



An Overview: Patient-Centric Herbal Formulations for Pediatric Use Current Perspectives and Future Directions

*Miss P.P. Sherekar¹, Dr. Jiwan P. Lavande²

¹Research Scholar, Department of Pharmaceutics, School of Pharmaceutical Sciences, Sanjay Ghodawat University, Kolhapur

²Professor, Department of Pharmaceutics, School of Pharmaceutical Sciences, Sanjay Ghodawat University, Kolhapur

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ABSTRACT:

Now a days due to poor palatability, swallowing issues, incorrect dose, and decreased compliance, conventional dosage forms frequently fail to produce sufficient therapeutic results in young patients [1, 2]. Pediatric compliance and treatment outcomes have been greatly enhanced by recent developments in patient-centric drug delivery systems, including oral thin films, mini-tablets, chewable tablets, multiparticulate systems, and nanoformulations [3, 5]. Because children and adults differ physiologically and psychologically, pediatric drug delivery continues to be one of the most difficult topics in pharmaceutical sciences. Because of their natural origin, safety, therapeutic efficacy, and cultural acceptance, herbal pediatric formulations have become potential substitutes [6]. Herbal medicines integrated with novel delivery systems. They enhanced bioavailability, taste masking, controlled release, and improved therapeutic efficacy [7]. In this review highlights the concept of patient-centric pediatric formulations also the role of herbal medicines in pediatric therapeutics, various novel herbal pediatric dosage forms, formulation challenges, evaluation parameters, regulatory considerations, and future perspectives.

INTRODUCTION:

Anatomy, physiology, metabolism, taste perception, swallowing abilities, and medication reaction are all different in children compared to adults [8,9]. As a result, traditional adult dose formulations are frequently inappropriate for usage in children. Children are a distinct and fragile group that needs pharmaceutical formulations made specifically for them.

Due to their natural origin, safety, and therapeutic potential, herbal medications are becoming more and more popular in pediatric healthcare [6]. Herbal remedies are frequently used to treat fever, colds, coughs, gastrointestinal issues, and boosting children's immunity. In pharmaceutical research, creating age-appropriate

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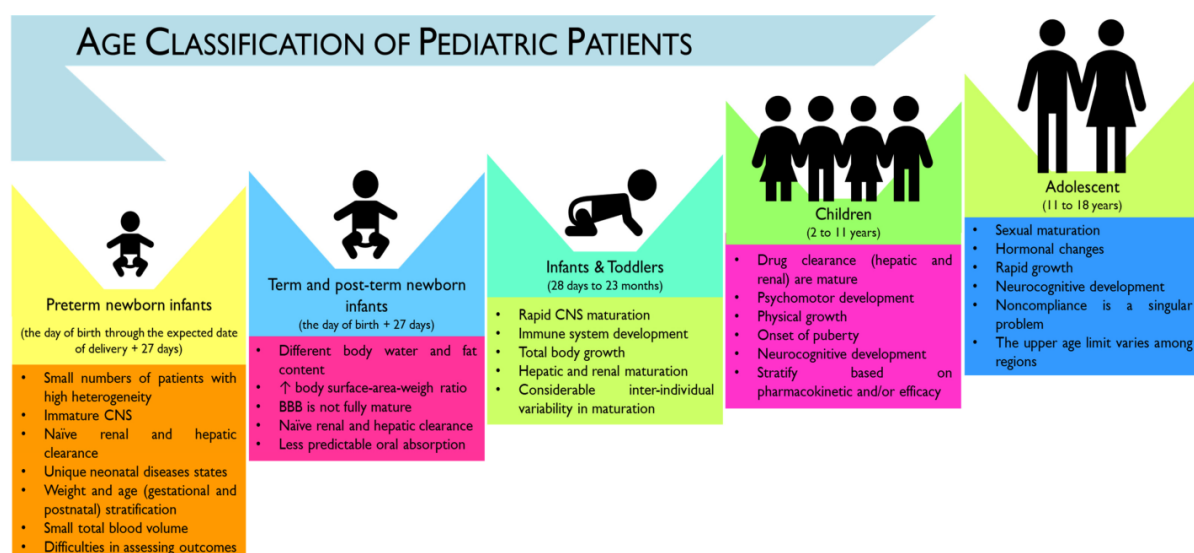
formulations has grown in importance. Unpleasant taste sensations, incorrect dose administration, poor compliance, and trouble swallowing tablets and capsules are common problems for pediatric patients [10]. Reduced therapeutic results and treatment failure are common effects of these constraints.

