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Pharmaceutical Formulations Using Artificial Neural Network- A Review

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ABSTRACT: A model of the human brain is an artificial neural network (ANN). The goal of an artificial neuron is to imitate the form and function of a real neuron. The input, hidden, and output layers constitute a neuron. Artificial neural networks are a different technique since statistical methods have limitations. Pharmaceutical formulation development is a developing sector for ANN. This review paper covers ANN structure, history, network types, implementations in pharmaceutical formulation and development, ANN software. In the pharmaceutical, academic, and research sectors, ANN is a particularly potent tool for developing new formulations.

KEYWORDS: AI, ANN, neural network, network architectures, optimization, *in-vitro* dissolution, capping tendency, *in-vitro* permeability, prediction, tablet, emulsion.

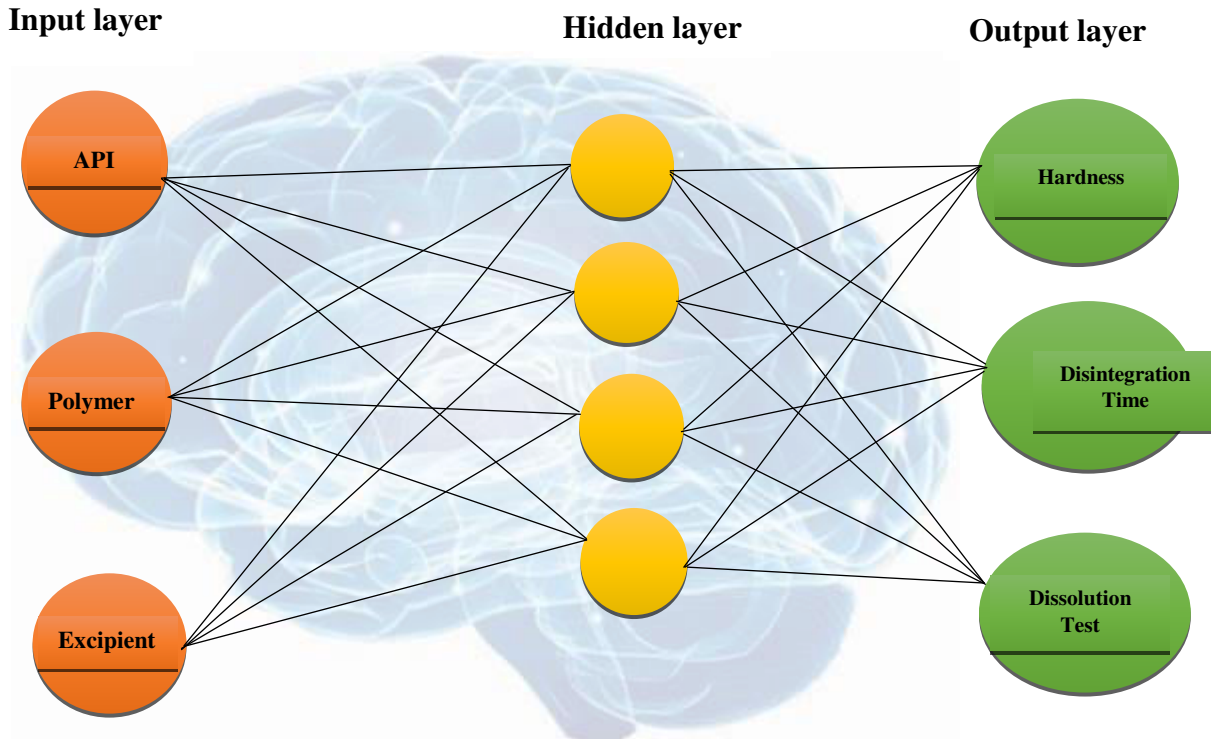
I. INTRODUCTION

Pharmaceutical industries have begun to experience a significant shift in the twenty-first century, driven by digitization, automation, and the enormous amount of data generated by the manufacturing processes^[1]. Recent years have seen the pharmaceutical industry find unique and creative methods to leverage this potent technology to help overcome some of the largest issues plaguing pharma today^[2]. In the pharmaceutical industry, artificial intelligence (AI) refers to the use of automated algorithms to tasks that typically involve human intellect^[2].

Artificial intelligence is usually used to describe computational techniques that carry out procedures typically linked to mental processes resembling those of humans, such as pattern recognition or decision-making^[1]. A terrific model with biological influences that develops from observational data is the neural network. That is a synthetic network that accurately mimics the neural network of the brain and has highly connected units^[3]. Two popular neural networks are Artificial Neural Networks (ANN) and Deep Neural Networks (DNN)^[3]. Other than these Static Neural Network (SNN), Modular Neural Network (MNN), Probabilistic Neural Networks (PNN), Learning Vector Quantization Networks (LVQ), Cascade Correlation Networks (CCN), Functional Link Networks (FLN), Kohonen Networks (KN), Hopfield Neural Network (HNN), Gram-Chalier Networks (GCN), Hebb Networks (HN), Adaline Networks (AN), Hetero-associative Networks (HN), Hybrid Networks (HN), Holographic Associative Memory (HAM), Spiking Neural Networks (SNN), Cascading Neural Networks (CNN), Compositional Pattern-producing Neural Networks (CPPNN)^[4].

