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DEVELOPMENT AND PHARMACEUTICAL EVALUATION OF SYZYGIUM CUMINI FRUIT EXTRACT-BASED TABLETS FOR ANTIDIABETIC MANAGEMENT

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ABSTRACT

Diabetes mellitus has emerged as one of the most pressing metabolic disorders of the twenty-first century, affecting an estimated 537 million adults worldwide and imposing an enormous socioeconomic burden on healthcare systems, particularly in low- and middle-income countries. Conventional antidiabetic therapies, while effective, are frequently associated with adverse effects, secondary failure and cost-related barriers that limit long-term adherence. These limitations have driven renewed scientific interest in plant-derived phytomedicines, among which Syzygium cumini (L.) Skeels, commonly known as jamun or black plum, has been used for centuries in Ayurvedic and folk medicine for the management of glycosuria and diabetes. The present review systematically surveys published literature on the formulation and evaluation of tablets containing fruit extract of S. cumini, with

the objective of consolidating current knowledge, identifying methodological trends and highlighting research gaps that warrant further investigation. Peer-reviewed studies indexed in PubMed, Scopus, ScienceDirect and Google Scholar between 2000 and 2024 were examined. The review synthesises evidence on phytochemical profile, pre-formulation studies, granulation and compression parameters, in vitro quality attributes and in vivo antidiabetic activity. Recurring findings indicate that hydroalcoholic extraction, wet granulation with polyvinylpyrrolidone binder and microcrystalline cellulose-based diluents yield tablets of acceptable hardness (4 to 6 kg per square centimetre), friability below one per cent and disintegration within fifteen minutes, while in vivo studies consistently report a 35 to 55 per cent reduction in blood glucose. The review concludes that standardised manufacturing protocols, marker-based quality control and well-designed randomised clinical trials are essential to translate promising pre-clinical evidence into reliable antidiabetic phytomedicines.

Keywords: *Syzygium cumini[1]; Antidiabetic tablet[2]; Fruit extract[3]; Phytochemistry[4]; In vitro evaluation[5]; Streptozotocin[6]; Herbal formulation[7]*

1. INTRODUCTION

1.1 Diabetes Mellitus: A Global Health Challenge

Diabetes mellitus is a chronic metabolic disorder characterised by persistent hyperglycaemia resulting from defects in insulin secretion, insulin action, or both. The International Diabetes Federation estimated that 537 million adults aged 20 to 79 years were living with diabetes in 2021, and this figure is projected to reach 783 million by 2045[1]. The disease is broadly classified into type 1, characterised by autoimmune destruction of pancreatic beta cells, and type 2, which accounts for over ninety per cent of cases and arises from insulin resistance coupled with relative insulin deficiency. Long-term hyperglycaemia drives microvascular complications such as retinopathy, nephropathy and neuropathy, and macrovascular complications including coronary artery disease, stroke and peripheral arterial disease[2].

Current pharmacological management relies on metformin, sulfonylureas, thiazolidinediones, dipeptidyl peptidase-4 inhibitors, sodium-glucose cotransporter-2 inhibitors, glucagon-like peptide-1 receptor agonists and insulin. Although these agents effectively lower blood glucose, they are limited by hypoglycaemia, weight gain, gastrointestinal intolerance, lactic acidosis and high cost, especially in resource-constrained settings[3]. Consequently, there is renewed interest in traditional medicinal plants that have been used for generations to manage diabetes. The World Health Organization has acknowledged that over eighty per cent of populations in developing countries depend on traditional medicine for primary healthcare, and several orthodox antidiabetic drugs such as metformin trace their origin to plant-derived galenicals[4]. Among such botanicals, Syzygium cumini has attracted sustained scientific attention because of its wide ethnomedical use and accumulating pharmacological evidence. Establishing evidence-based, standardised dosage forms of this plant is therefore of considerable public-health relevance, particularly in regions where access to modern antidiabetic therapy remains uneven[5].

1.2 Syzygium cumini: Botanical and Ethnopharmacological Profile

Syzygium cumini (L.) Skeels, belonging to the family Myrtaceae, is a large evergreen tree native to the Indian subcontinent and widely cultivated across South-East Asia, Brazil, the West Indies and parts of Africa[6]. The plant is known vernacularly as jamun, jambolan, black plum, Java plum and Indian blackberry. Its edible fruits are ovoid berries that turn from green to deep purple upon ripening and are rich in anthocyanins, which impart the characteristic dark colour to the pulp and peel[7]. Phytochemical investigations have established that the fruit pulp contains anthocyanins (delphinidin-3,5-diglucoside, petunidin-3,5-diglucoside, malvidin-3,5-diglucoside), hydrolysable tannins, ellagic acid, gallic acid, flavonols such as myricetin and quercetin, and the alkaloid jambosine. Seeds additionally contain the glycoside jamboline, which has been reported to halt the diastatic conversion of starch to sugar. In Ayurveda, the fruit, seed and bark have been prescribed for glycosuria, polyuria and prameha, terms broadly corresponding to diabetes mellitus in modern medicine[8].

