Program Profile		
Program	Program name	Design of Binary Amorphous Solid Dispersion of Loratadine Using Cellulose-Based Polymeric Carriers: Optimization, In vitro evaluation and Bioavailability Assessment.
	Category	A3

Summary of Program	
Program Name	Design of Binary Amorphous Solid Dispersion of Loratadine Using Cellulose-Based Polymeric Carriers: Optimization, In vitro evaluation and Bioavailability Assessment.
Category	**A3**
Abstract of Program	Loratadine, a second-generation antihistamine, exhibits poor aqueous solubility, which limits its oral bioavailability. Poor water solubility limits absorption, bioavailability, and therapeutic effect of a drug. The present study aimed to enhance the solubility and dissolution rate of loratadine by formulating solid dispersions using cellulose based polymers (Hydroxypropyl Methylcellulose, Microcrystalline Cellulose). Solid dispersions were prepared using the solvent evaporation and melt fusion methods in varying drug to polymer ratios (1:1, 1:2, and 1:3). The formulations were characterized by Fourier Transform Infrared Spectroscopy (FTIR), Differential Scanning Calorimetry (DSC), X-ray Diffraction (XRD), and Scanning Electron Microscopy (SEM) to assess drug-polymer interaction and changes in crystallinity. In vitro dissolution studies revealed a significant enhancement in the dissolution rate of loratadine from the solid dispersions compared to the pure drug, particularly with non-cellulosic and HPMC as cellulose derivatives. Stability studies conducted over a three-month period showed no significant degradation or variation in drug release. The ADMET analysis indicates that the drug is a suitable candidate for oral administration, and the Flory-Huggins analysis demonstrates the compatibility of the drug and polymers. Based on the compatibility of the drug and polymers, appropriate methods are established. These findings suggest that solid dispersion using suitable polymers is a promising approach for enhancing the bioavailability of poorly water-soluble drugs, such as loratadine.

Details of Program		
Planning		
Objectives	Long-term Goals	The primary goal of this study is to develop and characterise solid dispersion formulations of loratadine using cellulose polymers (such as different grades of HPMC and methylcellulose) to improve the solubility, dissolution rate, and potentially enhance the oral bioavailability of the drug.
	Short-term Targets	To enhance the solubility, dissolution rate, and oral bioavailability of loratadine by developing optimized solid dispersion formulations using cellulose based polymers.

