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# A Comparative Analysis of Generic Drug Assessment and Regulatory Approval in the USA, Europe and India

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**Abstract** The Abbreviated New Drug Application (ANDA) is used for the regulatory submission of generic drugs, which are pharmaceutical equivalents to brand-name drugs and distributed without patent protection. Different countries have their own regulatory requirements for the approval of generic drugs, enforced by authorities such as the CDSCO in India, EDQM in Europe, and USFDA in the United States. This review aims to compare the regulatory processes and requirements for generic drug approval in India, Europe, and the US, highlighting key differences and challenges. The involvement of regulatory authorities in the drug development process is crucial for expediting approval and addressing queries, helping to minimize delays. The Common Technical Document (CTD) format is employed across regions to harmonize submission requirements. This study underscores the differences in dossier submission for generics across the three regions, illustrating India's position in the global generic drug approval landscape. By comparing approval requirements, this work provides insight into the hurdles India must overcome to streamline its approval process. The ANDA allows generic manufacturers to submit bioequivalence studies, using the original innovator's safety and efficacy data. However, obtaining approval simultaneously from multiple regulatory authorities remains a challenging task. Careful review of regulatory documents by skilled personnel can reduce regulatory queries, ultimately accelerating the market launch of generic drugs. This review provides a comprehensive overview of the generic drug approval process, emphasizing the need for harmonization and improved efficiency in India's regulatory framework.

**Keywords** Generic Drug, Regulatory Approval, Abbreviated New Drug Application, Common Technical Document

## Introduction

Life expectancy of patients has increased globally during the last three decades due to the new drug discovery (brand-name drugs) as well as generic drug production. It is well known that most health

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care interventions occur through medication. The rising cost of medication has been contributing to the total overall cost of healthcare and thus receives considerable attention globally. A major strategy for lowering the cost of medication, and thereby reducing its contribution to total health care costs, has been the introduction of generic equivalents of brand-name drugs (innovator drugs).[1-4] This strategy has been effective in reducing total prescription cost by 11% without sacrificing quality.[5] Generic drugs have captured more than 65% of the global market.[6]

## Facts about generics and generics drug applications (ANDA)

• Generic drug applications are termed "abbreviated" because they are generally not required to include preclinical (animal) and clinical (human) data to establish safety and effectiveness.

• Generic applicants must scientifically demonstrate that their product is bioequivalent (i.e., performs in the same manneras the innovator drug).

• Bioequivalence is generally determined by measuring the time taken for generic drug to reach the bloodstream in 24 to 36 healthy, volunteers. This gives the rate of absorption, or bioavailability, of the generic drug, which can be compared to that of the innovator drug.

• The generic version must deliver the same amount of active ingredients into a patient's bloodstream in the same amount of time as the innovator drug. [7-8]

## Goals of ANDA

√ To reduce the price of the drug

√ To reduce the time of drug development

√ To increase the Bioavailability of the drug in comparison to the reference listed drug product.[9]

## Generic drug marketing

To gain regulatory approval for the generic drug, all companies have to prove that its generic version is pharmaceutically equivalent to the original. If the generics chemical makeup is the same, it's assumed that the preclinical, clinical trials and research are as applicable to the generic drug as they were to the original. Regulatory requirements like forms, CTD format whatever is required to the respective country must be compiled by the applicant and submitted to the respective regulatory authority.

## Regulatory authorities, regulatory aspects, and international efforts to harmonize approaches to bioequivalence assessment [10-11]

Due to significant recognition of the BA/BE concept all over the world, tremendous advancements have been made by the FDA as well as various national, international, and supranational regulatory authorities. In parallel, pharmaceutical industry and academia are also contributing exclusively in the area of assessment of BE. Currently available approaches to determine BE of generic products are largely standardized due to discussion and consensus reached among various stakeholders at numerous national and international meetings, conferences, and workshops (eg, American Association of Pharmaceutical Scientists, Federation International Pharmaceutics). Thus the currently available excellent scientific and regulatory guidance documents are due to the combined efforts of industry, academia, and regulatory scientists. Apart from the ICH and WHO other European and Asian organizations (national and international) are actively involved in harmonization efforts for assessing of BE and improving the quality of pharmaceutical products globally.