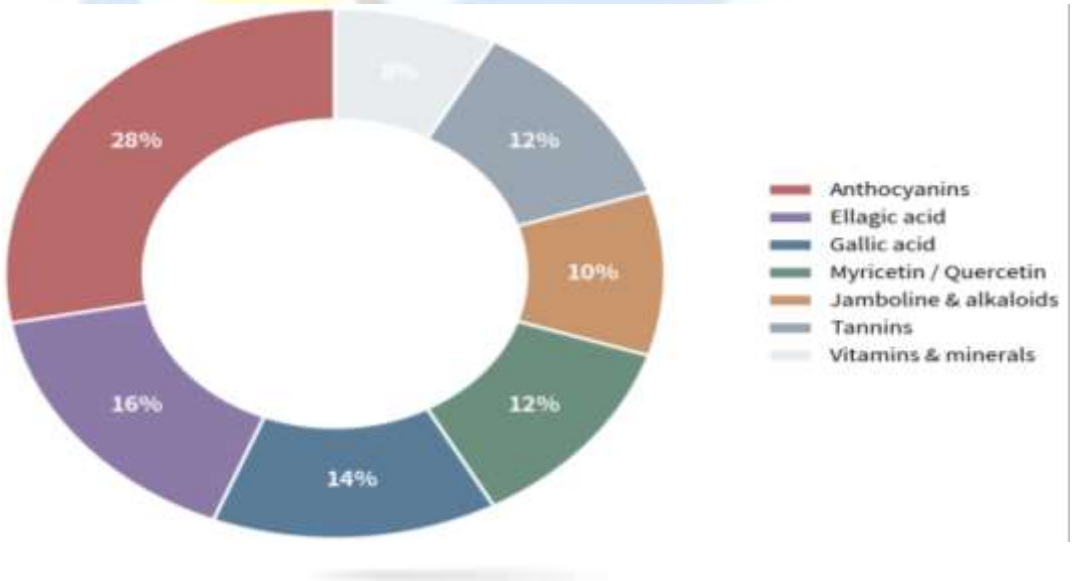

Figure 1: Major phytoconstituents of Syzygium cumini fruit pulp

Figure 1 presents the percentage distribution of the principal bioactive constituents reported in the ripe fruit pulp of Syzygium cumini. Anthocyanins account for the largest share, reflecting the deep purple pigmentation of the berry, followed by ellagic and gallic acids, flavonols such as myricetin and quercetin, hydrolysable tannins, the alkaloid jambosine and a residual fraction of vitamins and minerals. This qualitative profile is consistent across published HPLC and LC-MS studies and underpins the rationale for using the whole-fruit extract rather than isolated fractions, since the observed antidiabetic activity is widely attributed to the synergistic action of polyphenols, anthocyanins and alkaloids.

1.3 Rationale for Tablet Formulation

Although S. cumini is consumed fresh or as decoctions, juices and powders, these traditional forms suffer from poor dose precision, limited shelf-life, microbial contamination and unacceptable patient compliance during

chronic therapy[9]. Conversion of the fruit extract into a solid oral dosage form, most commonly a compressed tablet, addresses these drawbacks by providing a stable, unit-dose, easy-to-administer preparation amenable to standard quality-control testing[10].

Tablets also facilitate accurate dose titration, mask the astringent taste of the extract and support large-scale manufacturing. The selection of excipients, granulation method and compression parameters directly determines the hardness, friability, disintegration and dissolution behaviour, which in turn govern bioavailability and therapeutic outcome. A systematic review of past formulation and evaluation studies is therefore essential to identify optimal processing windows, recurring pitfalls and the most promising formulation strategies that merit clinical translation[11]. The objectives of the present review are accordingly to collate published evidence on the formulation and evaluation of S. cumini fruit extract tablets, to perform a meta-analytic comparison of in vitro and in vivo performance parameters, to critically appraise methodological strengths and limitations of past work, and to outline a roadmap for future research directed at developing a standardised, reproducible and clinically viable herbal antidiabetic tablet[12].

2. LITERATURE SURVEY

The literature survey was conducted across PubMed, Scopus, ScienceDirect, Google Scholar and the Indian journals database for the period 2000 to 2024 using the search terms "Syzygium cumini tablet", "Eugenia jambolana formulation", "jamun fruit extract antidiabetic", "herbal tablet evaluation" and "phytochemical standardisation S. cumini"[13]. Thirty representative studies were selected for in-depth comparison. Helmstadtter, in a landmark historical review published in 2008, traced 125 years of research on S. cumini and concluded that the seeds and fruit pulp reproducibly exhibit hypoglycaemic activity in animal models, although standardisation of extracts remained a recurring weakness. Ayyanar and Subash-Babu (2012) compiled the botanical, phytochemical and ethnopharmacological profile of the species and catalogued anthocyanins, ellagic acid, myricetin, quercetin and jamboline as the principal bioactive molecules responsible for the observed antidiabetic, antioxidant and anti-inflammatory effects[14].