In pharmaceutical technology recent advances have enabled the incorporation of herbal drugs into innovative pediatric dosage forms. There are different dosage forms such as oral thin films, orally disintegrating tablets, mini-tablets, gummies, and nanoformulations [11, 12].

Patient-Centric Pediatric Formulation

In pediatrics patients they are highly sensitive to taste, texture, odor, and appearance of medicines [16]. So pediatric formulations should possess pleasant organoleptic properties and ease of administration characteristics. Patient-centric formulations in pediatric populations seek to

- Boost adherence
- Reduce the strain on caregivers
- Improves palatability
- Boost the safety & efficacy
- Ensures accurate dosing
- Improves palatability
- Minimize difficulties in swallowing



Patient-centric pharmaceutical dosage forms design refers to the development of dosage forms according to the needs, preferences, and physiological characteristics of patients [21].

Modern pediatric formulation strategies involve Personalized medicines, taste masking technologies, flexible dosing systems, friendly dosage forms to child, novel drug delivery technologies.

Some dosage forms such as mini tablets and Orodispersible thin films are highly patient-centric because they eliminate swallowing difficulties and improvement in convenience level [5, 14].

Significance of Herbal Medicines in Pediatrics:

A significant section of the world's population relies on herbal remedies for primary healthcare, according to the World Health Organization. When used properly, herbal medicines are generally regarded as safer than synthetic drugs [6]. From ancient era traditional Herbal medicines have been used in pediatric healthcare. Plant-derived medicines possess multiple pharmacological activities including:

- Antipyretic
- Anti-inflammatory
- Immunomodulatory

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- Antitussive
- Antimicrobial
- Digestive stimulation.



Common Herbal Drugs Used in Pediatrics:

Table No.1-Common Herbs

Name of Drug	Botanical name	Pediatric Use	
Ajowan	<i>Trachispurpurnum ammi</i>	Carminative stomach pain relevant	
Fennel	<i>Fonniculum vulgare</i>	Carminative	
Asafetida	<i>Ferula foetida</i>	Carminative	

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Tulsi	<i>Oscium Santum</i>	Antitussive Anti-oxidant	
Ginger	<i>Zinziber officinalae</i>	Digestive, Apetite enhancer	
Turmeric	<i>Curcuma longa</i>	Antitussive Anti-bacterial	
Guduchi	<i>Tinospora cordifolia</i>	Immunity enhancer, Antipyretic	
Murad shenga	<i>Helicteres isora</i>	Anti-dysenteric, Stomach pain	

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Hirada	<i>Terminalia chebula</i>	Laxative	
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Novel Herbal Pediatric Dosage forms:

Innovative drug formulations and delivery methods created to satisfy the unique requirements of novel biological modalities, such as peptide, protein, and vaccine products, as well as cellular and gene therapies, are referred to as novel formulations.

1. Herbal oral syrup

liquid formulations with plant extracts that have been sweetened. For instance, ginger syrup and Tulsi cough syrup.[13]

2. Suspensions of Herbs

Herbal particles those are insoluble in a liquid media.

Beneficial for herbal medications that are poorly soluble.

3. Drops of Herbs

concentrated liquid formulas for newborns and infants.

Given in tiny, precisely regulated doses.

4. Chewable Herbal Tablets

Tablets with flavors that kids can easily chew.

For instance, immune boosters or herbal vitamins.

5. Herbal candies

Chewable dose forms based on pectin or soft gelatin.

Boost compliance and acceptability.

6. Lozenges with Herbs

Solid pharmaceutical preparations that gradually dissolve in the mouth.

Used for colds, sore throats, and coughs.

7. Orodispersible Herbal Tablets (ODTs)

Tablets that break down quickly in saliva without the presence of water.

Appropriate for young individuals who have trouble swallowing.

8. Granules of Herbs

Granulated dry herbal medicines for direct use or reconstitution.

