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Regulatory requirements for antidiabetic drugs as per CDSCO in India comparison with USA

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ABSTRACT

With India and the United States having the highest rates of the disease, diabetes mellitus is becoming a global public health concern. In India, which is expected to have the world's biggest diabetic population (more than 101 million by 2023), accessibility and price are major concerns. A significant component of the antidiabetic medication market, which is projected to reach a valuation of USD 1.7 billion in 2024 and is projected to grow at a compound annual growth rate (CAGR) of 3.5% to reach USD 2.01 billion by 2029[1]. The primary treatment for Type 2 Diabetes (T2DM) is still metformin, which is augmented by sulfonylureas, DPP-4 inhibitors, and more recently, SGLT2 inhibitors. With new limitations on illogical fixed-dose combinations, regulatory bodies such as the CDSCO are actively trying to guarantee the safety and effectiveness of pharmaceuticals [2]. Diabetes is a chronic, metabolic disease characterized by elevated blood glucose levels or hyperglycaemia, which results from abnormalities in either insulin secretion or insulin action, or both. According to the report from CDC's National Diabetes Statistics Report, there are about 37.3 million cases of diabetes in the US which is 11.3% of the US population. The kind of drug most frequently used to treat type 1 diabetes Insulin. Insulin, alpha-glucosidase inhibitors, biguanides, dopamine-2 agonists, DPP-4 inhibitors, GLP-1 receptor agonists, meglitinides and SGLT2 inhibitors, sulfonylureas, thiazolidinediones, and other drugs are commonly used orally to treat type 2 diabetes [3].

Keywords: Antidiabetics, Diabetes Mellitus, Regulatory Bodies, CDSCO, FDA, United States

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INTRODUCTION

The chronic metabolic disease known as diabetes is characterized by elevated blood glucose (blood sugar) levels. This happens as a result of either insufficient insulin production by the pancreas or inefficient insulin utilization by the body. Diabetes comes in various forms, each with unique symptoms, causes, and methods of treatment. Previously, it was referred to as insulin-dependent diabetes or juvenile diabetes. The most common types of diabetes are type 1, type 2, and gestational diabetes.es, type 1 diabetes is an autoimmune illness. It typically appears in children and teenagers, though it can occur at any age. About 90% of all occurrences of diabetes are type 2, making it the most common kind. Although the majority of those impacted are over 45, children and young adults are also increasingly receiving the diagnosis. Gestational diabetes is a form of the disease that can strike pregnant women who have never had diabetes before.[4].

A family of pharmaceuticals known as antidiabetic medicines is intended especially to regulate and control blood glucose (sugar) levels in people with diabetes mellitus. These medications' main objective is to lower blood sugar levels to a healthy range.

Controlling blood sugar and preventing complications are the main objectives of diabetes treatment. Treatment options for gestational diabetes, type 1 diabetes, and type 2 diabetes vary.

Diabetes management typically involves a combination of life style adjustment and, if monitoring blood sugar, dietary changes, exercise, and various oral or injectable medications, including insulin. Some individuals may also benefit from bariatric surgery or, in case of type 1 diabetes, pancreas transplantation.

As of 2023, the prevalence of diabetes in India stands at 10.1 crore (101 million) people, according to the Indian Council of Medical Research (ICMR-INDIAB) study. The International Diabetes Federation (IDF) in 2024 reported a prevalence of 10.5% in adults, accounting for nearly 90 million adult cases. These numbers are projected to rise significantly, with estimates reaching over 125 million by 2045[5].

