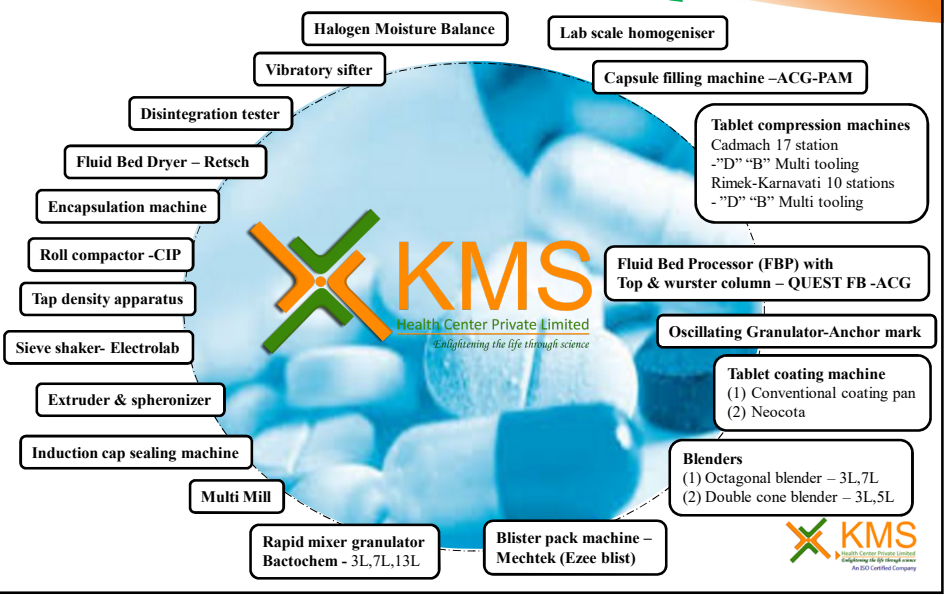
Formula



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Analytic

Waters Alliance HPLC systems with UV & PDA Shimadzu HPLC system with UV
Gas chromatography-Mass spectrometry (GC-MS)
Dissolution apparatus with Auto sampler Dissolution apparatus USP 3 & 7 – Electrolab
UV-Spectrophotometer LCMS, Centrifuge, Automatic Shaker, Sonicator, etc.
Temp/Humidity controlled Stability chambers & Photo stability chambers
Dionex Ion Chromatography
Franz diffusion apparatus

Contact details

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