### • *INDIA*

In India, drugs are regulated both at central and state level. At the state level, state drug regulatory authorities issue licenses to manufacture approved drugs to monitor the quality of the drugs along with Central Drugs Standard Control Organization (CDSCO). At the central level, CDSCO under the Ministry of Health and Family Welfare is responsible for approving of new drugs, clinical trials, and licensing of drugs in India; the regulation of drug, r-DNA, medical devices, and biological products is distributed within various ministries.[12]

### • *USFDA*

In the United States, FDA is the drug regulatory authority for approving food, human and veterinary drug products that are to be marketed in the USA.[13]

### • *EMA*

In Europe, European Medicines Agency is the regulatory agency for approving human and veterinary drug products centrally to market the drugs in European Union (EU). There is also entity National Competent Authorities for favorable the drug products in EU individual states. The objective of this study is to figure out the determinants for selecting a generic application and the rigid aspects concerned in generic drug development. Understanding the differences between three countries and highlighting the generic drug approval process in the US, EU, and India. Each and every study has some follows certain pathways and patterns to attain the goal.[14]

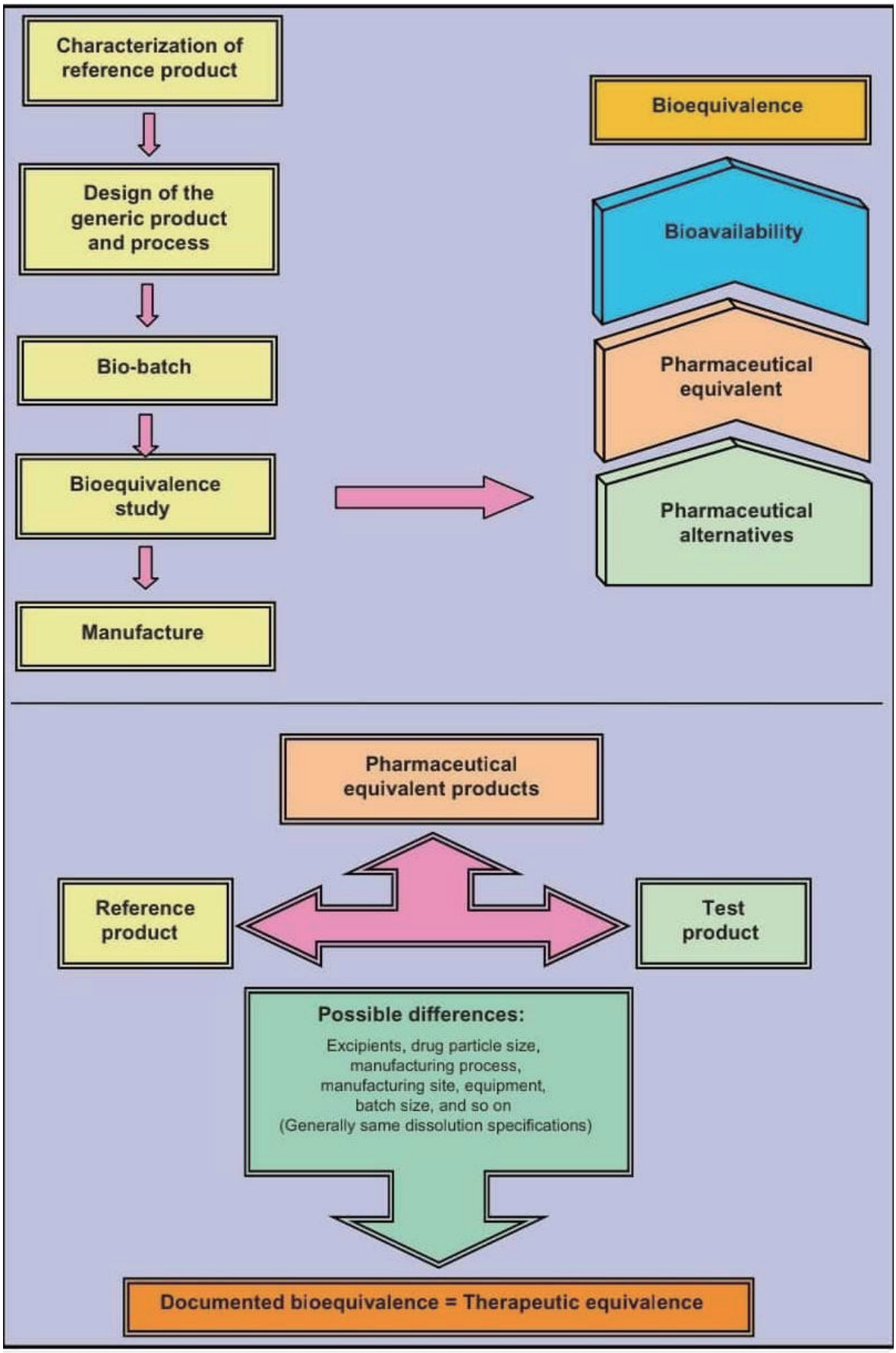


**Figure 1**: Critical pathway for the development of a generic drug product

**Table 1:** Comparison of ANDA approval process in USA, Europe, India

| Comparison Categories | USA | Europe | India |
|---|---|---|---|
| Agency | United states Food & Drug Administration | European Medicines Agency | Central drug standardization control organization |