Classification Of Antidiabetic Drugs

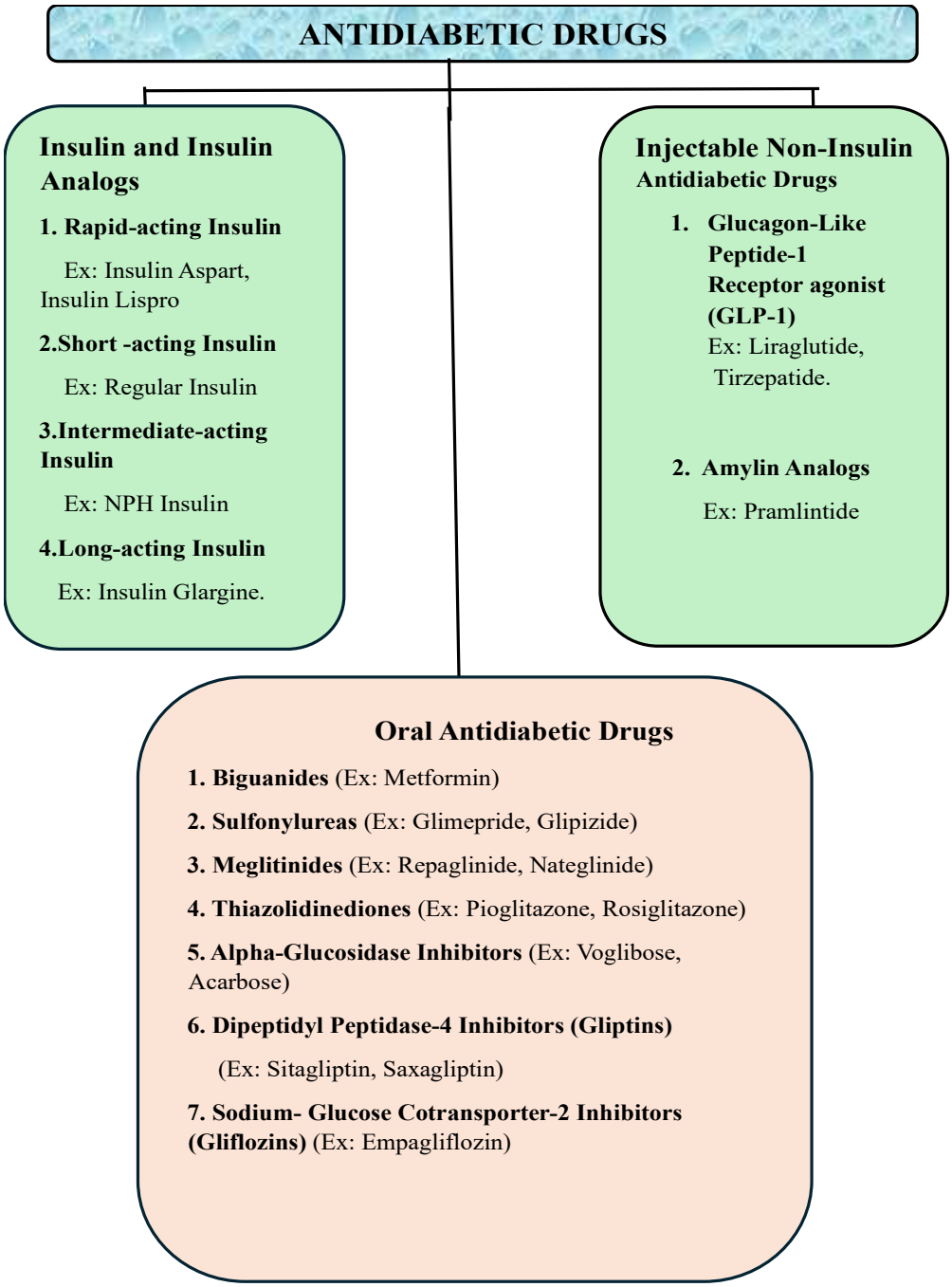

Figure 1: Antidiabetic Drugs

Insulin and Insulin Analogs

In order to initiate glucose uptake from the bloodstream and support different metabolic processes, insulin and its analogs mainly function via attaching to insulin receptors on cell surfaces [6].

Type	Examples	Onset	Peak	Duration
Rapid-acting	Lispro, Aspart, Gl	10–30 minutes	30 min – 2 hours	3–5 hours
Short-acting	Regular insulin	30–60 minutes	2–4 hours	5–8 hours
Intermediate-acting	NPH (not ananalog)	1–2 hours	4–12 hours	12–18 hours
Long-acting	(Lantus), Detemir	1–2 hours	Minimal peak	Up to 24 hours

ORAL ANTIDIABETIC DRUGS

1. Biguanides (Ex: Metformin)

Reduce intestinal glucose absorption, enhance insulin sensitivity in peripheral tissues (fat and muscle), and lessen hepatic glucose synthesis (gluconeogenesis).

2. Sulfonylureas (Ex: Glimepiride)

Sulfonylureas stimulate insulin release by binding to sulfonylurea receptors (SUR1) on pancreatic β-cells.

This closes ATP-sensitive potassium channels, causing membrane depolarization and calcium influx.

The rise in intracellular calcium triggers exocytosis of insulin granules, lowering blood glucose.

3. Meglitinides (Ex: Repaglinide)

Meglitinides stimulate insulin release from pancreatic beta-cells by closing ATP-sensitive potassium channels. Depolarization, calcium influx, and insulin secretion follow from this. Their quick, short-acting action makes them ideal for controlling postprandial glucose levels.

4. Thiazolidinediones (Ex: Pioglitazone)

Improve insulin sensitivity in muscle, fat, and liver by activating PPAR-\gamma (peroxisome proliferator-activated receptor-gamma).

5. Alpha-Glucosidase Inhibitors (Ex: Voglibose)

Reduce subsequent (after-meal) glucose spikes by delaying the small intestine's capacity to digest and absorb carbohydrates.

6. Dipeptidyl Peptidase-4 Inhibitors (Ex: Sitagliptin)

Dipeptidyl peptidase-4 (DPP-4) inhibitors, also known as gliptins, work by blocking the enzyme DPP-4. This enzyme normally breaks down incretin hormones like GLP-1 and GIP. By inhibiting DPP-4, these drugs increase the levels of active incretin hormones, leading to enhanced glucose-dependent insulin secretion and suppressed glucagon release, ultimately lowering blood glucose.

7. Sodium-Glucose Cotransporter-2 Inhibitors (Ex: Dapagliflozin) Increased glucose excretion in the urine (glycosuria) results from blocking SGLT2 in the kidneys, which stops glucose from being reabsorbed from the urine back into the bloodstream.

INJECTABLE NON-INSULIN ANTIDIABETIC DRUGS

1.Glucagon-Like Peptide-1 (GLP-1) Receptor Agonists

By promoting fullness, suppressing glucagon release, boosting the secretion of glucose-dependent insulin, and postponing stomach emptying, they replicate the actions of endogenous GLP-1.

2. Amylin Analogs:

Mimic the action of amylin, a hormone co-secreted with insulin from the pancreas. They increase satiety, inhibit postprandial glucagon secretion, and slow stomach emptying [7].

REGULATORY BODY OF INDIA

Central Drug Standard Control Organization (CDSCO)

The Central Drugs Standard Control Organization (CDSCO) is the national regulatory authority of India for pharmaceuticals and medical devices, functioning under the Ministry of Health and Family Welfare.