9. Herbal Jellies

Kid-friendly flavored semi-solid preparations.

10. Herbal Suppositories

When oral delivery is challenging, rectal dose forms can be helpful.

11. Herbal Inhalation

Nebulizers, inhalable powders, or herbal vapors for respiratory conditions.

12 Herbal Nanoformulations:

Herbal nanoformulations represent one of the most advanced approaches in pediatric drug delivery[7].

13. Herbal Hydrogels

Gel-based controlled delivery methods for mucosal or topical use.

14. Herbal Adjuvant Systems for Vaccines

Herbal bioactive substances used to boost vaccination responses.

15. Pediatric Herbal Nutraceuticals

Herbal-fortified functional foods for immunity and growth.

16. Formulations of Herbal Mucoadhesives

For extended medication release, stick to mucosal surfaces.

17. Herbal Formulations with Controlled Release

intended to have a long-lasting therapeutic impact and require fewer doses.

18. Herbal Oral Thin Films

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Oral thin films are thin polymeric strips that dissolve rapidly in saliva without water [5].

Patient-Centric Herbal Drug Delivery Technologies

Advanced pharmaceutical techniques created to enhance the safety, effectiveness, acceptability, convenience, and therapeutic results of herbal medicines in accordance with patient needs are known as patient-centric herbal drug delivery technologies. These systems are particularly crucial for managing chronic diseases, pediatrics, and the elderly, since traditional herbal dose forms may have drawbacks including bad taste, limited bioavailability, instability, or administration challenges.

Different taste masking technologies are

- **Controlled release system:**

Controlled release systems maintain therapeutic concentration for extended periods. It improves patient compliance, reduces dose frequency. Also it shows better therapeutic efficacy.[8]

- **Taste masking Techniques:**

It's one of the best techniques to increase more palatability of dosage form. Its essential because children's are highly sensitive to the bitter taste [20]

Multiparticulate drug delivery:

Multiparticulate systems include pellets, granules, beads, and sprinkles [28]. Its benefits that Flexibility of dosing, Reduces gastric irritation, and Improves compliances. I also gives better drug distribution [28]

Patient-Centric Herbal Drug Delivery Goals:

- Boost patient adherence
- Decrease dosage frequency
- Improve acceptance and palatability
- Boost the phytoconstituent bioavailability
- Reduce toxicity and adverse consequences.
- Boost stability of natural remedies
- Achieve controlled & focused medication delivery

Challenges in Herbal Pediatric Formulations

Despite significant advancements, several challenges remain in the development of herbal pediatric formulations.

Bioavailability Issues

Some phytoconstituent having poor aqueous solubility and low bioavailability [7].

Stability Problems

Herbal formulations may become unstable after some period, they undergoes oxidation and Degradation.

Safety Concerns

For safety purpose excipients and preservatives should be carefully selected for pediatric use [18].

Regulatory Limitations

Standardization and regulatory approval remain major challenges for herbal Formulation [13].

Poor Palatability

Many herbal extracts having bitter or unpleasant taste. So its unpalatable to pediatrics. [20].

Dose Variability

Herbal medicines may exhibit variability in phytochemical composition [6].



Challenges in Pediatric dosage forms

By fusing traditional phytotherapy with contemporary pharmaceutical advancements, patient-centric herbal drug delivery technologies mark a substantial breakthrough in herbal medicine. These technologies provide individualized and focused therapeutic approaches while enhancing bioavailability, safety, stability, and patient compliance. These cutting-edge methods have enormous potential for the future creation of safe and effective herbal remedies for the treatment of chronic, pediatric, and elderly illnesses.

Evaluation of Herbal Pediatric Formulations

In order to guarantee safety, efficacy, stability, and quality, and patient compliance, evaluation of herbal pediatric formulations is a crucial part of formulation development. In contrast to adult formulations; pediatric herbal medicines need extra consideration for excipient compatibility, taste masking, dose flexibility, and microbiological safety. Phytochemical variability, contamination, and standardization are further issues with herbal treatments.