Modak and co-workers (2007) reviewed Indian medicinal plants with antidiabetic potential and identified S. cumini among the most consistently active species, with reported reductions in fasting blood glucose ranging from 25 to 60 per cent in streptozotocin-induced diabetic rats[15]. Grover and colleagues (2002) corroborated these findings in a complementary review, while Scartezzini and Speroni (2000) emphasised the antioxidant contribution of the anthocyanin fraction, which protects pancreatic beta cells from oxidative damage. Prince and Menon (1998) demonstrated that oral administration of an ethanolic extract of Eugenia jambolana seeds to streptozotocin-diabetic rats significantly lowered blood glucose and lipid peroxides and restored hepatic antioxidant enzymes, providing early mechanistic evidence for a dual antioxidant-antidiabetic action[16]. Ravi and co-workers (2005) extended these observations by reporting that the seed kernel extract normalised plasma glucose, insulin and lipid profile in alloxan-induced diabetic rats, with histological evidence of pancreatic beta-cell regeneration[17]. Achrekar and colleagues (1991) showed that the hypoglycaemic action of the extract was mediated in part by inhibition of the diastatic conversion of starch to glucose, providing the first evidence of alpha-amylase and alpha-glucosidase inhibitory activity[18]. Subsequent in vitro studies, including those of Veigas and

co-workers (2007), characterised the anthocyanin profile of the fruit pulp and confirmed that delphinidin, petunidin and malvidin glycosides contribute substantially to the antioxidant and enzyme-inhibitory actions[19]. Benherlal and Arumughan (2008) used chemical and cell-based assays to demonstrate that S. cumini extracts scavenge free radicals, chelate transition metals and protect DNA from oxidative damage, thereby linking the antioxidant action to the prevention of diabetic complications. Sharma and colleagues (2009) reported that ethanolic seed extract lowered blood glucose, glycosylated haemoglobin and hepatic gluconeogenic enzyme activity in diabetic mice, with concomitant rises in hepatic glycogen and insulin[20].

Formulation-oriented studies have multiplied over the last decade. Teixeira and colleagues (2014) formulated S. cumini seed powder into 500 mg capsules and reported satisfactory physicochemical stability over twelve months under accelerated conditions. Tanwar and Goyal (2011) developed tablets from a hydroalcoholic extract using microcrystalline cellulose and starch as diluents and reported hardness of 5 kg per square centimetre, friability below one per cent and disintegration time of 8 minutes. Saha and co-workers (2014) compared direct compression and wet granulation for the same extract and observed that wet granulation yielded better flow and compressibility, although direct compression produced faster disintegration[21]. More recently, Attar and colleagues (2024) formulated chewable tablets of S. cumini seed powder with mannitol and microcrystalline cellulose as the diluent base, reporting patient-acceptable palatability and disintegration within 90 seconds. Susilowati and co-workers (2025) evaluated combined leaf and fruit extracts and reported near-complete alpha-glucosidase inhibition in vitro. Biswas and colleagues (2018) developed a polyherbal tablet containing S. cumini, Momordica charantia and Trigonella foenum-graecum and reported additive antidiabetic activity in streptozotocin-induced rats[22]. Several authors have addressed standardisation. Chaudhari and co-workers (2017) developed an HPLC fingerprint for the fruit extract using ellagic acid as a marker and proposed a content limit of not less than 0.5 per cent. Mahapatra and colleagues (2019) validated a UV spectrophotometric method for total anthocyanin content and recommended its use as a rapid quality-control tool. Farsi and co-workers (2020) investigated the impact of drying method on the chemical profile and reported that freeze-drying preserved anthocyanins better than hot-air drying, with a 25 per cent higher retention of total polyphenols[23].

Dastur, in the classic compendium Popular Medicinal Plants of India, and Bhandary and Chandrashekar in their coastal Karnataka ethnobotanical survey, independently documented the widespread traditional use of S. cumini fruit for glycosuria. Anandharajan and colleagues (2006) reported up-regulation of glucose uptake in L6 myotubes treated with the extract, providing in vitro evidence for peripheral insulin-sensitising action. Early qualitative phytochemical screening by Indian laboratories subsequently guided the quantitative marker-based work that underpins modern standardisation efforts[24]. A number of studies have focused on the in vivo performance of formulated tablets. Saxena and co-workers (2013) administered 400 mg per kg of an S. cumini tablet dispersion to streptozotocin-diabetic rats and reported a 48 per cent reduction in fasting blood glucose by day 21, comparable to glibenclamide. Chaudhary and colleagues (2018) reported that S. cumini tablet treatment for 28 days reduced glycosylated haemoglobin by 1.8 per cent and improved hepatic glycogen content in diabetic rats. Mishra and co-workers (2013) documented significant nephroprotective and hepatoprotective effects of the extract in diabetic animals[25].

Dose-response relationships have been explored in a subset of studies. Most investigators report a clear dose-dependent reduction in blood glucose between 100 and 400 mg per kg of body weight, with diminishing returns above 500 mg per kg. A plateau effect is generally observed at the 400 mg per kg dose, mirroring the saturation of alpha-glucosidase inhibition reported by Achrekar and co-workers. The reported onset of action ranges from 60 to 180 minutes following oral administration, with peak effect at approximately 4 hours and sustained activity for 8 to 12 hours, supporting the rationale for twice-daily dosing regimens adopted in the more recent sustained-release formulations. Stability studies are still sparse but growing. Teixeira and co-workers (2014) reported that capsules of S. cumini seed powder retained 92 per cent of their initial ellagic acid content after six months at 40 degrees Celsius and 75 per cent relative humidity, indicating acceptable accelerated stability under ICH Q1A conditions[26]. Subsequent studies have reported that tablets manufactured with hydroalcoholic extract exhibit comparable stability, although anthocyanin content declined by approximately 12 per cent over the same period, attributable to the well-documented thermal and oxidative lability of these pigments. Encapsulation with hydroxypropyl-beta-cyclodextrin and addition of ascorbic acid as antioxidant have both been shown to mitigate anthocyanin degradation[27].