| Authorities Involved in review/ Granting Generic Drug approval | 1. Centre for drug evaluation and research<br>2. Office of generic drugs. | 1. European medical agency.<br>2. Committee for Human Medicinal Products<br>3. European union | 1. Central drug control standardisation control organisation<br>2. Drug controller General of India |
| Application Type | ANDA- Abbreviated new drug application. | MAA-Marketing authorization application. | M&M |
| Registration Process | One registration process | Multiple registration process<br>1. Centralised procedure<br>2. Decentralised procedure<br>3. Mutual recognition procedure<br>4. National procedure | One registration process |
| Time Frame | 18 months | 12 months | 12 months |
| Fee Structure | $70,480 | £ 27,800 | $58730 |
| Presentation Format | eCTD | eCTD is mandatory for centralised procedure. For mutual recognition along with Nees and the paper submission for MAA, eCTD format are accepted. | Paper CTD |
| Data Exclusivity | Patent certification (paragraph I,II,III,&I V) | 10 years | Approved drug in India: 4 yrs old & Less than 4 yrs old, Unapproved drug in India |
| Validity of License | Five years | Five years | Three years |
| Applicable Regulation | USFDA (CFR) documents and FDA section (e.g. 505 (j) for ANDA) | Directive 2001/83/EC-Article 8(j) | Drug and Cosmetics Rules 122A, 122B, Appendix I, IA of Schedule Y |
| Submission Requirements | Three copies- (Archival, Review & Field) | One Copy | One hard copy and 3 soft copies i.e. CD in (PDF format) |

## Review of ANDA Filing

**• India[14]**

CDSCO is the Centre Drug Authority (CDA) for discharging function assigned to central government under D&C Act. In India issuance of license to manufacture approved drug, to monitor the quality are regulated both at state and central level. At the state level state drug regulatory authorities and at central level CDSCO under the Ministry of Health and Family Welfare (MHFW) are authorized for issuance of license.

