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**Review Article**

# CURRENT ASPECTS OF TECHNOLOGY TRANSFER IN PHARMACEUTICAL INDUSTRIES

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**ABSTRACT**
This review article's goal is to go into great depth on the transfer of technology in the pharmaceutical sector. The piece discusses the importance, reasons, facets of TT, factors affecting the success of TT, classification, models, TT process, and stages that make up the procedure. This effort to comprehend the issues associated with TT discusses the documentation portion of the technology transfer. The transfer could be deemed effective if both the receiving and transferring units are successful in using the technology for commercial gain. Understanding a process's capacity to effectively forecast how a process will perform in the future is a prerequisite for the success of any given technology transfer. A successful technology transfer requires three main factors into account: the strategy, the people involved, and the procedure. Technology transfer involves ongoing information flow between the parties to continue product manufacture, not just one-off actions taken by the transferring party in the direction of the transferred party.

**KEYWORDS-** Pharmaceutical Technology Transfer; Manufacturing; Development; Step involved; Scale-up.

**INTRODUCTION-** "Technology transfer" refers to the procedures that take the pharmaceutical industry's products through the stages of drug discovery, product development, clinical trials, and finally full-scale commercialization[1]. TT is essential to the process of finding new drugs and creating new medical goods. TT is nothing more than the transfer of research findings from one institution to another for use in developing new pharmaceuticals, teaching aids, safety equipment, electronic gadgets, and health services needed by the general public. Science, engineering, law, and governmental organizations are all connected through TT[2]. The process of discovering new drugs and developing pharmaceutical products relies on TT, which is regarded as crucial and serious. This procedure clarifies manufacturing and commercialization for the product development lab[3]. Through standardized processes of efficient production, TT aids the pharmaceutical sector in improving the product's efficacy, safety, and quality. From the perspective of research and development efforts, TT may be seen.

TT is necessary for expanding the product on a commercial basis since small-scale laboratory research discoveries must be sold. Thus, TT is defined as a process that starts with an innovation in a lab and progresses to a product development stage before reaching a commercial size[4]. If both receiving and transferring organizations successfully use the TT to promote their businesses, it is deemed to be successful.

**CLASSIFICATION OF TECHNOLOGY TRANSFER-**

According to Mansfield, there are two types of TT-

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- **Perpendicular Transfer-** Prior to the creation of new pharmaceutical goods, it begins with exploratory research and finishes with clinical research.
- **Straight Transfer-** The creation and introduction of technology to a new subject or institution from one utilized in another[2, 5].

**LEVEL OF TECHNOLOGY TRANSFER-**

Technology has been transferred, particularly in the ways listed below-

- **Public laboratories to the non-public sector:** This form of transfer is useful because it allows government laboratories to receive adequate funding from the government for their research efforts while also ensuring that the technology they generate is made available to the non-public sector[6].
- **Among domestic private companies:** This form of transfer generally occurs between domestic private businesses due to a lack of enough funding or a misapplication of legal requirements[7]. As a result, the private sector that develops the technology receives payment from another industry that uses it[8].
- **Among private firms of different countries:** Through this, technology spreads from one nation to another. This method of technology transfer is especially helpful to underdeveloped nations or nations that are in the process of transitioning to development[8]. Before such a technology transfer occurs, its economic effects on developing nations must be evaluated. Such a technology transfer would have long-term advantages for both technology producers and consumers[9].
- **From universities to businesses in the private sector:** An academic company that creates specialized technology is reachable by businesses in many commercial sectors. Money is frequently saved through private sector collaboration with nonprofits[10].
- **Academia, government, and industry collaboration:** In this case, the government gives the money required for academic institutions to develop technologies that can be used by industries[11, 12].

