

## Ophthalmics – action with vision

### Piramal Healthcare Ltd

We are a contract research and development organization. We offer ophthalmic product development services for solutions, suspensions and emulsions for NCE and Generic molecules.

Our services include formulation, analytical method development, microbiology testing, non cGMP aseptic sterile manufacturing and stability.

All contract laboratories may not have appropriate skills, facilities or timely availability to accomplish specific studies.

However, we are able to select from several GLP laboratories and cGMP manufacturing sites that we have prequalified for their expertise and offer our clients the most suitable resources to accomplish their projects.

### Our Clients are our Priority

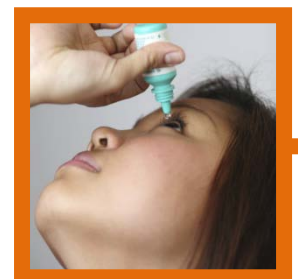
We deliver the best for our Clients.

Our qualified and experienced technical staff works closely with the Client to understand their requirements and design a strategy to accomplish the specific goal under defined timelines.

The services we render provide significant value - added benefits to our clients in terms of reducing cost and accelerating market growth.

We offer end - to - end solutions for ophthalmic products.

We believe *“Personalized client attention helps us meet client’s expectations & build long term relationships”*



### Product Development Services:

We anticipate and address challenges that are unique to ophthalmic products.

- **Preformulation studies:** Pre-formulation studies are conducted to determine the physiochemical properties of drug substances and excipient interactions.
- **Formulation development:** We offer specialized insight into preservative systems, ingredients, buffers and other excipients.
- **Stability studies (ICH guidelines and customer design):** We are equipped with precisely controlled environmental chambers to simulate long-term temperature and humidity conditions according to ICH or FDA guidelines.
- **Formula and process optimization through DOE:** We optimize your product around different parameters, determining the order of addition of ingredients, compounding limitations, equipment compatibility, and their impact on manufacturing, product performance and stability.
- **Fill volume and Packaging Identification:** Our flexible hand-fill process allows us to customize packaging requirements to address a variety of fill volumes and container option.
- **Additional studies:** Freeze Thaw studies, In-use stability studies, Weight loss studies, and Photostability studies



## Supportive Services

### Preformulation

- Physico-chemical characterization of drug substance
- Polymorphism studies
- Powder X-ray diffraction
- Qualitative and quantitative thermal analysis
- Solubility and partitioning studies
- Salt form selection
- Excipient compatibility studies
- Forced degradation studies

### Analytical and Microbiological

- Method development and validation to meet current ICH or USP / NF requirements.
- Process development support and release testing
- Non-compendial method development and validation
- Microbiological Sterility and Bacterial Endotoxin method development and validation
- Antimicrobial Preservative Efficacy method development and validation
- Container closure integrity testing.

### Project Management through Outsourcing

- Manufacturing of cGMP and Clinical Trials
- Drug substance impurity profiling (HPLC)
- Extractable and Leachables studies

We also render strong technology transfer and regulatory support to facilitate timely submissions.



## Laboratory Capabilities

Our R & D has the latest sophisticated equipment required for development and testing of formulations.

### a) Formulation laboratory

- D O meter – DO110, Oakton
- Colorimeter - Spectronic 20 D+
- Headspace O2 analyzer 898 025, Systech instruments
- Rheometer - LVDV III ULTRA, Brookefield
- Osmometer – OSMOMAT 030, Gonotec
- pH meter – pH Tutor, Eutech
- Turbidimeter - 2100 AN, Hach & Co.
- Tachometer - DT 209X, Shimpo
- Glove box, Mini 220W KH – 3475020, Plaslabs Inc USA
- Lyophilizer - Genesis 25 SQ EL, CIP
- High Intensity Lightmeter-EA30, Exttech Instruments

### b) Analytical Laboratory

- Gas chromatograph - GC 2014, Shimadzu
- HPLC [Waters Alliance system with UV / PDA detector and Empower client network server (2695 / 2487 – 2996) - Shimadzu LC solution with UV detector (LC-2010A HT)]
- FTIR - FTIR -8400S, Shimadzu
- Particle counter - Roycomodel 9705, HIAC Royco, USA
- UV Spectrophotometer -

### c) Pre - formulation Laboratory

- Cryogenic Differential scanning calorimetry- Diamond DSC Autosampler, Perkin Elmer
- Cryogenic microscopy – Linkam HFS91, Leica DMLP Linkam
- XRPD – D8 ADVANCE, Bruker AXS, Germany
- TGA – Pyris 1 TGA, Perkin Elmer, USA
- DVS (Dynamic vapor sorption)- DVS Advantage

### d) Microbiology laboratory

- Autoclave – Vaiktron SDH 111
- HLA – Klenzaid 1590-48-24-30



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