**• United States (US): FDA[15]**

Hatch-Waxman Act intended to balance interests of consumers, the brand name pharmaceutical industry (innovator), and the generic drug industry to "make available more low-cost generic drugs and to create a new incentive for increased expenditures for research and development of certain products which are subject to pre-market approval" Title I of Hatch-Waxman Act authorized marketing of generic drugs on approval of abbreviated new drug application (ANDA). Under this ANDA can be approved on submission of evidence

**Table 2:** Comparison of bioequivalence guidelines of US, Europe, India[14-16]

| Sr.No. | Criteria | FDA | EMA | CDSCO |
|---|---|---|---|---|
| 1 | General | Single dose, non-replicate cross-over study for immediate release and modified release dosage forms and a single-dose, two-period, two-treatment, two-sequence cross study designs for fed BE studies. | Single dose, randomized, 2-Period, 2-Sequence cross over design. | Single dose, randomized, 2-Period, 2- treatment, cross-over study design. |
| 2 | Long half- life drugs/highly variable drugs | Non replicate single dose crossover with adequate washout period | Parallel design for long half-life drug and replicate for highly variable drugs. | Parallel design for long half-life drugs and replicate designs for drugs with variable disposition. |
| 3 | Blinding | Not specified. | Not specified. | Not specified. |
| 4 | Number of subjects | Healthy Volunteers, minimum number of volunteers to be taken in the study should be 12. | Healthy Volunteers, Minimum number of volunteers should not be less than 12 unless justified. | Healthy Volunteers, Not less than 16 unless justified for ethical reasons. |
| 5 | Gender of subject | Male/female; If drug product is intended for use in both sexes, attempt should be made to include similar proportions of females and males in the study. | Male and/or female. | Male/female; the choice of gender should be consistent with usage and safety criteria. If drug product is intended for use in both sexes, attempt should be made to include similar proportions of females and males in the study. |
| 15 | Posture/ Physical activity | Not specified. | Not specified. | Standardization of post- dosing postured is recommended. |

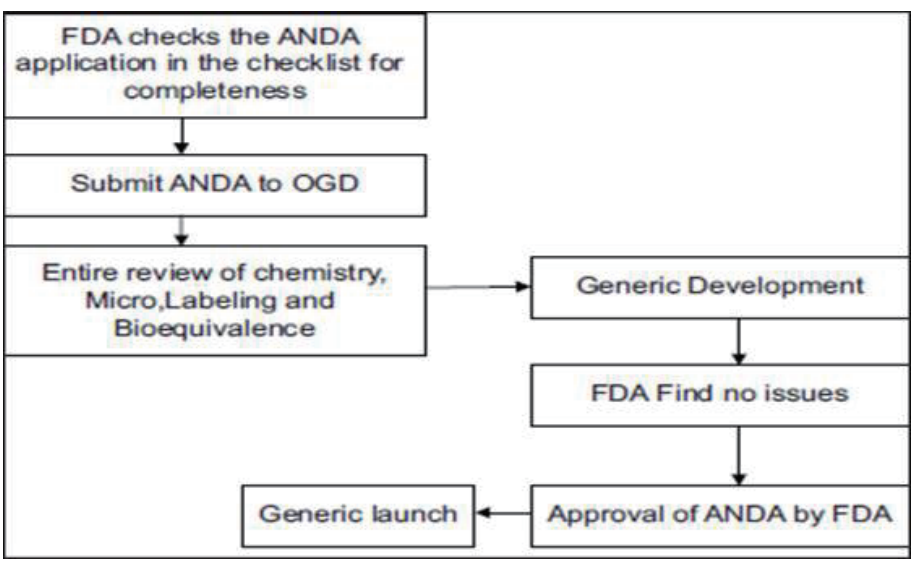


**Figure 2**: Steps for launching of generic drugs

that the active ingredient of the generic drug is the "bioequivalent" of a drug previously approved by the USFDA Title II of Hatch-Waxman Act, this section provided specific extensions of patents covering drugs and other products subject to "regulatory review" by the FDA and government agencies. Under section 505 (j) of Hatch-Waxman Act, an ANDA may be filed for a generic version of any "listed drug." Listed drug any drug for which an NDA has previously been approved is deemed to be a listed drug and is listed by FDA in the orange book. Drugs previously approved under ANDAs and antibiotics are also regarded as listed drugs. An ANDA must include all information required in an NDA except full reports of investigations demonstrating that the drug is safe and effective in use.