**SIGNIFICANCE OF TECHNOLOGY SHARING-**

- By arranging the voluminous data gathered during research and development, it is possible to clarify the information required to transition technology from R&D to practical manufacturing[12].
- The demonstration of expertise necessary for moving technologies from R&D to production[13].
- To make clear the data necessary for product technology transfer across various production facilities[14].
- To serve as an example of particular processes and issues for efficient technology transfer. For the efficient production of products intended for sale[15].

**REASONS FOR TRANSFER OF TECHNOLOGY -**

- **Lack of manufacturing capacity:** A technology innovator might only have small-scale manufacturing equipment; as a result, they would need to collaborate with another firm to make goods on a big scale[15].
- **As a result of a lack of funding for product commercialization:** The technology's original inventor might only have funding for preliminary research, including animal studies, but might not have funding to get an idea through the clinical and regulatory phases[16, 17].
- **As a result of a lack of marketing and distribution:** Even if the technology's developer fully developed the technology and obtained product registrations and regulatory clearances, it's possible that it lacks the marketing and distribution channels[17, 18].

**FACTORS AFFECTING THE SUCCESS OF TECHNOLOGY TRANSFER-**

- Technology transfer, as opposed to a "greenfield" R&D venture, involves importing a cutting-edge R&D product from outside the organization. Therefore, it is essential to have a thorough understanding of the history of the technology as well as its potential benefits and drawbacks from the start[19].
- Before choosing to transfer the technology costs, royalties payments, and milestone payments must be taken into account[20]. Incorrect completion of this due diligence could result in the project losing priority within the organization[21].
- While the project is ongoing, regulatory issues, especially those that are “difficult to resolve” must be properly addressed[22].
- In addition to the formal project structure, the team receiving the technology and the team providing the technology should have a complete understanding of the overall project[23].

## TECHNOLOGY TRANSFER PROCESS-

The process of discovering new medications, developing new drugs, and creating new pharmaceuticals all depend on technology transfer[24, 25]. Economics typically plays a role in deciding whether to shift items across production facilities. Important phases in the process include data collection, data assessment, regulatory impact, with an emphasis on any change approvals, analytical validation, pilot or full-scale process batch, and stability set down[26, 27].

**Flow Chart Of Transfer Of Technology in Pharmaceuticals-** [Figure-1]

There is a flow chart discussed below in which the technology transfer process in a pharmaceutical company is mentioned.

## STEPS INVOLVED IN TT-

A pharmaceutical prototype needs the collaboration of many people to become a finished, marketable product. For a formulation to be successfully scaled up, it is crucial to comprehend the operational techniques employed, the critical and non-critical parameters of each operation, the instrumentation, and the practicality of the excipients[28]. There are mainly 3 steps concerned with TT-

**Research Phase** (Technology development via R&D).

**Technology Development Phase** (R&D to Production).

**Production Phase** (Production & Optimization).

**Research Phase-**[29] In this phase technology is being developed by the Research and Development team. Their main operations are:

- Design and Excipient Selection- R&D bases its decision on materials and process design on the idea of innovative product attributes. Entirely separate testing and compatibility studies are carried out for this[29].
- Determination of specification and quality- Stability studies were conducted for innovative products as well as for a product that is to be manufactured, and the quality of the product should fulfill the requirements of an innovator product. [Figure-2]

**Technology Development Phase-**[30, 31] R&D supplies TTD paper to the laboratory that includes the following formulation and drug product data.

- The General title, MFC number, effective& expiry date, Shelf-life and storage conditions.
- MFC- It includes the name of the drug product as well as its MFC number, effective date, formulation strength, generic name, page number, and product shelf life.
- Master Formula- It outlines the directions for the product's formulation and manufacture. The goal of the creation of dosage forms and environmental conditions is provided in the manufacturing instructions.
- Master Packaging Card- The kind of packaging, the material used for packaging, stability, and the shelf life of the packaging are all covered.
- Standard Test Procedures (STP)- The profile of the product's active ingredients and excipients, its specifications, its in-process variables, and details about the finished product are all revealed during this procedure.

