
Dizhen Dizhi Journal

Design and Optimization of Polyherbal Mouth-Dissolving Film for the Management of Diabetes Mellitus.”

Dnyaneshwar k shingade1,
dnyaneshwarshingade31@gmail.com

Dr.pravin s. uttekar2,
uttekar.p.s@gmail.com

Late laxmibai phadtare college of pharmacy,kalamb

INTRODUCTION.

- Type 1 diabetes results primarily from autoimmune destruction of pancreatic beta cells and requires insulin replacement.
- Type 2 diabetes is characterized by insulin resistance with progressive beta-cell dysfunction and represents the largest clinical category.
- Gestational diabetes is first recognized during pregnancy and predicts increased future metabolic risk.
- Other specific types include monogenic diabetes, pancreatic disease, endocrinopathies and medicine-induced hyperglycaemia.

Need of the Work

The present research project proposes the design and optimization of a polyherbal mouth-dissolving film containing standardized dry extracts of *Gymnema sylvestre* leaves, *Syzygium cumini* seeds and *Cinnamomum verum* bark. The botanicals are selected because their reported phytoconstituents act through complementary metabolic pathways, including modulation of glucose absorption, insulin signalling, oxidative stress and carbohydrate-metabolizing enzymes. A concentrated extract blend is proposed at an exploratory ratio of 2:2:1, with a nominal total extract load of 60 mg per 3 × 4 cm film. HPMC E5 and pullulan are selected as film-forming polymers and glycerol as plasticizer.

A Quality-by-Design strategy is used to define the target product profile, critical quality attributes and critical material attributes. A three-factor, three-level Box-Behnken design evaluates the effects of HPMC E5 concentration, pullulan concentration and glycerol level on disintegration time, tensile strength, percentage elongation, folding endurance and marker release. Prepared films are proposed to undergo physicochemical, mechanical, spectroscopic, morphological, dissolution, content-uniformity, microbial and stability evaluation. The report contains an illustrative optimization dataset solely to demonstrate model fitting and desirability-based selection; it is not experimental evidence.

The anticipated output is a flexible, uniform, palatable and rapidly disintegrating film supported by marker-based quality control and statistically justified formulation settings.

DRUG PROFILE

Gymnema sylvestre: Botanical Profile

Gymnema sylvestre R. Br. is a climbing plant of the family Apocynaceae, traditionally used in South Asian systems of medicine. Leaves are the principal material investigated in glucose-related research. The botanical drug should be authenticated and distinguished from substitutes or exhausted material [15-18].

Key considerations

- Macroscopy includes leaf shape, venation, surface and organoleptic characters.
 - Microscopy and physicochemical constants support identity and purity.
 - Triterpenoid saponins collectively described as gymnemic acids are common analytical targets.
 - Geographical origin, harvest stage and extraction solvent influence composition. *Gymnema sylvestre* is a India, south Africa Belonging to the *Apocynaceae* family, its leaves contain *gymnemic acids*, which temporarily suppress sweet taste perception and are widely studied for supporting blood sugar homeostasis.
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LITERATURE REVIEW:

- Population statistics establish public-health relevance but do not validate a dosage form.
- Guideline-directed treatment is the ethical comparator for any future human study.
- Botanical use should be documented in medication reconciliation.
- Outcome measures should include safety, adherence and clinically meaningful glycaemic indices.
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OBJECTIVE:

1. .

A Quality-by-Design strategy is used to define the target product profile, critical quality attributes and critical material attributes. A three-factor, three-level Box-Behnken design evaluates the effects of HPMC E5

concentration, pullulan concentration and glycerol level on disintegration time, tensile strength, percentage elongation, folding endurance and marker release. Prepared films are proposed to undergo physicochemical, mechanical, spectroscopic, morphological, dissolution, content-uniformity, microbial and stability evaluation. The report contains an illustrative optimization dataset solely to demonstrate model fitting and desirability-based selection; it is not experimental evidence

Plan of work :

Month	Planned work	Documented output
1	Protocol, literature database, QTPP, risk assessment, procurement	Approved protocol and material list
2	Authentication, extraction/procurement, preliminary phytochemical and physicochemical testing	Voucher specimen and extract specifications
3	Analytical method selection, compatibility study and polymer screening	Methods and screening-batch report
4	Box-Behnken batches and physical/mechanical evaluation	Complete DoE batch records
5	Marker assay, dissolution, model fitting and optimization	Regression models and predicted optimum
6	Verification batches, microscopy and final method refinement	Verification report
7-9	Accelerated and initial long-term stability observations	Interim stability report
10	Interpretation, thesis compilation and future-study protocol	Final research project

Category	Proposed material	Purpose / specification
Botanical active	Gymnema sylvestre leaf dry extract	Authenticated; standardized for gymnemic-acid marker
Botanical active	Syzygium cumini seed dry extract	Authenticated; chromatographic fingerprint and selected marker
Botanical active	Cinnamomum verum bark dry extract	True cinnamon; cinnamaldehyde/coumarin profile documented
Film former	HPMC E5	Pharmaceutical grade; viscosity grade recorded
Film former	Pullulan	Pharmaceutical/food grade with microbial compliance
Plasticizer	Glycerol	Pharmacopoeial grade
Sweetener	Sucralose	Low-dose intense sweetener
Saliva stimulant	Citric acid	Pharmacopoeial/food grade; optimized for pH and taste
Flavour	Peppermint or compatible mint flavour	Screened for acceptability and stability
Solvent	Purified water; limited hydroalcoholic co-solvent if justified	Controlled microbial and residual-solvent quality
Analytical	Certified marker standards and HPLC/analytical solvents	Method validation and assay