• **Europe: European Union (EU)[16]**

It is a unique economic and potential partnership between 27 countries of the Europe. There is one single market developed by Europe through a standardized system of laws also known as internal market apply in all member state. On 1st January 1994 the agreement of European Economic Area (EEA) was established between the member states of European Community (EC), the European Free Trade Association (EFTA), later on and the EU.5

Marketing Authorization (MA): A medicinal product may only be placed on the market in EEA when MA has been issued by the competent authority for the member state for its own territory. National

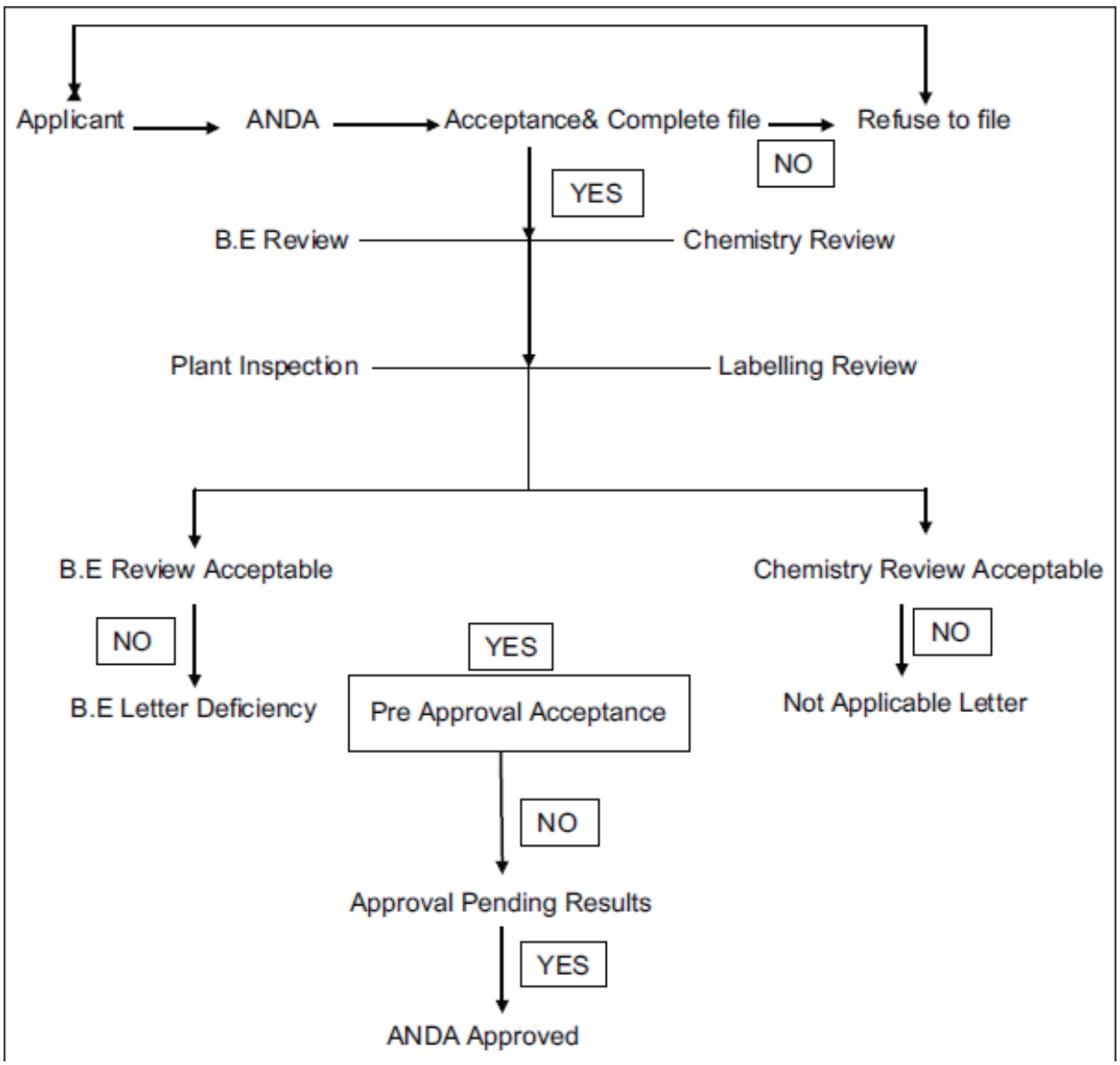


**Figure 3**: Abbreviated new drug application review process

authorization: Application must be submitted to the competent authority of the member state.