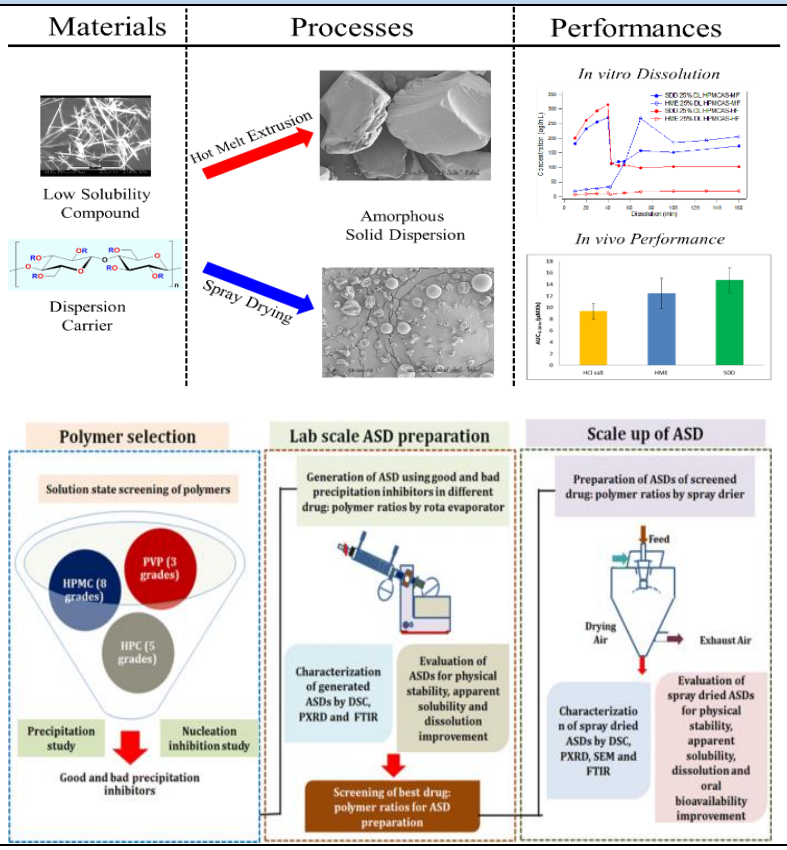
<table>
<tr><td></td><td>Rationale</td><td>Loratadine exhibits poor water solubility, resulting in low oral bioavailability and a reduced therapeutic effect. Solid dispersion with cellulose-based hydrophilic polymers offers a practical strategy to enhance solubility, dissolution, and stability. This approach not only improves drug performance but also provides a cost-effective, scalable solution for the pharmaceutical industry and can be applied to other poorly soluble drugs.</td></tr>
<tr><td rowspan="3">Subject (Leader)</td><td>Initiator(s)</td><td>JAHAN Khurshid</td></tr>
<tr><td>Champion(s)</td><td>CHOUDHURY, Musfiq Mannan</td></tr>
<tr><td>Major team member(s)</td><td>RASHID MHO, ARIFUZZAMAN S, RUPON FA, SHAKIL M, AKTER M, SHIKDER Z</td></tr>
<tr><td rowspan="3">Environment</td><td>Nature/Society</td><td>Pharmaceutical companies will be able to formulate effective versions of challenging drugs, extend the patent life of existing medications through improved formulations, and reduce the failure rate of new chemical entities (NCEs) in clinical trials.</td></tr>
<tr><td>Industry/Market</td><td>This research offers cost-effective formulation strategies that directly benefit pharmaceutical manufacturers, particularly in addressing solubility challenges associated with BCS Class II drugs. By enhancing the bioavailability through solid dispersion with well-characterized hydrophilic polymers, the findings can be leveraged to develop differentiated, market-ready oral formulations.</td></tr>
<tr><td>Citizen/Government</td><td>This research supports national goals for public health improvement by offering a cost-effective method to enhance the efficacy of essential drugs. The development of solid dispersions with enhanced solubility can reduce healthcare expenditures, improve treatment outcomes, and encourage local pharmaceutical innovation. Furthermore, it aligns with regulatory interests by enabling bioavailability enhancement within established safety profiles empowering governments to deliver better, more accessible, and more affordable healthcare.</td></tr>
<tr><td rowspan="3">Resources</td><td>Human resources</td><td>Five faculty members and two students as research assistants will participate in conducting the research.</td></tr>
<tr><td>Financial resources</td><td>300000/ (three lacs taka only)</td></tr>
<tr><td>Technological resources</td><td><table><tr><th>Equipment</th><th>Purpose</th></tr><tr><td>Hot Plate, Magnetic Stirrer</td><td>For solvent evaporation, mixing</td></tr><tr><td>Water Bath, Oven</td><td>For drying the solid dispersions</td></tr><tr><td>Mechanical Mixer, Blender</td><td>For uniform mixing of powders</td></tr><tr><td>Mortar and Pestle</td><td>Particle size reduction, homogenization</td></tr></table></td></tr>
</table>

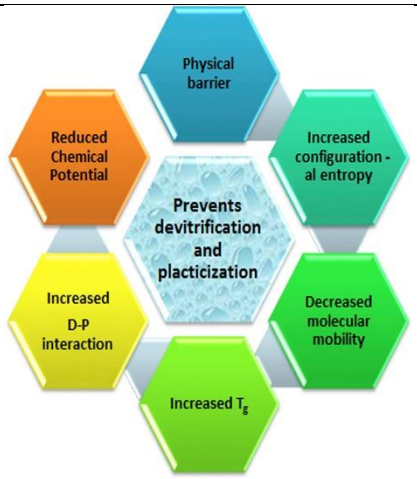
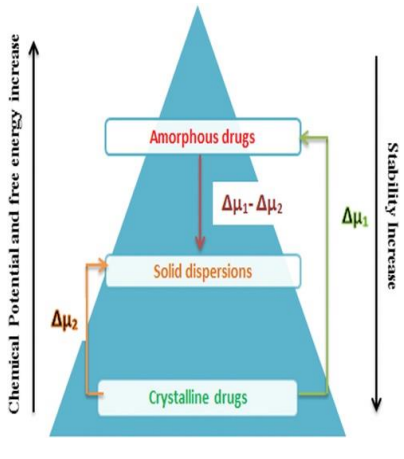
		Weighing Balance (analytical) — Precise measurement of drug and polymers Desiccator — For drying and moisture control
Mechanism	Strategy (Weight/Sequence)	**Different experimental pathways, formulation strategies, polymer choices, and process techniques.** 1.Choice of Polymers (Formulation Strategy) **Cellulose-based polymers** • HPMC (Hydroxypropyl Methylcellulose) • MCC (Microcrystalline Cellulose) • EC (Ethyl Cellulose) **Non-cellulose polymers** • PVP K30 (Polyvinylpyrrolidone) • PEG 4000/6000 (Polyethylene Glycol) • Poloxamer 2. Method of Solid Dispersion Preparation 3. Drug to Polymer Ratio 4.Characterization Techniques Basic strategy**:** Use FTIR, UV, and DSC 5.Evaluation Parameters Solubility studies Dissolution profiling in various media Stability studies (short-term or ICH-compliant) Release kinetics modeling
	Organization	World University of Bangladesh
	Culture	The project is not only about improving the solubility of loratadine but also about fostering a culture of innovation and applied research within the university. For example: **Research Mindset:** The project encourages students and faculty to go beyond theoretical learning and engage in practical, problem-solving research on real pharmaceutical challenges. **Collaboration:** It builds a culture of teamwork among faculty, students, and industry, bridging academic knowledge with real-world application. **Values of Scientific Integrity:** Through characterization techniques (FTIR, DSC, XRD, SEM), the project strengthens a culture of rigor, accuracy, and ethical research practices. **Innovation Orientation:** By introducing solid dispersion techniques and novel use of cellulose polymers, the project cultivates a value system that embraces experimentation and new methodologies rather than relying solely on traditional drug formulations.