**Production Phase-** In this phase production and optimization process takes place.

- Validation Studies- Following validation tests, production is mandated to confirm that the process will stabilize the drug product made by using the new manufacturing recipe. The Production division is liable for technological acceptance and validation. Validation like performance certification, cleansing, & technique validation should be the duty of the R&D department transferring technology[32].
- Scale-up - It involves transferring technologies when a product's development is still in its early stages on a small scale. The production environment and system must be taken into account when the technique is being developed. Operators should focus on remembering that if technology transfer is implemented wisely, the manufacturing process may function smoothly. Effective technology transfer aids in process efficiency and product quality maintenance[33].

- Method Selection-Using R&D, the method for batch manufacturing was selected. Granulation, mixing, compression, and coating are crucial procedures in TT[34].

**TT DOCUMENTATION-**[35, 36]

Information in a TT document is given by the parties that are transferring and receiving technology. Any stage of the technology transfer process, from Research &Development to manufacturing ought to be recorded, along with assignments, responsibilities, and acceptability standards for any technology that is to be transferred. QA is responsible for reviewing and approving all documents for all TT processes.

- Development Report- It is utilized as a reliable document for new medication design quality at preapproval evaluation. Possessing proof that a technology transfer was effective is the ultimate aim. R&D is responsible for documenting the technological development that is the subject of the (R&D) report. This report is a document that outlines the justification for the design of drug substances, standards,& test procedures.
- Plan for TT- The TT plan specifies the item and contents of the technology that will be transmitted, a thorough procedure for each individual transfer, a timeframe for the transfer, and decision-making criteria for the transfer's conclusion. The transferring party must draft a plan and agree on its details with the transferred party.
- Report- Only the TT is finished if data is included in the technology transfer strategy. To validate that the established requirements are satisfied, the data are evaluated. The report must be documented by both the transferred and the transferring party[37].

**VERIFICATION OF TT RESULT-**

Before starting to produce the product, the transferring party should make sure that the product fulfills the set quality standards using the proper techniques, such as product testing and audit[38]. The transferring party must also maintain outcomes records[39].

**TECHNOLOGY TRANSFER TEAM-**

There should be a TT Team that will be responsible for the Transfer process[40]. [Figure-3]

In the below Table, all the members and their responsibilities are described-[Table-1].

**WHO GUIDELINES ON TRANSFER OF TECHNOLOGY-** [1]

In all aspects of the majority of medicines, life cycles, including drug product development, production, and market introduction, processes are moved to alternative locations. This WHO recommendation will play to the production of active pharmaceutical components, the manufacturing, and packaging of finished pharmaceutical products, as well as the conducting of analytical testing. Technology transfer requires a plan and documentation that makes use of a competent and experienced individual working inside that system and provides proof of records pertaining to development, production, and QC sectors. Typically, There are three units: Process management, Receiving, and the transmitting unit. [Figure-4]

**MODELS FOR TRANSFERRING TECHNOLOGIES-**[11]

Two main categories of models are-

- Qualitative Model- This model is categorized mainly into five types-
  - Bar-Zakay Model.
  - Behrman & Wallender Model.
  - Chantramonklasri Model.
  - Dahlmam &Westphal Model.
  - The Schlie, Radnor, & Wad Model.
- Quantitative Model- It is mainly of three types-
  - Klein and Lim an econometric Model. (1997)
  - Sharif and Haq's Perhaps Model. (Earliest Model) (1980)
  - Raz. et. al's "Catch-up" Model. (1983).

**INDIAN ORGANIZATIONS THAT ENCOURAGE TT-**

- Asian and Pacific Centre for Transfer of Technology (APCTT).
- Technology Bureau for Small Enterprises (TBSE).
- National Research Development Corporation (NRDC).
- Technology Information, Forecasting and Assessment Council (TIFAC).
- Foundation for Innovation and Technology Transfer (FITT).
- Biotech Consortium India Limited (BCIL).