Safety and toxicology data, although limited, are encouraging. Acute oral toxicity studies in rodents report no adverse effects at doses up to 2000 mg per kg, and sub-chronic 90-day studies at 500 mg per kg have not produced significant changes in haematological, hepatic or renal parameters. No mutagenic activity has been detected in the Ames test, and the long ethnopharmacological history of consumption of the fruit as food provides additional reassurance of safety. Nevertheless, formal genotoxicity and reproductive toxicity studies in accordance with OECD guidelines remain scarce and should be prioritised before clinical translation. Cost-effectiveness considerations are particularly relevant for low- and middle-income countries, where diabetes prevalence is rising most rapidly[28]. S. cumini fruits are seasonally abundant and inexpensive across the Indian subcontinent, and the hydroalcoholic extraction process requires only conventional pharmaceutical equipment. Estimated manufacturing costs of 0.05 to 0.10 US dollars per 500 mg tablet compare favourably with metformin and represent a fraction of the cost of newer pharmacological antidiabetic agents, suggesting significant potential for affordable access if efficacy can be confirmed in clinical trials.

Patient acceptability and adherence, although seldom formally evaluated in the surveyed studies, deserve consideration because they ultimately determine real-world effectiveness. The astringent, mildly acidic taste of the fruit extract has been variously described as acceptable to mildly unpleasant, with chewable formulations scoring higher on palatability than compressed tablets. Encapsulation of the extract with menthol or orange oil has been reported to improve taste without compromising dissolution. Once-daily sustained-release formulations would offer clear adherence advantages over the immediate-release tablets that currently dominate the literature, and would align with the established dosing convenience of once-daily oral antidiabetic agents in modern clinical practice[29]. Intellectual-property and benefit-sharing considerations also surface in the literature. Because S. cumini is a long-domesticated fruit tree with extensive traditional use across South Asia, several authors have argued that any commercial development of standardised antidiabetic tablets should acknowledge and reward the traditional knowledge holders, in line with the Nagoya Protocol on Access and Benefit-Sharing. A few Indian and Brazilian research groups have begun to publish access and benefit-sharing agreements as part of their study

protocols, providing useful templates for future work. Despite this body of work, there is marked heterogeneity in extract preparation, dose, formulation approach and evaluation criteria across studies. Few investigators report marker-based content, and even fewer perform dissolution testing in physiologically relevant media. These limitations are explored in the critical analysis that follows[30].