## Comparative Study of CTD Requirements for Filing of Generic Drugsin India, Europe & US[14-16]

**Table 3:** MODULE-1

| S.No. | Parameters | India | Europe | US |
|---|---|---|---|---|
| 1 | General information Covering letter, Table of Components (Module 1 to Module 5) | Required | Required | Required |
| 2 a) | Administrative information: Forms | Form 44 (See Annexure V) (Application for grant of permission to import or manufacture a new drug or to undertake clinical trials) Along with treasury challan of requisite amount Fee- Rs.15,000 | Application form Fee- €278,500 | Form 356h (See Annexure IX) (Application to market a New or Abbreviated New Drug or Biological for Human Use) Form 3794 (GDUFA Generic drug user fee cover sheet) Fee- $58,530 |
| b) | Agent authorization | Not required | Not required | Required |
| c) | Legal and critical document For | Copy of BE/NOC issued by CDSCO Copy of drug sale | Not Required | Field copy certification, financial |
| | Import and marketing for manufacturing and marketing | license (Form20B, & Form 21B), Copy of Free sale certificate, Batch release certificate, Copy of Form 11 Copy of existing manufacturing license in Form 25/28/26 COA | | Certification, debarment certification, patent information |
| d) | General information of drug product | Required | Required | Required |
| e) | Product information already approved in the country | Regulatory status in other countries | Required | Required |
| f) | Labeling | Summary of packaging procedures for Indian shipments Proposed draft labels and cartons: Primary package label Secondary package | Summary of Product Characteristics (SPC) Specimen for labels and cartons Mock-ups for outer and immediate packaging of medicinal product | Package inserts are provided for drug product. Labeling history also provided Proposed draft label for each strength and container including package size |
| g) | Annoted draft labelling (side by side) compared with RLD | Not Required | No annotation required as such but all information is provided in SPC and package insert | Required |

| | | | | |
|---|---|---|---|---|
| h) | Summary of testing protocol | Required | Not required | Not required |
| i) | Medicinal product name specify in Braille‖ format | Not required | Required | Not required |
| j) | Information(curri culum-vitae) about experts | Regarding involvement of expert | Non-clinical and clinical experts name, address, date and signature | Not required |
| k) | Request for waiver | Not required | Not required | Required |
| l) | Data/market exclusivity | Not required | Required | Patent certification |
| m) | Environment Assessment Statement (EAS) | Not required(GMO) or Non-GMO | Environment risk certification is given in the information for Genetically Modified Organism | For categorical exclusion certification in compliance with the law of Environmental Protection |
| n) | Risk management system | Not Required | Required | Risk management plan for the Policy Management System (PMS) and controlling the adverse effect by proper management |
| o) | Other Requirements | Brief profile of manufacturer research activity and its business activity in domestic and global market. Samples of drug product required | Information relating to Pharmacovigilance | Approved suitability petition must be submitted if required |

**Table 4:** MODULE-2

| S. No. | Parameters | India | Europe | US |
|---|---|---|---|---|
| 1 | (2.3) Quality based review | Not required | Not required | Required |