Herbal pediatric formulations are specifically created pharmaceutical preparations made from plant-based ingredients that are given to newborns, kids, and teenagers. Drug absorption, distribution, metabolism, excretion, palatability, and therapeutic response are all greatly impacted by the distinct physiological and psychological traits of pediatric patients

Therefore, in order to maintain consistent treatment performance and guarantee acceptability for pediatric usage, detailed evaluation parameters are necessary.

The major objectives for evaluation of herbal pediatric formulations include:

1. To give safety and efficacy of herbal preparations.
2. Maintenance of consistency and quality of phytoconstituent.
3. Improvement in pediatric patient compliance.
4. To establish stability and shelf life of formulation.
5. To detect microbial contamination and adulteration.
6. Evaluate physicochemical and pharmacological properties.
7. Ensure accurate dosing and bioavailability.

Different evaluation parameters includes physical biological, organoleptic chemical evaluation. For pediatric formulation following are the different evaluation parameters mentioned in tabular format. Organoleptic,

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physicochemical, phytochemical, microbiological, toxicological, and pharmacokinetic evaluations are all part of the interdisciplinary process of evaluating herbal pediatric formulations. The creation of safe, stable, effective, and kid-friendly herbal medications is ensured by proper evaluation. Standardized evaluation techniques and cutting-edge formulation technologies will be essential to the future development of herbal pediatric dosage forms as interest in herbal therapies and pediatric healthcare grows.

Evaluation of herbal pediatric formulation [7, 11, 12]:

Novel pediatric formulations are evaluated using several parameters. Additional consideration must be given to flavor masking, dose flexibility, microbiological safety, and excipient compatibility in pediatric herbal preparations. Phytochemical variability, contamination, and standardization are further issues with herbal treatments. Therefore, in order to maintain consistent treatment performance and guarantee acceptability for pediatric usage, detailed evaluation parameters are necessary

Table No.2- Evaluation of herbal formulation

Sr. No.	Evaluation Parameter	Parameters/Tests Included	Methods/Techniques	Importance/Application
1	Organoleptic Evaluation	Color, odor, taste, texture, appearance, consistency	Visual inspection, sensory panel, hedonic scale analysis	Enhances pediatric acceptability, detects instability, improves compliance
2	Physicochemical Evaluation	pH, viscosity, specific gravity, moisture content, particle size	pH meter, Brookfield viscometer, Ostwald viscometer, Karl Fischer titration, microscopy	Ensures stability, accurate dosing, gastrointestinal compatibility, bioavailability
3	Phytochemical Evaluation	Alkaloids, flavonoids, glycosides, tannins, saponins, terpenoids	Preliminary phytochemical tests, spectrophotometry, chromatographic analysis	Ensures therapeutic consistency and standardization
4	Chromatographic Evaluation	Fingerprint profiling, biomarker identification, impurity detection	TLC, HPTLC, HPLC, GC-MS	Standardization and detection of adulteration
5	Microbial Evaluation	Total bacterial count, fungal count, pathogen testing	Microbial culture methods	Ensures microbiological safety and prevents infections
6	Stability Studies	Appearance, color, pH, drug content, viscosity, microbial load	Accelerated and real-time stability studies	Determines shelf life and storage conditions
7	Palatability Evaluation	Sweetness, flavor, mouth feel, after taste	Human volunteer studies, electronic tongue analysis	Improves patient acceptance and adherence
8	Rheological Evaluation	Flow rate, Spreadability, thixotropic, yield value	Rheometer, viscometer	Maintains physical stability and ease of administration
9	Uniformity of Dosage	Weight variation, content uniformity	Pharmacopoeial methods	Prevents overdosing and underdosing
10	In-vitro Drug Release Studies	Drug release pattern, dissolution profile	Dissolution apparatus, diffusion membrane studies	Predicts bioavailability and therapeutic performance
11	Toxicological Evaluation	Acute, subacute, chronic toxicity, hepatotoxicity, nephrotoxicity	Animal toxicity studies	Ensures safety and determines safe dose limits
11	Toxicological Evaluation	Acute, subacute, chronic toxicity, hepatotoxicity, nephrotoxicity	Animal toxicity studies	Ensures safety and determines safe dose limits
12	Preservative Effectiveness Testing	Antimicrobial activity of preservatives	Antimicrobial challenge test	Prevents microbial spoilage during storage
13	Bioavailability and Pharmacokinetic Evaluation	Absorption, distribution, metabolism, excretion (ADME)	Pharmacokinetic studies	Optimizes pediatric dosing and efficacy
14	Packaging Evaluation	Child resistance, light resistance, compatibility	Packaging integrity testing	Protects formulation and improves safety
15	Patient Compliance Evaluation	Taste acceptability, swallowing ease, dosing frequency	Patient and caregiver surveys	Enhances therapeutic outcomes
16	Safety of Herbal Ingredients	Toxicity and alcohol content	Toxicological screening	Prevents adverse effects in children
17	Excipients Safety Evaluation	Artificial colors, sweeteners, preservatives	Compatibility and safety testing	Ensures excipient safety in pediatric use
18	Dose Accuracy Evaluation	Dose calculation according to	Pediatric dosing calculations	Ensures accurate