Doing	
Launch date	October, 2024
Responsible organization	World University of Bangladesh, Wazed Miah Science Research Centre, Jahangirnagar University, Dhaka University, Bangladesh Council of Scientific and Industrial Research
Program content and process	The program focuses on the development of binary solid dispersions of loratadine using cellulose-based hydrophilic polymers, with the goal of enhancing solubility, dissolution rate, and oral bioavailability. Loratadine, a second-generation antihistamine, is a poorly water-soluble BCS Class II drug, and improving its solubility remains a significant pharmaceutical challenge. The research integrates formulation science, material characterization, and in vitro evaluation to establish a robust and reproducible drug delivery approach. The content of the program includes: (i) selection of suitable hydrophilic polymers such as Hydroxypropyl Methylcellulose (HPMC) and Microcrystalline Cellulose (MCC), (ii) preparation of solid dispersions using solvent evaporation and melt fusion techniques, (iii) optimization of drug-to-polymer ratios, and (iv) detailed physicochemical characterization through Fourier Transform Infrared Spectroscopy (FTIR), Differential Scanning Calorimetry (DSC), Scanning Electron Microscopy (SEM), and X-ray Diffraction (XRD). In vitro dissolution studies and stability testing further validate the performance of the formulations. The implementation process begins with a comprehensive literature review and preformulation studies to refine experimental design. Subsequently, polymers and loratadine are selected, and solid dispersions are prepared under varying conditions. Analytical and characterization methods are employed systematically to examine drug–polymer interactions, amorphous transformation, and dissolution enhancement. Based on preliminary results, optimized formulations are subjected to stability studies and advanced evaluation. The project also incorporates ADMET analysis and Flory–Huggins modelling to assess compatibility and predict long-term behaviors. Throughout the process, students and faculty members collaborate in laboratory activities, guided by a structured research plan. The findings are expected to not only improve loratadine delivery but also establish a transferable framework for other poorly soluble drugs. The program thus demonstrates a comprehensive approach, integrating innovative formulation strategies with rigorous implementation to generate both academic and industrial impact.
Key highlights of the content/process	Solid dispersions showed significantly improved solubility compared to pure drug. Some polymers give the best improvement in solubility and dissolution rate.