Objective: To guarantee the quality, safety, and effectiveness of medications, cosmetics, and medical equipment in India. In India, the Drugs Controller General of India (DCGI), a CDSCO officer, has the last say over whether clinical studies are approved. The DCGI receives input from the Drug Technical Advisory Board (DTAB) and the Drug Consultative Committee (DC

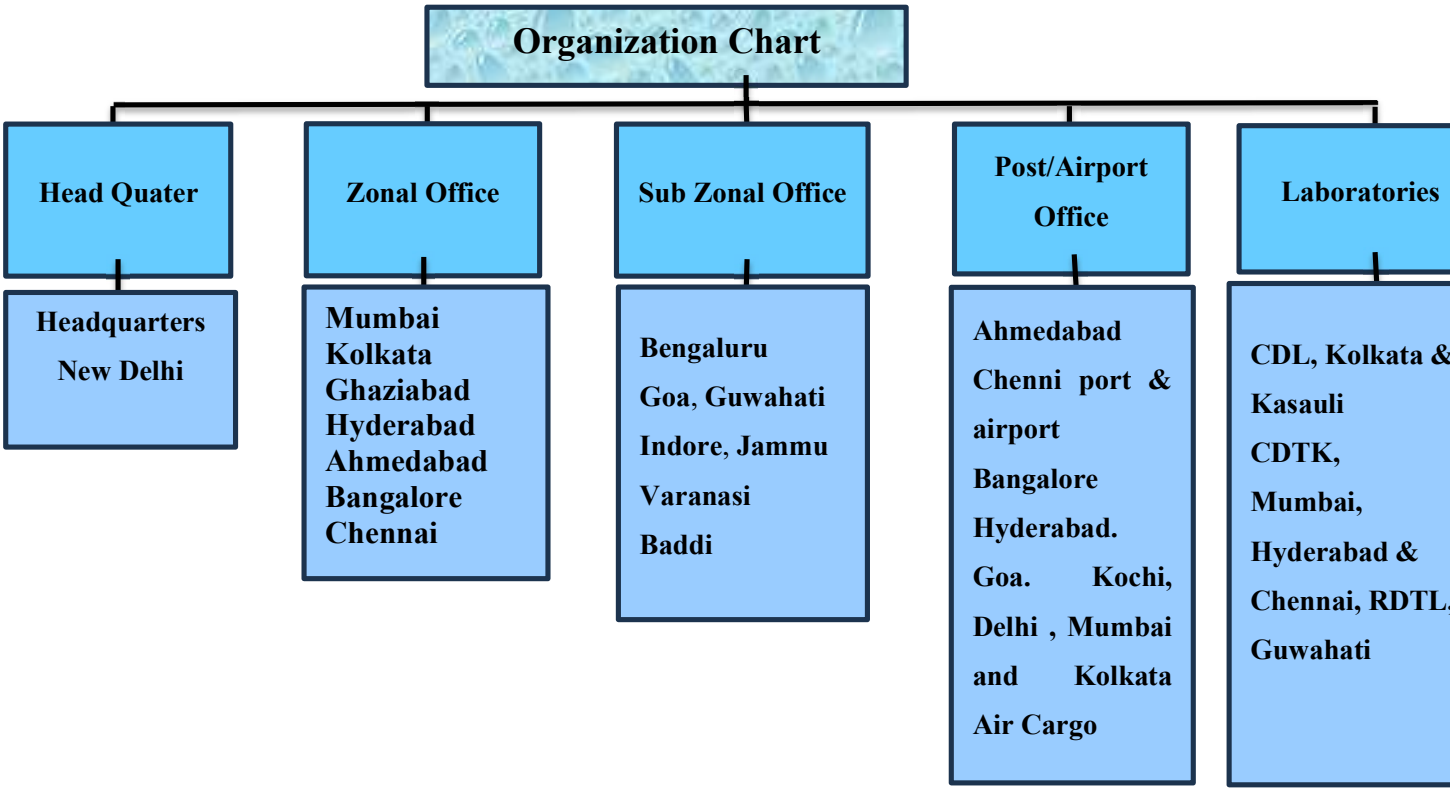

Figure 2: Organization of CDSCO

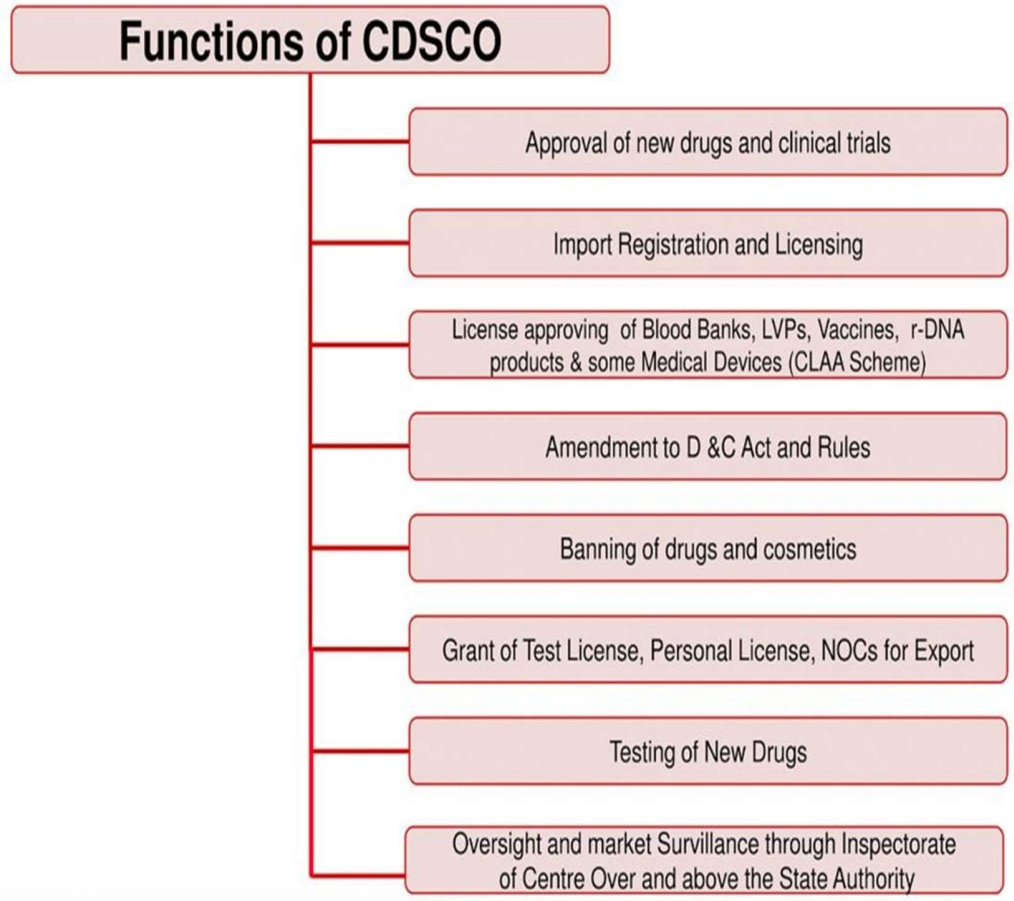

Figure 3: Functions of CDSCO

REGULATORY REQUIRMENTS FOR ANTIDIABETIC DRUGS AS PER CDSCO

The Drugs and Cosmetics Act of 1940 and the Rules of 1945 regulate the regulatory requirements for antidiabetic medications in India, according to the Central Drugs Standard Control Organization (CDSCO).

1. Drug Classification: Due to differences in the process, the applicant must first place the antidiabetic medication into one of the following groups before applying:

New Drug (ND): In India, this compound has never been offered for sale.

Subsequent New Drug (SND): A new dosage form, strength, route of administration, or indication for an already approved antidiabetic drug.

Fixed-Dose Combination (FDC): a novel mix of two or more antidiabetic medications in a predetermined proportion.

Investigational New Drug (IND): a substance that is still being researched or tested and has not yet been given commercial approval.

2. Pre-clinical Studies:

Before testing in humans:

- Toxicological studies (acute, sub-acute, chronic)
- Pharmacology studies (mechanism of action, pharmacodynamics)
- Animal models (efficacy, especially in diabetic models)

3. Clinical Trials Approval

Submit Clinical Trial Application (CTA) with Form CT-04.

Conduct trials in 3 or 4 phases as per New Drugs and Clinical Trials Rules, 2019:

- Phase I: Safety in healthy volunteers
- Phase II: Efficacy and dose-ranging in patients
- Phase III: Confirmatory trials on larger population
- Phase IV: Post-marketing surveillance

4. New Drug Application (NDA)

Submit Form CT-21 for marketing authorization.

Include:

- Complete clinical trial data
- CMC data (Chemistry, Manufacturing & Controls)
- Stability studies (as per ICH guidelines)
- Risk Management Plan (RMP

5. Review and Evaluation: Relevant Subject Expert Committees (SECs) evaluate applications

Applications are reviewed by relevant Subject Expert Committees (SECs), which comprise medical and scientific experts. The SEC provides recommendations to the DCGI.

DCGI Approval:

The DCGI provides marketing approval (Form 45 for import, Form 46 for production) based on the SEC's recommendations and a careful examination of the data supplied.

Post Manufacturing Approval:

Manufacturers are required to submit periodic safety update reports (PSURs) and conduct post-marketing surveillance to continually monitor the drug's safety profile.