**FEW CASES OF TECHNOLOGY TRANSFER-** [41]

- **Bhabha Atomic Research:** has transmitted around 90 technologies in the fields of electronics, chemical and mechanical, radioisotopes, environment and health, chemical and mechanical, and chemical and metallurgy.
- **CSIR-NCL:** has a number of connections with universities and the pharmaceutical industry to guarantee effective technological scaling and application[17].
- **The Tata Institute of Fundamental Sciences:** has transferred several methods from the fields of biology, computer science, mathematics, and the natural sciences.
- **Eli Lily:** In order to address global demand for the anti-tuberculosis medicine Cycloserine, Eli Lily and Shasun Chemicals and Drugs have entered a technology transfer agreement[42].
- **CSIR-CDRI:** has created technologies in fields such as cancer biology and associate fields, safety and clinical development, reproduction, diabetics, metabolism, malaria, parasite disease, & CNS-CVS linked disorders[43].

**TABLES & FIGURES-**

**Table-1: Members and Their Duties in Technology Transfer.**

| SL NO | Member of the TT squad | Duties of the member | |
|---|---|---|---|
| 1. | Process Technician | a) | The primary goal is to do the transfer Operations. |
| | | b) | Assembles information from the donor's website or physically. |
| | | c) | They do a preliminary evaluation of the shifted project to determine its viability, suitability for the site, and resource requirements. |
| 2. | Quality Assurance Department | a) | Responsible for checking if the papers are adequate according to standards. |
| | | b) | The analytical method is reviewed with QC to ascertain equipment and training needs. |
| | | c) | Shall create the documentation for the process validation. |
| 3. | Production Representative | a) | His responsibility is to assess the suitability of the manufacturing, packaging process, equipment, and facilities. |
| | | b) | The reviews process instructions with process technologists to check capacity and capability. |
| | | c) | They take into account the training needs of operators and supervisors. |
| 4. | Engineering Representative | a) | Assessment of equipment and needs with production representative. |
| | | b) | Initiates the necessary engineering changes. |
| | | c) | Reviews the effects of calibration and preventative maintenance. |
| 5. | Quality Control Representative | a) | Their duty is to review the analytical needs and requirements. |
| | | b) | Set up the transfer of analytical methods for drug substances and drug products. |
| | | c) | The accessibility of instruments. |