		age and weight		therapeutic dosing
19	Standardization Challenges	Seasonal, geographical, processing variations	Standardization protocols	Maintains batch-to-batch consistency

Challenges & future perspective in evaluation [30]

- Pediatric herbal guidelines that are not standardized.
- Variation in the raw materials used in herbal products.
- Difficulty in taste masking.
- Limited clinical trials for children.
- Problems with stability in natural formulations.
- Dangers of microbial contamination.

Future herbal remedies for children could include: • Formulation design based on artificial intelligence

Customized medications for children

Dosage formulations that are 3D printed

Intelligent medication delivery systems

sophisticated herbal nanocarriers

Pediatric precision medicine [30]

Artificial intelligence-based formulation design

Pediatric herbal medicine delivery is predicted to undergo a revolution thanks to nanotechnology and patient-centered formulation techniques [26, 27].

Regulatory Guidelines Used in Evaluation [7, 11, 12, 30]

Table no.3

SR. No.	Organization	Role in Evaluation
1	World Health Organization	Herbal medicine quality and safety guidelines
2	International Council for Harmonization	Stability study guidelines
3	Indian Pharmacopoeia Commission	Standards for pharmaceutical evaluation
4	Organization for Economic Co-operation and Development	Toxicological evaluation standards
5	Ayurvedic Pharmacopoeia of India	Standardization of herbal drugs

CONCLUSION

Herbal pediatric formulations have shown promise as patient-centered drug delivery methods that enhance children's therapeutic outcomes, safety, efficacy, and compliance [1, 5]. Compared to traditional dosage forms, novel technologies such as oral thin films, mini-tablets, multiparticulate systems, and nanoformulations provide substantial benefits [3,14]. The problems of poor palatability, low bioavailability, and dose variability can be solved by combining herbal medications with cutting-edge drug delivery systems [7]. Future developments in technology and ongoing research are anticipated to revolutionize pediatric herbal therapies, despite a number of formulation and regulatory obstacles.

Herbal pediatric formulations represent a promising patient-centric approach that combines medicinal plants with advanced pharmaceutical technologies to address children's unique healthcare needs. By emphasizing age-appropriate dosage forms, improved palatability, flexible dosing, safety, and ease of administration, these formulations enhance treatment adherence and therapeutic outcomes. Advances in phytopharmaceutical research, taste-masking, extraction methods, and novel drug delivery systems have enabled innovative formulations with improved stability, bioavailability, and efficacy, overcoming many limitations of traditional herbal medicines. (31-35)Despite significant progress, herbal pediatric formulations face challenges including limited pediatric clinical evidence, phytochemical variability, inadequate pharmacokinetic and pharmacodynamics data, herb–drug interactions, and non-uniform regulatory standards [32,35–38]. Addressing these issues requires standardized herbal materials, bioactive marker identification, Good Manufacturing Practices (GMP), comprehensive toxicological evaluation, and well-designed randomized controlled clinical trials. All things considered, by fusing the rich legacy of traditional medicine with evidence-based pharmaceutical innovation, herbal pediatric formulations mark a substantial step toward patient-centered healthcare. The establishment of herbal pediatric formulations as safe, effective, acceptable, and globally accessible therapeutic options for enhancing children's health and quality of life while promoting sensible and sustainable healthcare practices will depend on ongoing scientific validation, strict regulatory oversight, and technological advancement.

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