	The hydrophilic and interactive nature of polymers led to: • Amorphous transformation of the drug • Hydrogen bonding**,** reducing crystallinity • Improved wettability and dispersion
Differences from traditional approaches	This study departs from traditional pharmaceutical formulation by using scientifically tailored solid dispersion techniques and functional polymers that not only carry the drug but actively enhance its solubility, stability, and bioavailability**.** Solid dispersion transforms drug to amorphous form and embeds it in functional polymers, resulting in better solubility, faster dissolution, and enhanced bioavailability. Traditional approaches maintain the crystalline form, relying on excipients and tablet mechanics with limited improvement in solubility.
Progress as of today	My research aims to investigate the thermodynamic compatibility between some polymers and Loratadine in a drug delivery system. I have completed a detailed literature review, characterized the polymers used, and performed the Flory–Huggin's compatibility calculations, which revealed poor thermodynamic compatibility with Loratadine. I'm now exploring ways to improve this interaction by modifying the polymer properties. In the next phase, I will be testing drug release profiles using different cellulose derivatives. The project is on track, and I expect to complete experimental validation within the next 6 months.
Problems in implementation	While solid dispersions significantly improve drug solubility and bioavailability, their instability, manufacturing complexity, and scalability issues present real barriers to routine use in industry. Careful formulation design**,** polymer selection**,** and stability optimization are required to overcome these problems. Sufficient Laboratory facilities are needed with some advanced instrumentation.
Approaches to solve the problems	**Limited Laboratory Facilities** • Establish collaborations with national research centers or industry partners for access to advanced instrumentation (e.g., XRD, SEM). • Apply for research grants to support procurement of essential equipment. • Train research assistants and students in efficient use of existing equipment to maximize output. **Resource Management** • Implement cost-effective formulation strategies by carefully selecting polymers and minimizing experimental redundancy. • Prioritize experiments that directly address the research objectives to avoid unnecessary delays.
Completion date, if completed	December, 2026
Seeing	

Impacts on students	• Bridges theoretical learning and real-world applications. • Enhances technical, analytical, and professional skills**.** • Prepares students for research, academia, and pharmaceutical careers**.** • Encourages critical thinking, innovation, and lifelong learning**.**
Impacts on professors	Research on solid dispersion technologies has a significant impact on both Professors and the University by advancing academic excellence, and strengthening institutional visibility. For professors, it provides a platform to conduct high impact research, publish in peer reviewed journals**.** It also enhances opportunities for grants, interdisciplinary collaboration, and conference participation**.** For the University, such research boosts its academic reputation, attracts external funding, and promotes industry partnerships with pharmaceutical companies. It enriches the curriculum by integrating practical, research-based learning, helping align education with real-world applications.
Impacts on university administration	The implementation of this research program has several positive implications for university administration. Firstly, it strengthens the institution's academic reputation by showcasing cutting-edge pharmaceutical research that addresses global challenges in drug development. This enhances the university's visibility in national and international rankings, which is a strategic priority for most administrations. Secondly, the program fosters institutional partnerships with the pharmaceutical industry, regulatory agencies, and government bodies. Such collaborations not only bring recognition but also create opportunities for external funding, joint projects, and technology transfer agreements, which are crucial for sustainable university growth. Thirdly, the successful execution of the project demonstrates the university's ability to manage and support research infrastructure, thereby justifying administrative investment in laboratory facilities, equipment, and research grants. This creates a virtuous cycle in which demonstrated research capacity attracts further resources and talent.
Responses from industry/market	It bridges academia and industry, with shared resources and collaboration.
Responses from citizen/government	Governments should proactively support research and application of solid dispersion technologies through updated regulatory frameworks, research funding, and skill-building initiatives. By facilitating industry-academic collaboration and incentivizing local manufacturing of SD-based formulations, policymakers can enhance access to high-quality, effective, and affordable medicines.
Measurable output (revenues)	• Thermodynamic interaction parameter (χ) values between Loratadine and used polymers • One or more optimized polymer-based drug delivery formulations • Quantitative in vitro release data

	• Spectroscopic and thermal characterization data (FTIR, DSC) • Submission of a scientific manuscript or poster presentation • Standardized protocol for compatibility testing
Measurable input (expenses)	• Purchasing polymers ---------- 40% • Expenses in research Lab ---------- 35% • Transport ---------- 10% • Salary/wages ---------- 15%
Cost-benefit analysis for effectiveness	The solid dispersion of loratadine is cost-effective**,** particularly when the therapeutic benefits**,** patent potential**,** and commercial scalability are considered. This approach aligns with current pharmaceutical trends to improve poorly soluble drugs and can be justified in a research or pre-commercial context.
Future Planning	
Where does the project go from here?	• Advanced In-Vitro and In-Vivo Studies. • Molecular-level drug–polymer interactions (e.g., NMR, XRD) • Collaborate with industry partners or apply for government grants**.** • Prepare manuscripts for peer-reviewed journals. • Apply the same SD methodology to other BCS Class II drugs (e.g., ketoconazole, ibuprofen, glimepiride). Include specific polymer ratios, preparation methods, and performance outcomes.
Addendum	
Exhibits, pictures, diagrams, etc.	

Reports, mimeos, monographs, books, etc.	 
Others which may help explain the program (including website links)	https://link.springer.com/article/10.1208/s12249-020-01849-z https://pubs.acs.org/doi/abs/10.1021/acs.molpharmaceut.8b00021