

Pediatrics – welcome to our world

Piramal Healthcare As A Centre Of Excellence For Pediatrics

The development of dosage forms for pediatrics presents special challenges because of the unique pathophysiology and responses to therapy in this population. The complexity and ethical considerations involved in the study of pediatrics suggest the need for careful product development.

Age classification of pediatric population

Newborn infants (preterm & term)

Infants & toddlers

Children

Adolescents



Challenges in developing pediatric medicines:

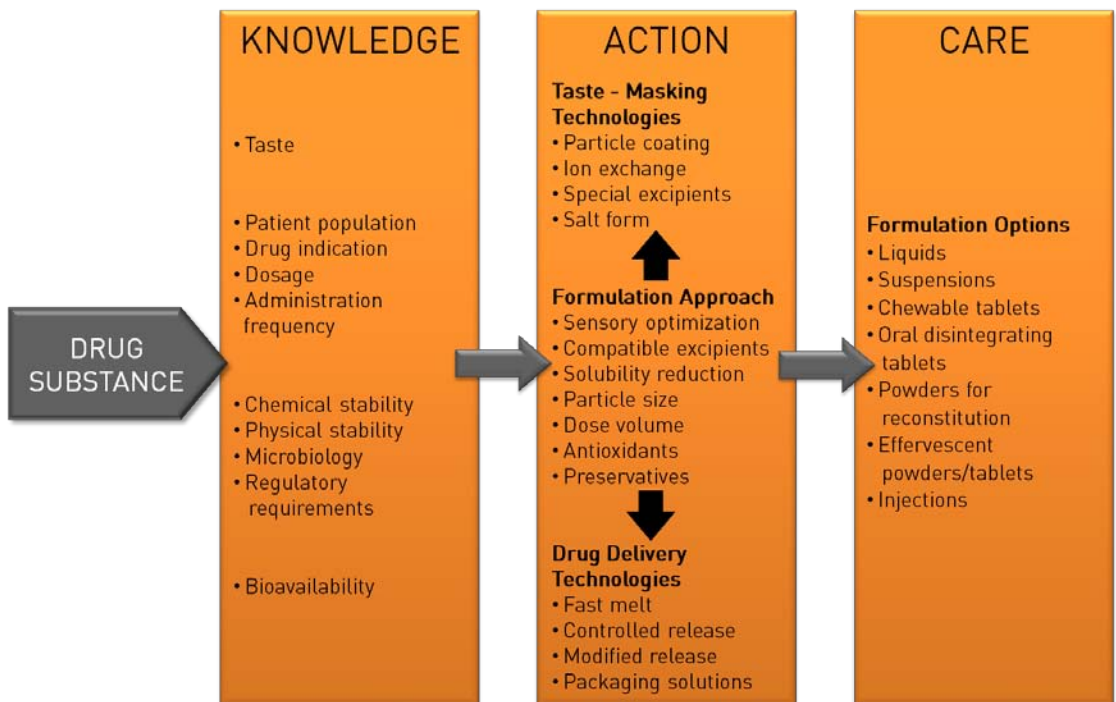
- 1) A child compliant dosage form
- 2) A convenient dosage scheme
- 3) A good taste



Design and Development

To develop a child compliant dosage form the right formulation is essential. Our Mumbai site is well equipped for developing all pediatric dosage forms for oral as well as systemic administration.

A DECISION TREE FOR SELECTING THE FORMULATION AND TECHNOLOGY FOR A PEDIATRIC DRUG



A DEVELOPMENT PROGRAM FOR A PEDIATRIC FORMULATION

FORMULATION AND PROCESS DEVELOPMENT

Development Preliminary Base

- Excipient compatability
- Confirm dosage form
- Regulatory strategy
- Initial physical and chemical evaluation

Lead Formulations

- Preservative assessment
- Stability assessment
- Pack development

Formulation/Process Optimization

- Process development
- Formulation optimization
- Refine product characteristics
- Confirm specification
- Confirm administration

Develop Pivotal Stability/Clinical Programs

- Clinical and regulatory submission
- Bioavailability and clinical studies

TASTE ASSESSMENT AND OPTIMIZATION

Taste Assessment with GCP-compliant Test Panels

- Quantify taste – masking challenge –
API and critical excipients
- Identify candidate sweeteners and taste
modifiers for excipient compatibility
testing

Optimize Flavor System

- Identify aromatics
- Flavor extenders
- Mouth-feel modifiers

Drug product should be palatable, stable and bioavailable

Packaging development strategy

1. Product type e.g.. Liquid/powder etc.
2. Type of withdrawal: pouring/straight/inverted
3. Cost acceptability for product
4. Development of tailor-made device

Our scientists at the Mumbai, India site can perform all the formulation development, analytical method development along with validation and stability studies as per ICH. Clinical Trial Supplies could be done at our Centre of Expertise. Our regulatory affairs team will work with you to prepare your dossier and will assist you to follow all requirements that are necessary to fulfill the pediatric guidelines. We provide timely comprehensive reports, enabling you to constantly monitor the progress of the product.

Piramal Healthcare has a long tradition of developing pediatric dosage forms. Come to us and let us explain to you our expertise.

To find out more, please contact:

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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

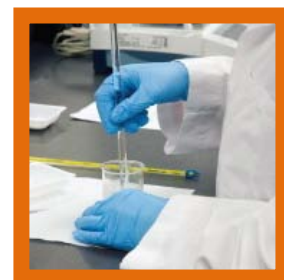
- Gas chromatograph - GC 2014, Shimadzu
- HPLC [Waters Alliance system with UV / PDA detector and Empower client network server (2695 / 2487 – 2996) - Shimadzu LC solution with UV detector (LC-2010A HT)]
- FTIR - FTIR -8400S, Shimadzu
- Particle counter - Roycomodel 9705, HIAC Royco, USA
- UV Spectrophotometer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

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
- HLAf – Klenzaid 1590-48-24-30



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