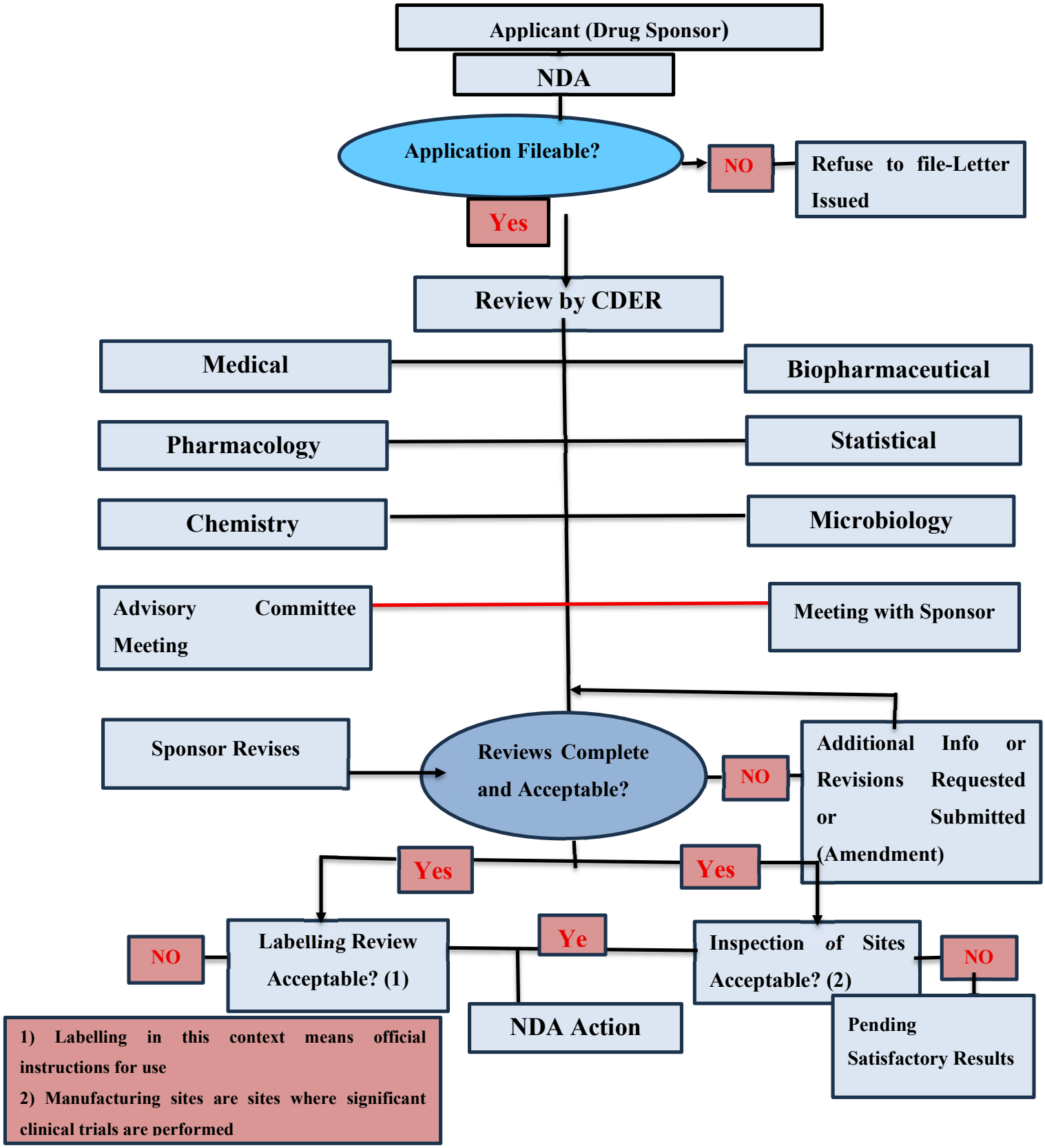

Figure 4: NDA chart

6. Fixed-Dose Combinations (FDCs)

For antidiabetic FDCs (e.g., Metformin + Glimepiride):

Must comply with CDSCO FDC guidelines.

Pharmacokinetic compatibility, safety information, and combination justification are required.

7. Post-Marketing Surveillance (PMS) Phase IV research may be required.

Phase IV studies may be mandated.

Periodic Safety Update Reports (PSURs) must be submitted every 6 months for the first 2 years and annually for the next 2 years.

Adverse Drug Reaction (ADR) monitoring is required.

8. Labelling and Packaging

As per Drugs and Cosmetics Rules, include:

- Drug name, strength.
- Manufacturer details.
- Warnings (e.g., hypoglycemia).
- Storage conditions.
- Prescription drugs with a Schedule H or G classification.

Regulatory Requirements for Manufacturing of Antidiabetic Drugs

The primary agency in charge of overseeing the manufacturing of antidiabetic drugs is the Central Drugs Authority of India

Standard Control Organization (CDSCO) under the Drugs and Cosmetics Act, 1940 and

Rules, 1945. Here are the key regulatory requirements:

1. Manufacturing License: Manufacturers need to get a current manufacturing license from the appropriate State Licensing Authority (MD-5/MD-9 for medical devices like glucometers, or Form 25/28 for medications).

2. Good Manufacturing Practices (GMP): strict compliance with Schedule M of the 1945 Drugs and Cosmetics Rules, which describes the extensive GMP specifications for operations, plant, facilities, and equipment.

3. Quality Management System: installation of a strong quality control system that guarantees constant product quality across all stages, from raw materials to final products.

4. Qualified Personnel: deployment of sufficient and skilled technical personnel for production, quality assurance, and control.

5. Approved Facilities: Manufacturing premises must meet specific design and

environmental control standards to prevent contamination and ensure product integrity.

6. Calibration and Qualification of Equipment: All production and testing equipment must undergo regular maintenance, calibration, and qualification.

7. Raw Material Control: Stringent control over sourcing, testing, and release of all raw materials and excipients, including adherence to pharmacopoeia standards.

8.In-process Controls: the use of designated in-process controls to monitor and control important parameters during various stages of manufacturing.

9. Finished Product Testing: Comprehensive testing of finished products for identity, purity, potency, and dissolution as per pharmacopoeia specifications.

10. Stability Studies: Conducting accelerated and real-time stability studies to establish shelf-life and appropriate storage conditions.

11. Documentation and Records: Meticulous maintenance of batch manufacturing records, analytical records, SOPs, and validation documents.

12. Validation: Validation of critical manufacturing processes, analytical methods, and cleaning procedures to ensure consistent results.

13. Change Control: A documented system for managing and approving any changes to processes, equipment, or materials.

14. Recall Procedures: Established procedures for rapid and effective recall of defective products from the market.

15. Pharmacovigilance: procedures for keeping track of and informing CDSCO of adverse medication reactions once they occur.

5.REGULATORY BODY OF USA

UNITED STATE FOOD AND DRUG ADMINISTRATION

In the U.S. Department of Health and Human Services (HHS), the Food and Drug Administration (FDA) is a crucial government department. By regulating and overseeing a broad range of products and guaranteeing their security, efficacy, and safety, its main goal is to safeguard and advance public health [9].