**Table 5:** MODULE-3

| S. No | Parameters | India | Europe | US |
|---|---|---|---|---|
| 1 | (3.2.S.1.1) Specified numbers | Chemistry Abstract Number (CAN) | CAN | Central File Number (CFN), Data Universal Numbering System (DUNS), Facility Establishment Identifier (FEI) |
| 2 | (3.2.S.4.6) Justification of Specification | Not required | Required | Required |

| | | | | |
|---|---|---|---|---|
| 3 | (3.2.R) Regional Information | Not applicable | i) Process validation scheme are provided<br>ii) According to ICH limit mention in the Q3C(R3) declaration is impurities given for the residual solvents limits or present in drug substance and excipient<br>iii) Information on components are generally not provided<br>iv) Comparability protocol not provided<br>v) Methods validation packages are not provided<br>vi) Certificate of suitability obtained from EDQM are attached with this section<br>vii) Bovine Spongiform Encephalopathy (BSE) and Transmissible Spongiform Encephalopathy (TSE) certificate are not attached | i) Executed batch record and blank master batch record for manufacturing and packaging are provided<br>ii) According to USP declaration is impurities given for the residual solvents limits or present in drug substance and excipient<br>iii) Information on components including and not limited to applicant and suppliers COA for drug substance lots, package material etc. are provided) Comparability protocol are provided<br>iv) Comparability protocol are provided v)Methods validation packages are provided<br>vi) Certificate of suitability are not provided<br>vii) BSE and TSE certificate are to be attached |

**Table 6:** MODULE 5

| S. No. | Parameters: For BE studies | India | Europe | US |
|---|---|---|---|---|
| 1 | Study design | Two separate (one in fasted state and other in the fed state), Two way cross over design, Parallel design | Randomized, Crossover, Non replicated | Randomized, Crossover, Non replicated |
| 2 | Fasting/Fed state studies | Fasting and Fed | Fasting | Fasting and Fed |
| 3 | Number of subjects | Minimum number of subjects not less than 16 | More than12 (Min 80% power of acceptance criteria) | Sufficient to achieve adequate power |
| 4 | Study dose (test reference) | Made by the manufacturer in or outside India | Made by the manufacturer RLD in Europe | Made by the manufacturer RLD in US |
| 5 | Sampling points | 12-18 samples to be collected, to be continued upto 3 or more half-lives, atleast 3-4 samples should be collected at Tmax | 3-4 samples during terminal log linear phase | 3 samples during absorption phase, 3-4 at Tmax, 4 points during elimination phase |
| 6 | Reserve sample | Not required | Not required | 5 times sample required for analysis |
| 7 | Analytical method validation parameters | Stability of the drug, Specificity/Selectivity, Sensitivity,Precision, Accuracy, Recovery, Range and Linearity | Precision, Intermediate precision, Accuracy, Repeatability, Detection, Limit of Quantitation (LOQ), and Linearity range | Accuracy, Precision, Sensitivity, Selectivity, Reproducibility, Calibration curve, LOQ and Stability |

| | | | | |
|---|---|---|---|---|
| 8 | Moieties to be measured in plasma | Active drug/Metabolite | Active drug/ Metabolite if Applicable | Active drug/ Metabolite if applicable |
| 9 | Pharmacokinetics Parameters | For plasma-time concentration curve: Cmax, Tmax, AUC0-∞, AUC0-t<br>For steady state: AUC0-τ, Cmax, Cmin | Cmax, Tmax, AUC0-t, AUC0-∞, t1/2, λz | Cmax, Tmax, AUC0-∞, AUC0-t,<br>t1/2, λz |
| 10 | Criteria for BE | 90% Confidence index, 80.00-125.00% for Cmax, | 90% Confidence index, 80.00-125.00% for Cmax, AUCt, AUC0-∞<br>(For highly variable drugs 75.00-133.00%) | 90% Confidence index, 80.00-125.00% for Cmax AUCt, AUC0-∞ |
| 11 | Retention of sample followed | As such no requirements but usually 3 years from priority | As such no requirements but usually 3 years from priority date | 5 years from priority date |
| 12 | Good Clinical Practices (GCP) requirements | CDSCO GCP guidelines | ICH GCP guidelines | ICH GCP guidelines |