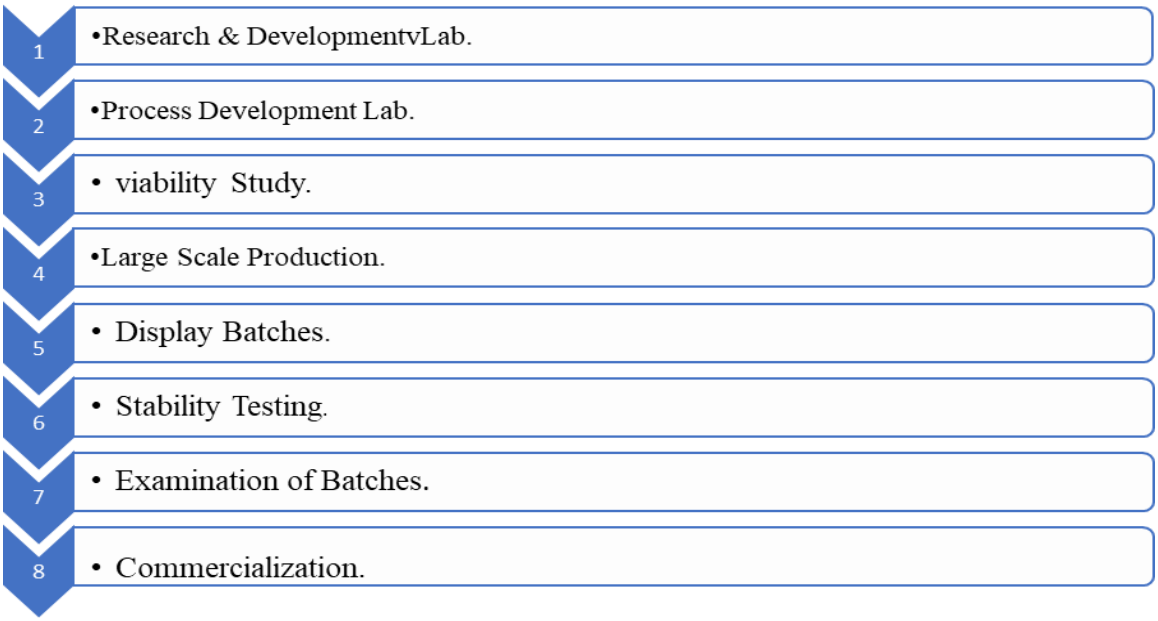


**Figure-1: Flow chart of Technology Transfer in the Pharmaceutical Industry.**

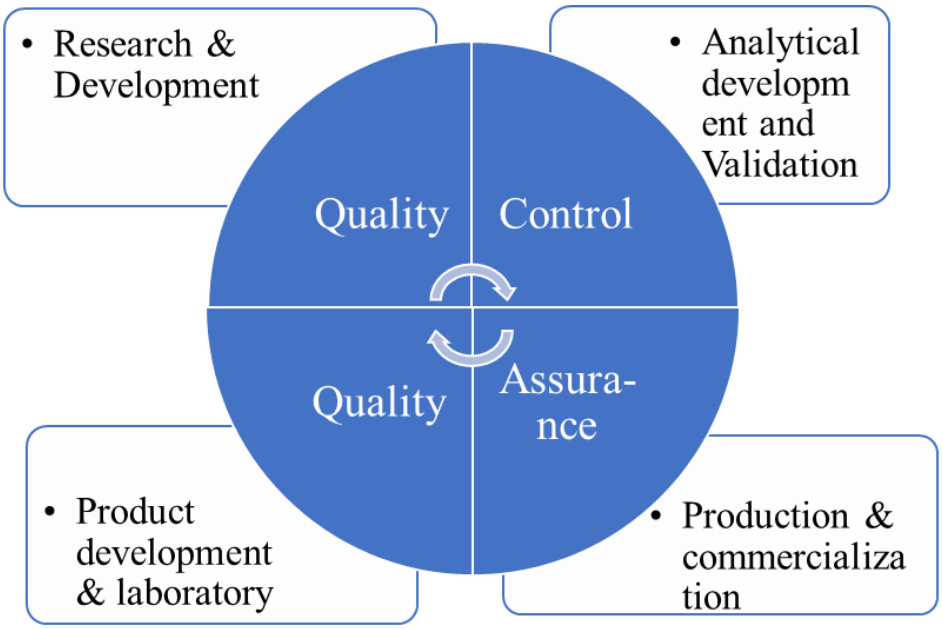


**Figure-2: Determination of specification and Quality by Quality control and Quality Assurance.**


**Figure-3: Technology Transfer Team.**


**Figure- 4: WHO guidelines on technology transfer**

## RESULT-

The transfer of knowledge, processes, & products from one organization to another—often from research & development to manufacture or between manufacturing facilities—is a crucial process in the pharmaceutical industry. Successful TT is essential to maintaining consistent quality, cost-effectiveness, adherence to legal requirements, risk reduction, knowledge retention, resource utilization, continuous improvement, cooperation, and customer happiness. TT can be a difficult procedure involving various scientists, engineers, regulatory specialists, and manufacturing staff. Planning, documentation & attention to detail are essential for attaining the goals of technology transfer in the pharmaceutical industry.

## DISCUSSION-

For such, a study to be broadly successful, Technology transfer is essential for the large-scale commercialization of this research to be effective, particularly in the manufacture of products. Technology transfer includes not just parts of manufacturing that are patentable but also commercial procedures like knowledge and skills. TT is crucial for the quality, safety & efficacy of the products as well as for documenting the effectiveness of the process. These documents are necessary for the exchange of data among interested parties within the drugs industry & regulatory compliance.