Organization of the USFDA

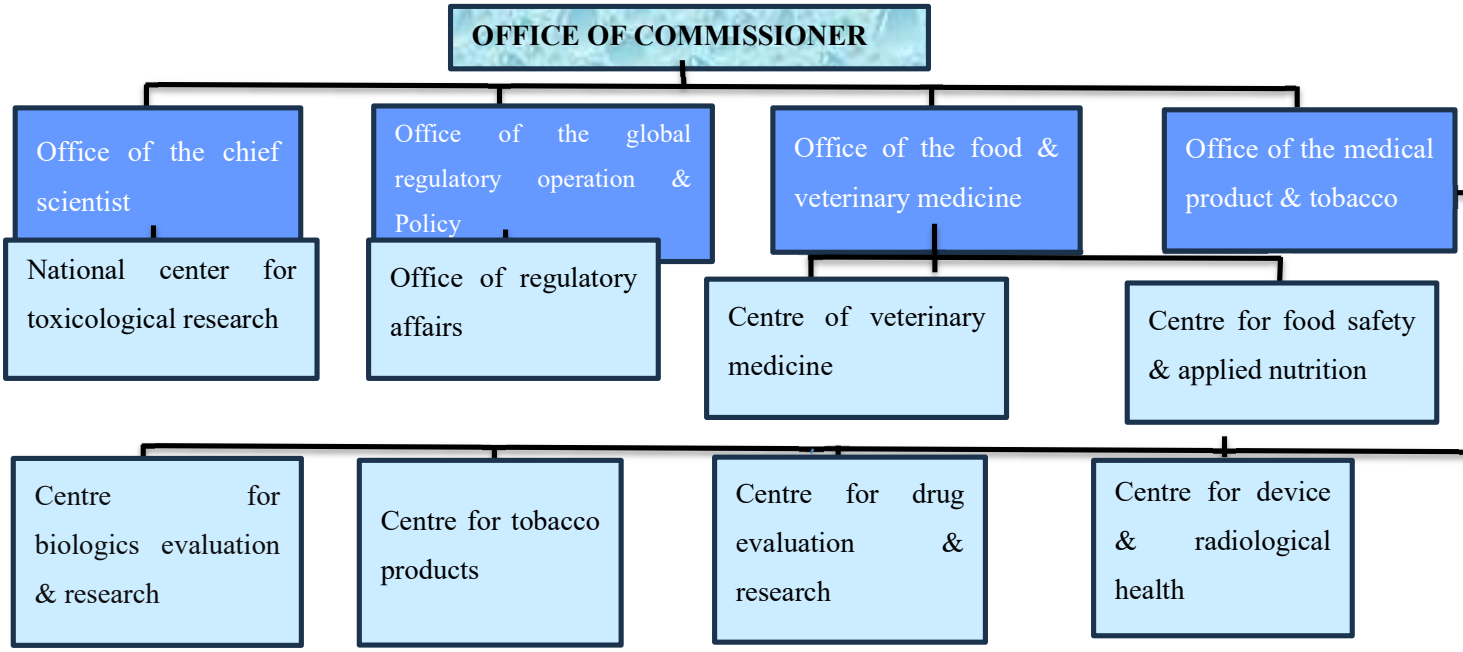

Figure 5: Organization of USFD

Functions of USFDA

Category	Functions
Drug Regulation	Approves new drugs (NDA, ANDA, BLA) Monitors drug safety and labeling
Biologics Control	Regulates vaccines, blood products, and gene therapies
Medical Devices	Examines and categorizes medical equipment Grants premarket approvals
Food Safety	Ensures food labeling accuracy Monitors food additives and contaminants

6. REGULATORY REQUIRMENTS FOR ANTIDIABETIC DRUGS AS PER USFDA

The regulatory requirements for antidiabetic drugs in the USA are primarily governed by the U.S. Food and Drug Administration (FDA). These requirements ensure the safety, efficacy, and quality of the drugs before and after they reach the market.

1. Regulatory Authority

U.S. Food and Drug Administration (FDA)

- Center for Drug Evaluation and Research (CDER) evaluates all antidiabetic drugs.

2. Preclinical Requirements

Before testing in humans, the drug sponsor must:

- Perform studies on toxicity, pharmacodynamics, and pharmacokinetics in animals and in vitro studies
- Follow Good Laboratory Practices (GLP).
- Apply to the FDA for an Investigational New Drug (IND).

3. Clinical Trials (Human Studies)

Clinical trials must follow Good Clinical Practice (GCP) and are conducted in 4 phases:

Phase	Purpose	Participants
Phase I	Safety, dosage	20–100 Healthy volunteers or patients
Phase II	Efficacy, side effects	100–300 Diabetic patients
Phase III	Confirmation, comparison	300–3000 + Patients
Phase IV	Post-marketing surveillance	General public

New Drug Application (NDA)

If trials show safety and efficacy:

- Sponsor submits an NDA to the FDA, including:
- Clinical data
- Chemistry, Manufacturing and Controls (CMC)
- Labeling
- Risk Evaluation and Mitigation Strategy (REMS), if needed
- Advisory groups may be consulted by the FDA following the assessment of the NDA.

5. Labeling Requirements

Must include clear indications, dosage, warnings, and instructions.

Must follow FDA labeling guidelines (21 CFR Part 201).