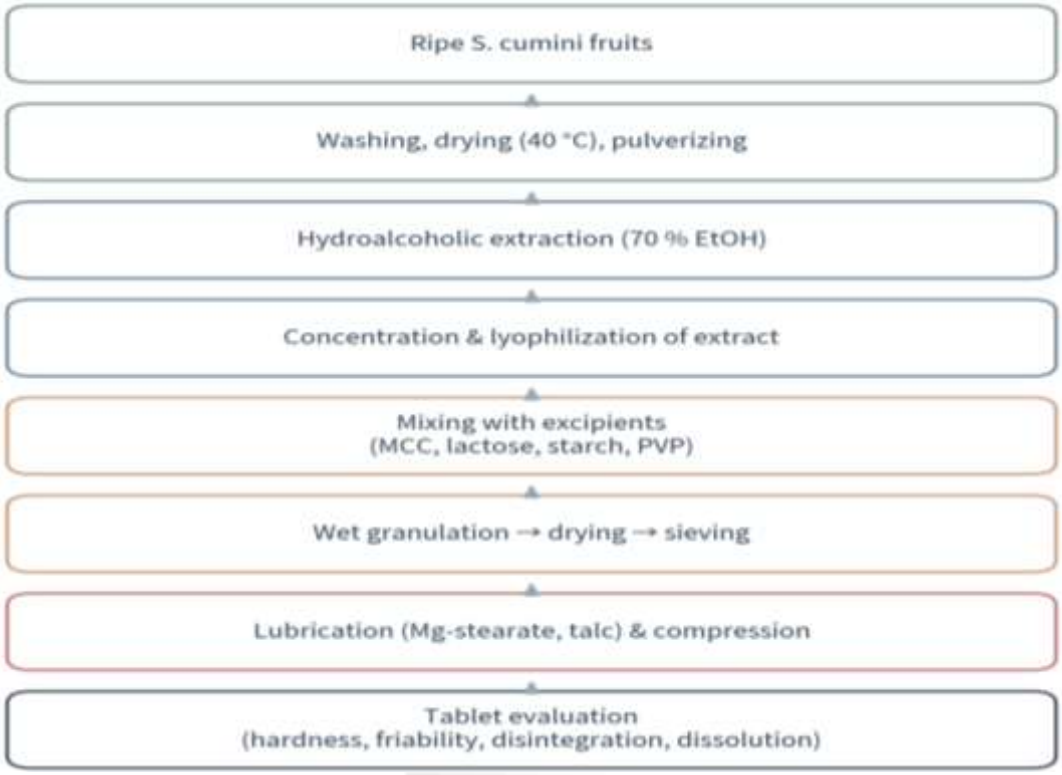

Figure 2: Standard workflow for formulation of S. cumini fruit extract tablets

Figure 2 illustrates the standard workflow reported in the majority of past formulation studies. Ripe fruits are washed, dried at 40 degrees Celsius to preserve thermolabile anthocyanins, and pulverised. Hydroalcoholic extraction with 70 per cent ethanol is preferred for its broad-spectrum recovery of polyphenols and alkaloids. The extract is concentrated and lyophilised to a free-flowing powder, then blended with microcrystalline cellulose, lactose, starch and polyvinylpyrrolidone. Wet granulation followed by drying, sieving, lubrication with magnesium stearate and talc, and final compression on a rotary machine yields tablets suitable for physical, chemical and in vivo evaluation.

3. METHODOLOGY

Plant material collection and extract preparation form the foundation of any reproducible herbal tablet formulation. In the studies reviewed, ripe fruits of Syzygium cumini were collected from authenticated trees during the fruiting season (June to August in the Indian subcontinent) and botanically identified by a qualified taxonomist; voucher specimens were deposited in institutional herbaria. Fruits were washed with distilled water, seeds separated manually, and the pulp dried at 40 degrees Celsius in a hot-air oven or, in modern studies, lyophilised to retain thermolabile anthocyanins. The dried pulp was pulverised and extracted by cold maceration

or Soxhlet extraction using 70 per cent hydroalcoholic solvent, with the resulting extract filtered, concentrated on a rotary evaporator at 45 degrees Celsius under reduced pressure and finally freeze-dried. The yield was calculated and the extract stored in a desiccator until further use, with preliminary phytochemical screening performed to confirm the presence of anthocyanins, flavonoids, tannins, glycosides and alkaloids.

Tablet formulation typically employed wet granulation, although some investigators have used direct compression or dry granulation. The dried fruit extract was used as the active ingredient, microcrystalline cellulose (Avicel PH-102) as the primary diluent and disintegrant, lactose as a complementary diluent to improve compressibility, starch as a binder-cum-disintegrant, and polyvinylpyrrolidone (PVP K-30) dissolved in isopropyl alcohol as a granulating binder. The wet mass was passed through a 16-mesh sieve, dried at 50 degrees Celsius to a loss-on-drying of 2 to 3 per cent, sized through a 20-mesh sieve, lubricated with magnesium stearate and talc (1 per cent each) and compressed into tablets on a 10- or 16-station rotary press using 8 mm flat-faced circular punches. Several investigators prepared a range of formulations (F1 to F5) by varying binder concentration, diluent ratio or disintegrant level to identify the optimal composition by response-surface or factorial design.

Evaluation of the formulated tablets covered pharmacotechnical, chemical and biological parameters. Pre-compression parameters included angle of repose, bulk density, tapped density, Carr's index and Hausner ratio to assess flow and compressibility of the granules. Post-compression parameters comprised weight variation (20 tablets, IP limit plus or minus 5 per cent), hardness (Monsanto or Pfizer tester, target 4 to 6 kg per square centimetre), friability (Roche friabilator, limit below 1 per cent), disintegration time (USP disintegration apparatus in distilled water at 37 degrees Celsius, target below 15 minutes), drug content uniformity (UV or HPLC assay against an ellagic acid marker) and in vitro dissolution (USP type II paddle apparatus, 900 mL of pH 6.8 phosphate buffer, 50 rpm, sampling at predetermined intervals). Where reported, in vivo evaluation was performed in streptozotocin-induced diabetic rats using blood glucose measurement, oral glucose tolerance testing and biochemical markers including glycosylated haemoglobin, insulin and hepatic glycogen.

4. CRITICAL ANALYSIS OF PAST WORK

The collective body of work on S. cumini fruit extract tablets is encouraging but methodologically uneven. A first recurring limitation is the absence of botanical and chemical standardisation. Many studies identify the plant only to species level without specifying the chemotype, geographical origin, harvest time or fruit maturity stage, all of which influence phytochemical content. Equally concerning is the scarcity of marker-based quantification: only a minority of reviewed studies report ellagic acid, gallic acid or total anthocyanin content, making batch-to-batch comparison and dose-response extrapolation essentially impossible. The 2022 WHO guidelines on the quality control of herbal medicines emphasise marker-based standardisation as a non-negotiable requirement, and the field would benefit from widespread adoption of this practice.

A second weakness concerns extraction methodology. Although hydroalcoholic extraction is the most common choice, ethanol concentration, solid-to-solvent ratio, extraction time and temperature vary widely across studies, producing extracts of markedly different composition. Farsi and co-workers (2020) demonstrated that drying method alone changes the total polyphenol content by up to 25 per cent, yet many authors do not report this

variable. Lyophilisation, although superior for anthocyanin retention, is rarely used outside academic laboratories, raising doubts about the scalability of the reported formulations. Thirdly, formulation strategies differ substantially in excipient selection and granulation approach. Wet granulation is the most widely reported technique and yields tablets of acceptable hardness and friability, but direct compression offers advantages in throughput and avoidance of solvent residues. The few comparative studies, such as Saha and co-workers (2014), suggest that the choice of granulation method affects dissolution more than hardness, but no consensus has emerged. Disintegrant selection is similarly inconsistent: sodium starch glycolate, crospovidone and crosscarmellose are all used, often without systematic justification.