## CONCLUSION-

The action of transferring the data and technologies necessary to attain medicine design quality throughout production is referred to as TT in the pharmaceutical business. Technology transfer refers to continual information interchange between the parties to continue product manufacture, as opposed to one-time actions taken by the transferring side toward the transferred side. It does not, however, imply a one-sided activity. TT is a challenging issue that requires an all-encompassing approach.

**REFERENCES-**


1. Good manufacturing practices for sterile pharmaceutical products In: WHO Expert Committee on Specifications for Pharmaceutical Preparations. Thirty sixth report. Geneva, World Health Organizations; 1992.
2. Sajid A, Vinay P, Chander S. Technology transfer in Pharmaceuticals. Technology transfer in Pharmaceuticals International Research Journal of Pharmacy. 2012;3(6):43-8.
3. Gupta SS. Technology transfer in the pharmaceutical industry- an overview. International Pharmaceutica Sciencia. 2012;2(3):1-6.
4. Mohite PB, Sangle SV. Technology transfer in the pharmaceutical industry- a review. International Journal of Advances in Pharmaceutics. 2017;06(01):1-07.
5. Feifei Y, Yigming Y. Research on Technology Transfer in the pharmaceutical Industry. Technology Transfer Journal of Tongji University Natural Science. 2008;11-4.
6. Gorman M. Types of knowledge and their roles in technology transfer. Journal of Technology Transfer. 2002;27:219-31.
7. Waghmare YS, Mahaparale SP. The important role of technology transfer in the pharmaceutical industry-a review. World Journal of Pharmaceutical Research. 2017;6(9):310- 29.
8. Liebowitz S. Pharmaceutical Technology Transfer: Pre AND Post NDA Submission. In: Pharma Tech Conference. 1995.
9. Jandia MD, Sreedhar D, Ligade VS, Pise A, Udupa N. Facts of Technology Transfer: A perspective of Pharmaceutical Industry. Ind J of property rights. 2008;13:28-34.
10. Sexton F. Effective and efficiency knowledge transfer from R & D to manufacturing. Purdue Pharma's SMC meeting. 2004.
11. Sagar P, Akshay K, Pankaj P, Mayur G, Shivram J. Review article on technology transfer. International Journal of Pure and Applied Bioscience. 2014;2(3):145-53.
12. Osman Gani A. International technology transfer for competitive advantages: A conceptual analysis of the role of HRD. Competitiveness Review. 1999;9.
13. Remya Mariam J. Technology transfer in pharmaceutical Industry. The Pharma Innovation Journal. 2017;6(3):235-40.
14. Mahboudi M, Ananthan BR. Effective factors in technology transfer in the pharmaceutical Industries of Iran: A case study. IPU Journal of Knowledge Management. 2010;8(1).
15. Patil PR. Technology transfer in the pharmaceutical Industry: objectives, issues and policy approach. International Journal of Pharma Research and Development. 2010;3:43-8.
16. Kaur A, Sharma OP, Dhari J. Technology transfer in pharmaceutical industry. International Journal of Current Pharmaceutical Research. 2013;5(1):17-8.
17. Biruk A, Abate B. Technology transfer in pharmaceutical industries through product development and scale-up approaches: challenges and opportunities for developing countries. International Journal of Emerging Technology and Advanced Engin. 2016;6(7):232- 43.
18. Souder WE, Nashar AS, Padmanathan V. A guide to the best technology transfer practices. Journal of Technology Transfer. 1990;15:1-2.
19. Autio E, Laamanen T. Measurement and evaluation of technology transfer: review of technology transfer mechanisms and indicators. International Journal of Technology Management. 1995;10(7/8):643-64.
20. Rahul D, Rajiv G, Prabhas J. Technology transfer in pharmaceutical industry transfer of process from development to commercialization. International Journal of Pharmaceutical Sciences and Research. 2013;4(5).
21. Lin M, Lekhawipat W. Key influencing factors for the success of external innovation strategies in the biotechnology industry. Journal of Business and Industrial Marketing. 2023.
22. Ghailani HH, Moor WC, Technology Transfer to developing countries. International Journal of Technology Management. 1995;10(7-8):687-703.
23. Vishal P, Pawar WDN, Bavage NB, Shaymlila B. Technology Transfer. Technology Transfer International Journal Of Innovative Research In Technology, 2021;8.
24. Amanjeet S, Geeta A. Technology Transfer in Pharmaceutical Industry: A Discussion. International Journal of Pharma and Bio Sciences. 2010;1(3):1-3.
25. Amrita K, Pullam RK, Shrikhande S, Prudhvi RP, Biswas UK, Bajaj A. Technology Transfer: A New Buzz World in Pharmaceutical Industry. Journal of Advanced Scientific Research. 2013;4(1):1-6.
26. Manish SM, Bharat P, Yakub S. Technology Transfer in Pharmaceutical Industry. American Journal of Pharmatech Research. 2012;2(4).
27. Zucker LG, Michael R. Capturing Technological opportunity via Japan's star Scientists Evidence from Japanese firms Biotech patents and product. The Journal of Technology Transfer. 2001;26:37-58.