6. Manufacturing Compliance

- Manufacturing must follow Current Good Manufacturing Practices (cGMP) under 21 CFR Parts 210 and 211.
- Facilities are subject to FDA inspection.

7. Post-Marketing Surveillance

- Monitor adverse effects via the FDA MedWatch system.
- Periodic safety update reports (PSURs) may be required.
- Phase IV studies might be mandated to further assess long-term safety [10].

8. Special Considerations for Antidiabetic Drugs

- Must demonstrate glycemic control (e.g., HbA1c reduction).
- May require cardiovascular outcome trials (CVOTs) to assess heart safety (especially for Type 2 diabetes drugs).
- Long-term safety, especially regarding weight gain, hypoglycemia, pancreatitis, and cancer risks, is emphasized.

REGULATORY REQUIRMENTS FOR MANUFACTURING OF ANTIDIABETIC DRUGS IN USA

To guarantee product safety, effectiveness, and quality, strict regulations must be followed throughout the manufacturing of antidiabetic medications (such as metformin, sulfonylureas, DPP-4 inhibitors, insulin analogs, etc.). These requirements are laid out by the national regulatory authorities, most notably the U.S. Food and Drug Administration (FDA).

1. Compliance with current good manufacturing practices, or cGMP

All facilities manufacturing antidiabetic drugs must comply with cGMP as defined under 21 CFR Parts 210 and 211.

cGMP covers:

- Facility design and hygiene
- Proper training of personnel
- Controlled manufacturing processes
- Documented standard operating procedures (SOPs)
- Validation of equipment and processes
- Cleanroom standards for sterile products like insulin

2. Quality Assurance and Quality Control (QA/QC)

- A dedicated QA/QC department must be in place to oversee:
- Raw material testing
- In-process and finished product testing
- Stability studies
- Environmental monitoring

Product must meet pharmacopoeia standards (e.g., USP, BP, IP).

3. Active Pharmaceutical Ingredient (API) and Excipients

- API must be sourced from GMP-certified suppliers.
- Complete Drug Master File (DMF) may be required.
- Pharmaceutical-grade excipients backed by safety evidence are required.

4. Validation of Manufacturing Process

Process validation is mandatory for all manufacturing steps:

- Blending, Granulation, Compression or filling, Coating, Sterilization (if applicable) Ensures the process yields consistent quality.

5. Analytical Method Validation

- All analytical tests (e.g., assay, dissolution, impurities) must be:

- Validated for accuracy, precision, specificity, and robustness.
- Based on ICH Q2 (R1) guidelines.

6. Documentation and Records

- All manufacturing activities must be recorded in:
- Batch Manufacturing Records (BMR)
- Batch Packaging Records (BPR)
- Equipment logs

Records must be kept for a minimum of 1 year after expiry of the product.

7. Packaging and Labeling Controls

Packaging materials must be tested and approved.

Labels must comply with:

- FDA regulations (21 CFR Part 201)
- Include dosage, warnings, expiry, lot number, etc.

8. Stability Studies

- Conducted under ICH guidelines (Q1A–Q1F).
- Determines the product's shelf life under various conditions.
- Supports the expiry date and storage conditions.

9. Regulatory Filings

For US market:

- ANDA (Abbreviated New Drug Application) for generics
- Novel antidiabetic compounds' New Drug Applications (NDAs)
- Require a comprehensive CMC (Chemistry, Manufacturing & Controls) section.

10. Inspections and Audits

Manufacturing facilities must be ready for audits by the FDA, which regularly inspects them.

Non-compliance can result in Form 483, warning letters, or import alerts.

7. COMPARISION BETWEEN REGULATORY REQUIRMENTS FOR ANTIDIABETIC DRUGS IN INDIA AND USA

Figure 6: India and USA

Table 1: Comparison between Regulatory Requirements for antidiabetic drugs in INDIA and USA

SL.NO	Features	India	USA
1.	Regulatory Bodies	The Central Drugs Standard Control Organization (CDSCO)	The Food and Drugs Administration (FDA)
2.	Role	The CDSCO is responsible for regulating drugs, medical devices, and clinical trials in India.	By regulating pharmaceuticals, medical devices, and biologics, the FDA guarantees their efficacy and safety.
3.	Guidelines	The CDSCO follows the Drugs and Cosmetics Act, 1940, and various rules formulated under it	The Federal Food, Drug, and Cosmetic Act (FDCA) governs this industry.
4.	Regulatory department working for drug approval	Drug Controller General of India (DGGI)	Centre of Drug Evaluation and Research (CDER)
5.	Fees	50,000 INR	Under USD 2 Million
4.	Approval Process	The approval process includes Clinical Trials Phase I-III, followed by a review. For new drugs, there is a need for a new drug application (NDA). The process can take several months to years, depending on how well the trial data supports efficacy and safety.	FDA also needs comprehensive clinical trials (Phase I–III). The New Drug Application (NDA) is submitted, and the review process includes inspections and recommendations from an Advisory Committee, typically resulting in decisions within 10 months for standard applications or 6 months for priority applications.
5.	Approval Timelines	Generally, approval timelines can be longer due to bureaucratic processes,	The FDA's typically more efficient procedures allow for faster access, especially for novel devices and