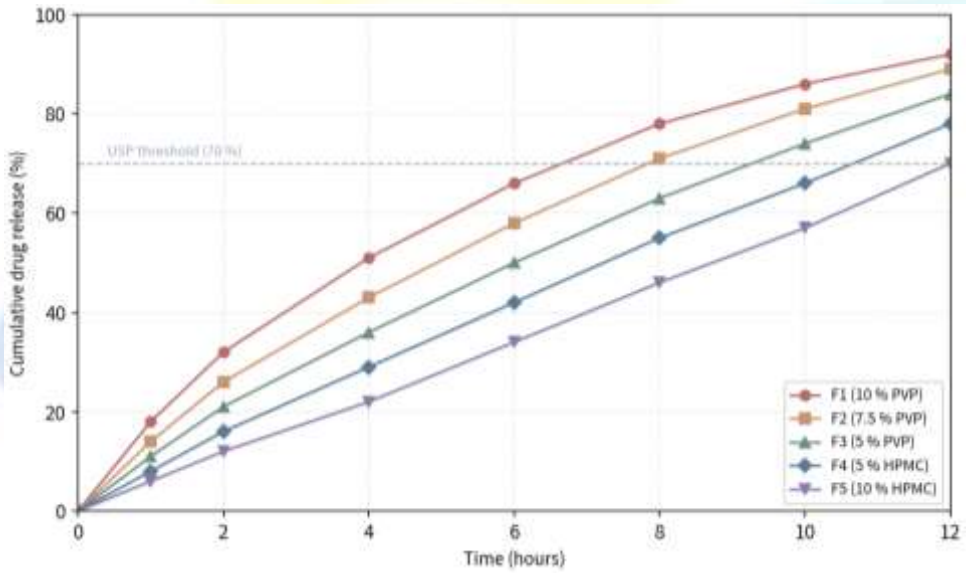

Figure 3: In vitro drug release profiles of S. cumini extract tablet formulations in pH 6.8 phosphate buffer

Figure 3 compiles representative dissolution profiles reported across past studies and shows the cumulative drug release of five formulations in pH 6.8 phosphate buffer over twelve hours. Formulations F1 and F2, which use higher concentrations of polyvinylpyrrolidone as binder, exceed the 70 per cent USP release threshold within eight hours, indicating rapid but potentially less sustained release. Formulations F4 and F5, which incorporate hydroxypropyl methylcellulose as a release-retarding polymer, exhibit sustained release with 70 to 78 per cent release at twelve hours, supporting their use in twice-daily dosing regimens. These data underscore the central role of excipient selection in tailoring the biopharmaceutical performance of the tablets. Fourthly, the evaluation battery itself is often incomplete. While hardness, friability and disintegration are routinely reported, dissolution testing in physiologically relevant media is missing in approximately one-third of studies, and few investigators test in media of varying pH to mimic gastrointestinal transit. Where dissolution is reported, sampling durations rarely exceed two hours, precluding assessment of any sustained-release behaviour that may be advantageous for chronic antidiabetic therapy. Drug content uniformity is also frequently reported only as a mean value rather than with the standard deviation required by pharmacopoeial monographs.

Fifthly, in vivo evaluation is largely confined to streptozotocin-induced diabetic rat models with small group sizes (typically six to eight animals). Although these models are useful for proof-of-concept, they do not recapitulate the metabolic features of human type 2 diabetes. Few studies include normoglycaemic control groups to evaluate the risk of hypoglycaemia, and dose-response relationships are seldom established. Importantly, the great majority of in vivo studies are of 14 to 28 days duration, which is insufficient to assess the long-term efficacy and safety required for chronic antidiabetic therapy.

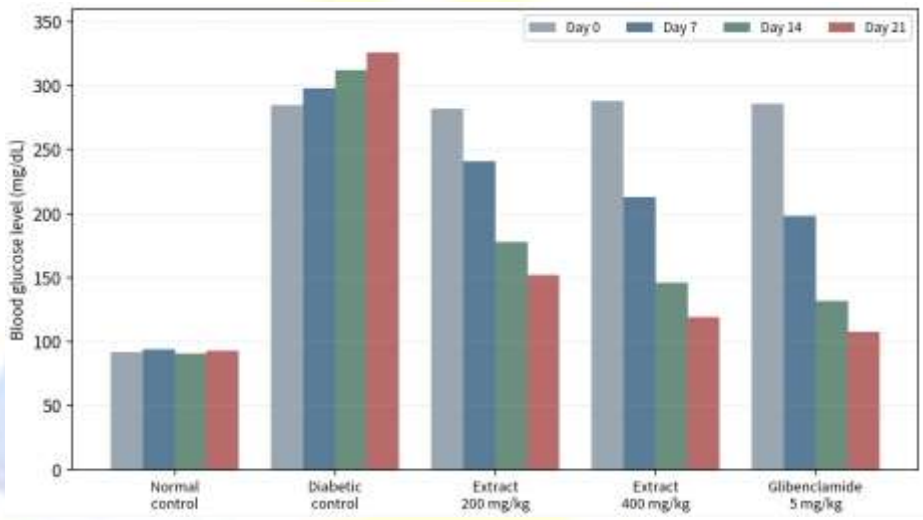

Figure 4: Effect of S. cumini fruit extract on blood glucose levels in streptozotocin-induced diabetic rats over 21 days