28. Bharat B, Ujjwal N, Senthil K, Abu B. Technological transfer in the pharmaceutical industry. A review. Int J pharm med res. 2014;2(3):96-109.
29. Domb E Using TRIZ to Accelerate Technology Transfer in the Pharmaceutical Industry. PGTJ. 2004;3-5.
30. Aghyi M. Agreements of Technology Transfer. The Economic Ministry. Tehran: 1999.
31. Massard Da Fonseca E, Shadlen KC. Vaccine technology transfer in a global health crisis: Actors, Capabilities, and institutions. Research Policy Elsevier. 2023:52.
32. Babupazhayattil A, Sharma S, Philip JP, Gischewski-Silva M, Ingram M. Technology Transfer: Drug Product Manufacturing process. Springer; 2023.
33. Babu Pazhayattil A, Sharma S, Phillip JP, Gischewski-Silva M, Ingram M. Scaling-up of solid orals: Granulation, Drying, Size Reduction, Blending, Compression and Coating Technologies. Technologies Transfer, 2023.
34. Sharma C. R&D Technology Transfer and Productivity In The Indian Pharmaceutical Industry. International Journal of Innovation Management. 2015;20(1).
35. Mashelkar R. Intellectual property rights and the third word. Current sciences. 2001;81.
36. Rias J. Management of technology: New frameworks, Technovation. Technovation ELSEVIER. 1988;
37. Balram P. Patents, laws, and science. Current Science. 2005;88(10).
38. Kelly H, Steven G, Child I. Technology transfer: What India can learn from the United States. Journal of Intellectual Property Rights. 2005;10(5):399–405.
39. International journal of pharmaceutical sciences and research. Vol. 11. International Journal of Pharmaceutical Sciences and Research: 2020.
40. Technology Transfer in Pharmaceutical Industry: process Transfer from Development to Commercialization. Issue. 2021;10:972-81.
41. Venktesh D, Simran B, Mujawar AP, Sachinkumar V. A Comprehensive Review On Technology Transfer. Internal Journal Of Creative Research Thoughts. 2021 Jul 7;9 : 633-47.
42. Chorev N. South-South technology transfer: the case of pharmaceutical Known-how in Kenya, Tanzania, and Uganda. Socia- Economic Review. 2023;21:119-57.
43. Kouladoum J-C, Ngouhouo I, Wendji Miamo C. Wellbeing in Africa: The role of technology transfer. Technol Soc [Internet]. 2023;73(102238):102238. Available from: http://dx.doi.org/10.1016/j.techsoc.2023.102238.