		though recent reforms aim to expedite the process.	therapies.
6.	Clinical Trial	The Drugs and Cosmetics Act regulates clinical trial guidelines, which include ICH-GCP recommendations. Requirement for ethical approval from an Institutional Review Board (IRB) and informed consent from participants are mandatory.	The FDA has stringent rules for clinical trials, including Good Clinical Practice (GCP) guidelines. Institutional Review Boards (IRBs) must approve studies, and informed consent is strictly enforced.
7.	Funding	Whereas CDSCO relies on government funding.	FDA is self-funded through user fees
8.	Regulatory Framework	Governed by the Drugs and Cosmetics Act of 1940 and rules laid down in CDSCO notifications. Although recent amendments seek to streamline procedures, enforcement is still difficult.	The Federal Food, Drug, and Cosmetic Act (FDCA) governs this industry. Every facet of drug regulation is covered by the FDA's extensive guidance materials and clearly defined procedures.
9.	Risk-Benefit	Analysis The CDSCO evaluates risks based on clinical trial data, but resources for thorough analysis may be limited.	The FDA conducts a detailed risk-benefit analysis, utilizing extensive data from trials, real-world evidence, and other scientific resources to assess the safety and effectiveness of drugs.
10.	Specific Guidelines for Antidiabetic Drugs	CDSCO reviews antidiabetic drugs, the specific guidelines and their enforcement regarding long-term cardiovascular outcomes or the rationale for certain FDCs have been subjects of discussion and reform. CDSCO's Subject Expert Committees (SECs) review and suggest applications for anti-diabetic drugs.	The FDA has specific guidance documents for the development of antidiabetic drugs, emphasizing the need to rule out an unacceptable increase in cardiovascular risk. As a result, all participants underwent thorough cardiovascular outcome trials (CVOTs).

7. MARKET SCENARIO FOR ANTIDIABETIC DRUGS IN INDIA AND USA

The antidiabetic medication industry in India is growing and prospering. The market for diabetes medications was expected to be worth USD 6.86 billion in total by 2024. Forecasts indicate that the sector will expand significantly, reaching approximately USD 11.46 billion by 2032[1].

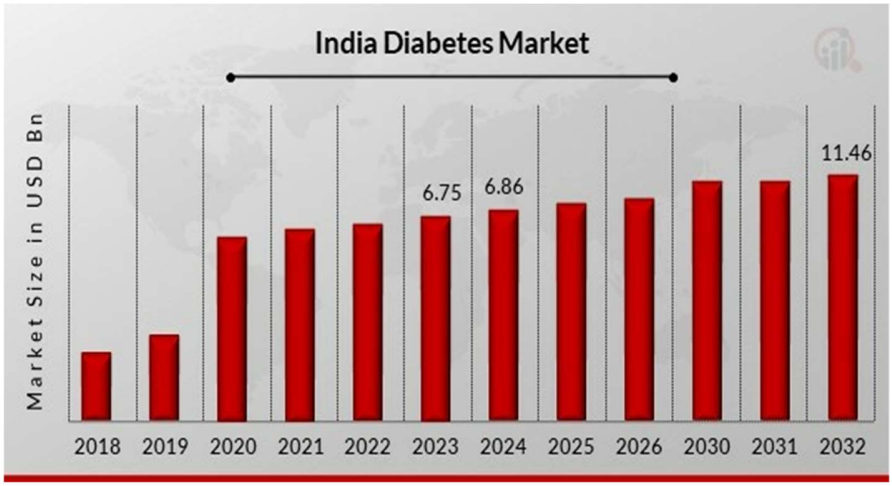

Figure 7: Indian Diabetes Market

In North America, the United States has the largest market share., the U.S. antidiabetic medicine market is a pillar of the worldwide diabetes treatment landscape. It is expected to grow from its 2023 valuation of about USD 31.50 billion to USD 42.50 billion by 2033.

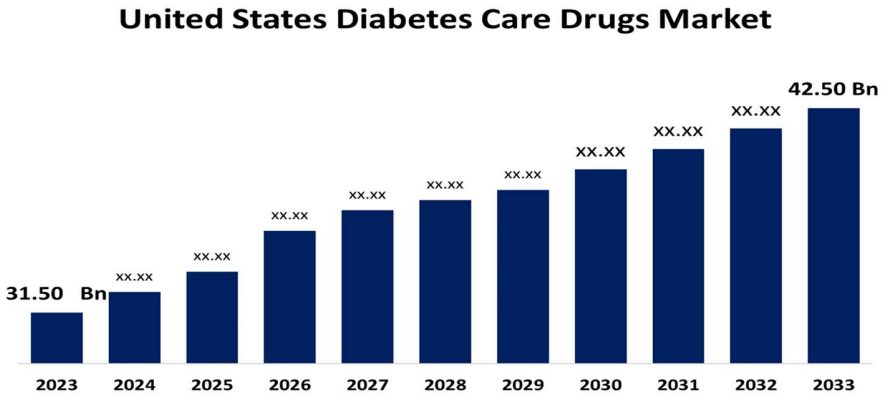

Figure 8: US Diabetes Care Drug Market

CONCLUSION

The safety and effectiveness of antidiabetic medications are the goals of regulatory standards in the USA and India, although their methods vary. India's CDSCO focusses on centralized approval for new drugs and combination therapies, while the USFDA employ a more structure review process, including standard and priority reviews, with emphasis on cardiovascular outcomes trails for certain drugs. Despite the fact that both India and the USA employ a range of antidiabetic drugs, their approaches vary because of the disparities in patient requirements and healthcare systems. While the use of newer medicine classes like SGLT-2 and DPP-4 inhibitors is increasing, India still prioritizes traditional therapies and affordable generics. Though price is still an issue, the USA

leads the world in innovation and diversity, providing state-of-the-art treatments including combo injectables and GLP-1 agonists.

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