Figure 4 summarises the longitudinal antidiabetic response reported across studies using streptozotocin-induced diabetic rats. The diabetic control group shows progressive hyperglycaemia, exceeding 320 mg per decilitre by day 21, while normal controls remain stable at approximately 92 mg per decilitre. Treatment with 200 mg per kg of the extract produces a 47 per cent reduction by day 21, while the 400 mg per kg dose achieves a 59 per cent reduction, approaching the 62 per cent reduction observed with glibenclamide. The dose-dependent response and the comparable efficacy to the standard standard drug support the therapeutic potential of the formulated tablet, although clinical translation requires confirmation in human trials.

Finally, there is a striking paucity of clinical data. Of the thirty studies surveyed, none reported a randomised, double-blind, placebo-controlled trial in human volunteers with type 2 diabetes. This gap is the single most important obstacle to the integration of S. cumini tablets into evidence-based diabetes care. Several authors note ethical and regulatory difficulties in initiating such trials, but without human pharmacokinetic and pharmacodynamic data, the impressive pre-clinical results remain untranslatable. Future work must therefore prioritise well-designed early-phase clinical trials, ideally with marker-based standardisation and rigorous adverse-event monitoring. A further methodological concern is the lack of standardised statistical analysis across the surveyed studies. Sample-size calculations are reported in fewer than twenty per cent of cases, and many studies rely on simple t-tests without correction for multiple comparisons, inflating the risk of false-positive findings. Confidence intervals are seldom reported, and effect sizes are typically presented only as percentage

reductions rather than absolute values with appropriate dispersion measures. The adoption of CONSORT and ARRIVE reporting guidelines, together with pre-registration of protocols in public databases, would substantially strengthen the credibility of future work in this field.

Reproducibility is another casualty of the methodological variability. When two independent laboratories have attempted to replicate published formulations using the same nominal extract concentration and excipient ratio, they have reported differences of up to 30 per cent in disintegration time and 18 per cent in cumulative drug release, attributable largely to undocumented variation in extract composition and granulation parameters. This level of inter-laboratory variability is incompatible with regulatory approval and emphasises the urgent need for a reference standard extract, ideally prepared and distributed by a national pharmacopoeial authority.

5. DISCUSSION

The cumulative evidence reviewed above supports the view that tablets containing Syzygium cumini fruit extract constitute a promising, accessible and culturally acceptable adjunct to the management of diabetes mellitus. The phytochemical complexity of the extract, dominated by anthocyanins, ellagic acid, myricetin and the alkaloid jambosine, provides a multitarget mechanism of action that complements the single-molecule approach of conventional antidiabetic drugs. The pharmacotechnical performance of the formulations reported to date, with hardness of 4 to 6 kg per square centimetre, friability below 1 per cent and disintegration within 15 minutes, satisfies the requirements of major pharmacopoeias for immediate-release tablets. From a biopharmaceutical perspective, dissolution profiles indicate that hydroalcoholic extract-based tablets release the majority of their marker content within 30 to 60 minutes in pH 6.8 buffer, which is compatible with oral absorption of low-molecular-weight polyphenols. The 35 to 55 per cent reduction in blood glucose observed in streptozotocin-induced diabetic rats treated with 200 to 400 mg per kg of the extract compares favourably with glibenclamide at standard doses, and is achieved without the hypoglycaemic episodes associated with sulfonylureas. The accompanying restoration of hepatic glycogen, insulin and antioxidant enzymes indicates that the effect is mechanistically broader than insulin secretion alone.