## Future Prospects

The global adoption of the Bioavailability/ Bioequivalence (BA/BE) concept over the past 20 years has significantly advanced the production and approval of high-quality generic drugs. Scientific, technical, and regulatory improvements, such as replicate study designs, the Biopharmaceutics Classification System (BCS), and scaled average BE, have enhanced the evaluation of BE for various complex drugs. This success is largely due to collaborative efforts from international regulatory authorities, pharmaceutical and academic researchers, and organizations like ICH and WHO. However, there is still a need for further global harmonization of BA/BE approaches. Key areas to focus on include standardizing nomenclature, refining test procedures, addressing outliers, agreeing on BE criteria, and ensuring long-term product quality for both innovator and generic drugs. Continued efforts from international health organizations, the pharmaceutical industry, and regulatory bodies are essential to developing more efficient, scientifically valid, and cost-effective methods for assessing BE, which will ultimately improve the development and approval process for generic drugs worldwide.

## Conclusion

In conclusion, generic drug companies play a crucial role in making healthcare more affordable by bringing generic versions of innovator drugs to the market quickly and at lower costs. These drugs are rigorously tested and regulated to ensure they meet the same standards of safety and efficacy as their branded counterparts, although differences in composition may exist, typically limited to excipients. The approval process for generics, regulated by authorities such as the USFDA, EDQM, and CDSCO, involves an extensive evaluation to ensure the safety and effectiveness of the drugs reaching the market.

The Abbreviated New Drug Application (ANDA) format, widely used in the US, Europe, and India, provides a structured way for manufacturers to submit their generic drug applications. Despite efforts toward global harmonization, significant differences remain in the regulatory requirements and review processes across these regions. The Common Technical Document (CTD) format helps streamline submissions, but administrative requirements, particularly in Module 1, differ between countries. Each regulatory authority has its own unique procedures for handling drug submissions, from the composition of review teams to timelines and the specifics of the approval process.

This work highlights the comparison of regulatory guidelines across the US, Europe, and India, providing valuable insights into the various parameters involved in filing generic drugs in these regions. Understanding these differences is critical for pharmaceutical

companies and academics to navigate the regulatory landscape effectively. The US is considered to have the most stringent drug approval process, requiring manufacturers to provide substantial proof of a drug's safety and effectiveness. In Europe, three distinct approval procedures are followed: centralized, decentralized, and mutual recognition procedures. Meanwhile, in India, the CDSCO plays a key role in regulating and approving generic drugs. This comparative analysis underscores the challenges and complexities involved in achieving generic drug approval in different regulatory environments.

### Glossary and Abbreviation of Pharma Terms

**Adverse event** Any adverse occurrence in the health of a clinical trial subject who is administered a drug, that may or may not be caused by the administration of the drug, and includes an adverse drug reaction.

**AUC (area under the curve)** The area under the concentration versus time curve.

**AUCI (AUC to infinity)** The area obtained by extrapolating to infinity the AUCT. This can be calculated by adding CT/λ to AUCT where CT is the estimated last quantifiable concentration and λ is the terminal disposition rate constant.

**AUC ratio** The ratio of geometric means of the test and reference AUCs. It is calculated as the antilogarithm of the difference between the means of the logarithms (ln) of the test and reference AUCs

**AUCReftmax** The area under the curve, for a test product, to the time of the maximum concentration of the reference product, calculated for each study subject.

**AUCT (AUC to the last quantifiable concentration)** The area under the concentration versus time curve to the time of the last quantifiable concentration.

**AUCtau (AUC over a dosing interval)** Area under the concentration versus time curve at steady state, over the dosing interval in a multiple-dose study.

**AUC0-72h (AUC to 72 hours)** The area under the concentration versus time curve from time 0 to 72 hours.

**CDCSCO** The Central Drugs Standard Control Organisation (CDSCO)under Directorate General of Health Services, Ministry of Health & Family Welfare, Government of India is the National Regulatory Authority (NRA) of India.

**iCF** informed consent form

**iEC** independent ethics committee

**iRB** institutional review board

**RLD** reference listed drug

**USFDA** The United States Food and Drug Administration is a federal agency of the Department of Health and Human Services in US.

### Conflict of interest

There are no conflicting interests, as the authors have stated.

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