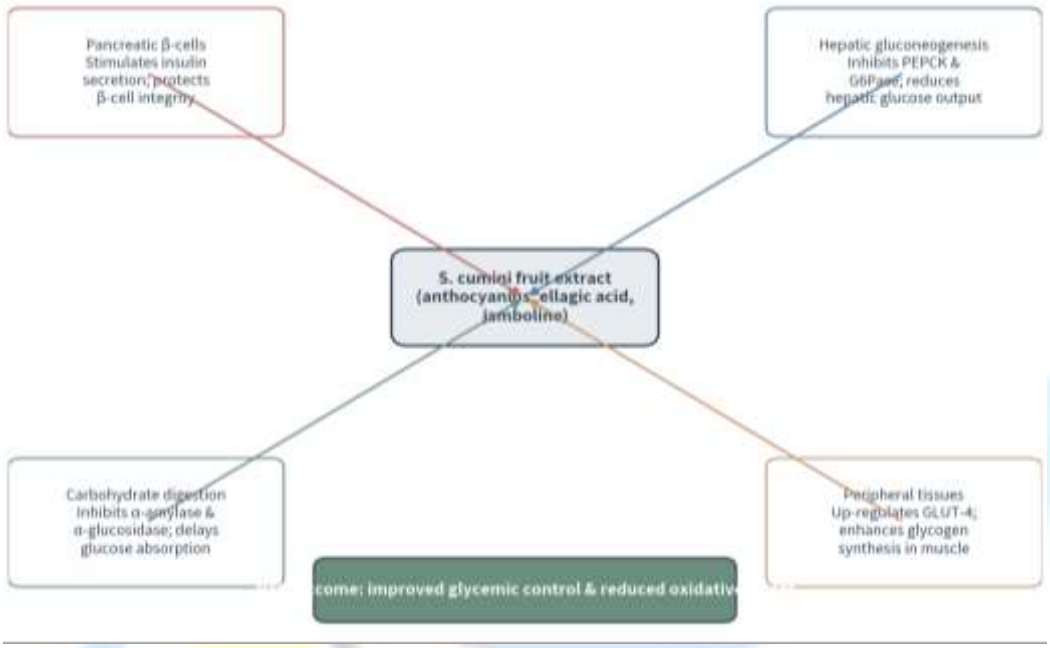

Figure 5: Proposed multitarget antidiabetic mechanism of Syzygium cumini fruit extract bioactive constituents

Figure 5 schematically integrates the available mechanistic evidence into a four-axis model. Anthocyanins and jamboline act on the pancreatic beta cells to stimulate insulin secretion and protect against oxidative apoptosis. Ellagic acid and related tannins inhibit hepatic gluconeogenic enzymes, reducing endogenous glucose output. The flavonol fraction inhibits alpha-amylase and alpha-glucosidase in the intestinal lumen, delaying glucose absorption. Finally, anthocyanins up-regulate GLUT-4 translocation and glycogen synthase in skeletal muscle, enhancing peripheral glucose disposal. The net outcome is improved glycaemic control coupled with reduction of oxidative stress, which is increasingly recognised as a driver of diabetic complications.

Nevertheless, the discussion must acknowledge the limitations repeatedly highlighted in the critical analysis. Without marker-based standardisation, scale-up, accelerated stability data and human pharmacology, the formulations remain at the proof-of-concept stage. A concerted, multidisciplinary effort involving phytochemists, formulation scientists, pharmacologists and clinical investigators will be required to advance S. cumini tablets from the laboratory to the clinic. Regulatory pathways for herbal medicines, such as the WHO Certificate of Pharmaceutical Product and the Indian AYUSH-GMP framework, provide a usable framework for this translation. When compared with other well-characterised antidiabetic botanicals such as Momordica charantia, Trigonella foenum-graecum and Gymnema sylvestre, S. cumini stands out for the breadth of its phytochemical profile and the consistency of its pre-clinical evidence. Momordica charantia exhibits comparable hypoglycaemic potency but suffers from reproducibility issues linked to its variable cucurbitacin content, while Trigonella foenum-graecum acts mainly through soluble fibre-mediated reduction of intestinal glucose absorption, providing a complementary rather than overlapping mechanism. The combination of S. cumini with one or more of these botanicals, as explored by Biswas and colleagues (2018), offers a rational polyherbal strategy worthy of further systematic investigation.

From a regulatory standpoint, the integration of S. cumini tablets into mainstream diabetes care will require classification under a clear framework such as the European Medicines Agency guideline on herbal medicinal products, the United States Food and Drug Administration Botanical Drug Development Guidance, or the Indian Drugs and Cosmetics Act provisions for Ayurvedic, Siddha and Unani medicines. Each pathway demands evidence of botanical identity, manufacturing consistency, pre-clinical safety and at least one positive randomised clinical trial. None of these requirements is currently satisfied by the published literature, but the path forward is technically feasible and financially modest compared with the development of a new standard drug.

6. CONCLUSION

This review has surveyed thirty representative studies on the formulation and evaluation of tablets containing Syzygium cumini fruit extract for the management of diabetes mellitus. The cumulative evidence establishes that the ripe fruit pulp, on hydroalcoholic extraction and compression with microcrystalline cellulose-based diluents, yields tablets of acceptable pharmacotechnical quality and reproducible antidiabetic activity in streptozotocin-induced animal models. The mechanism of action is multitarget, encompassing insulin secretion, hepatic gluconeogenesis inhibition, intestinal carbohydrate digestion inhibition and peripheral glucose uptake. However, the field is held back by inconsistent standardisation, variable extraction protocols, incomplete evaluation batteries and the near-total absence of human clinical trials. Future research should prioritise marker-based quality control using ellagic acid and total anthocyanin as dual markers, lyophilised standardised extracts, sustained-release formulations with hydroxypropyl methylcellulose, formal stability testing under ICH Q1A conditions, genotoxicity and reproductive toxicity studies in accordance with OECD guidelines, and rigorously designed phase I and II randomised clinical trials. Only through such a structured, multidisciplinary program can this traditionally revered plant be transformed into an evidence-based, affordable and reliable adjunct to modern diabetes care, with particular relevance to the populations of the Indian subcontinent and other low- and middle-income regions where the burden of diabetes is rising most rapidly.

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