Artificial neural networks (ANN) are a complement for RSM's mathematical techniques^[5]. A data processing model known as an Artificial Neural Network (ANN) is based on how biological nerve systems, like the brain, process data^[3]. Similar to how the human brain is built, artificial neural networks have neuron nodes connected in a web-like pattern. In order to analyze data and information in order to learn and develop new knowledge, such networks are primarily motivated by the way the biological neural system functions^[6]. The elements of the ANN architecture are:

- Input layer:** Have access to the input values.
- Hidden layer:** A group of neurons situated between the input and output layers. There can be one or several layers.
- Output layer:** Typically, it has one neuron, and its output is higher than or equal to 0 and less than 1, or between 0 and 1. But there can be several outputs as well.



(Fig 1: Structure of Artificial Neural Network)

1.2 ADVANTAGES OF ANN^[5]:

- The neural network has a unique capacity for pattern recognition.
- It does not require any prior understanding of the underlying mathematics of the problem.
- In circumstances when the response variables are significantly nonlinear, ANN accurately predicts results.
- The issue of dimension Additionally, curse governs a neural network that hides attempts to simulate several variables in nonlinear processes.
- Networks are more tolerant of noisy and fractured knowledge than mathematical modelling programmes. Therefore, literature or historical evidence can also be employed as preparation.
- They can reduce the cost and timing of product invention while still being effective when fitted with neural nets.
- An ANN model uses experimental data without any data manipulations, as contrast to mathematical simulations.
- Regarding the relevance of the connections between the formulation's ingredients and its qualities, ANN does not impose any presumptions.

1.3 DISADVANTAGES OF ANN^[5]:

- Overworking, a scenario in which the neural network starts to duplicate stimulus similar to a specific portion in the training data, is the main concern while creating a model. If network inspection was done, the issues mentioned above may be eliminated.
- The major downside of ANNs was that because they are by nature computer systems, the interaction that they receive cannot easily be captured in statistical form.
- ANN makes use of specialized technology, whereas RSM (response surface methodology) works with older programmes like Excel.

1.4 STRENGTHS OF ANN^[7]:

- **Studies can help:** In the way that it picks up new skills while learning, ANNs mimic the human brain. Normal programmes are unable to adjust to different types of inputs.

- **Self-organization:** As it learns, an ANN can construct its own organization. A typical programme is fixed for its mission and will only carry out what it was designed to.
- **Parallel operation:** As in the human brain, ANN operates in parallel. This is not like a serially-running computer application.
- **Adaptability:** One of the most intriguing characteristics of neural networks is their capacity to function even in the presence of imperfect, erratic, and ambiguous data. A typical software cannot handle confusing or incomplete data and will crash if it comes across even the tiniest amount of incorrect information.

1.5 LIMITATIONS OF ANN^[7]:

- Considering that the human brain processes information more slowly, ANN is relatively quick in contrast.
- When the nature of the input and output is precisely known and what must be done is obvious, ANN cannot be used.
- When compared to a typical programme, the ANN's output calculation approach is unclear. Despite the fact that the input sets are similar, the time required varies with each new set.
- Applications where data is ambiguous and for pattern recognition can both use ANN.

II. HISTORY

The pursuit of scientific knowledge about the functioning of the human brain in the late 1800s is arguably where the history of neural networking began.

- **William James** wrote the first book on patterns of brain activity in 1890.
- The neuron model, **McCulloch and Pitts** developed in 1943 is still employed in modern artificial neural networks.

Artificial Neural Network (ANN):

- A law governing synaptic neuron learning was presented in "**The Organization of Behavior**," published by **Donald Hebb** in 1949. One of the simplest and most straightforward learning laws for artificial neural networks, this law was later referred to as **Hebbian Learning** in honor of Donald Hebb.
- While employed by Princeton, **Narvin Minsky** created the **first Artificial Neural Network (ANN)** in 1951.
- The publication of "**The Computer and the Brain**" took place in 1958, one year after **Jhon von Neumann** passed away. Von Neumann made a number of radical alterations to the way analysts had been simulating the brain in that book.
- **Frank Rosenblatt** developed the **perceptron** at **Cornell University** in 1958. The perceptron was an attempt to impose character recognition neural network techniques.
- **Rosenblatt's** book *Principles of Neurodynamics*, which included some of his analysis and theories on brain modelling, was released in 1960.
- **Werbos** first devised the **backpropagation algorithm** in 1974, and **Rumelhart, Hinton, and Williams** published *Learning Internal Representation by Error Propagation* in 1986. With artificial neural networks, backpropagation is a sort of gradient descent technique used for curve-fitting and reduction.
- For ANN scientists, the IEEE annual international ANN conference was established in 1987. **The International Neural Network Society (INNS)** and the INNS neural Networking journal were established in 1987 and 1988, respectively.
- In 1990, **Hecht-Nielsen** demonstrated a two-layer perceptron (Mark), a three-layer technology that was capable of handling non-linear separation issues.

III. NETWORK ARCHITECTURES

a. Feed forward networks:

There are no feedback loops in feed forward systems since one unit provides information to another unit while receiving none in return. There are fixed inputs and outputs. Each unit gets input data from the units to its left, and the inputs are multiplied by each connection's weight. The output results pertaining to the weight of each link can therefore be acquired. When the desired network outcome is known, the system is applied to network applications.

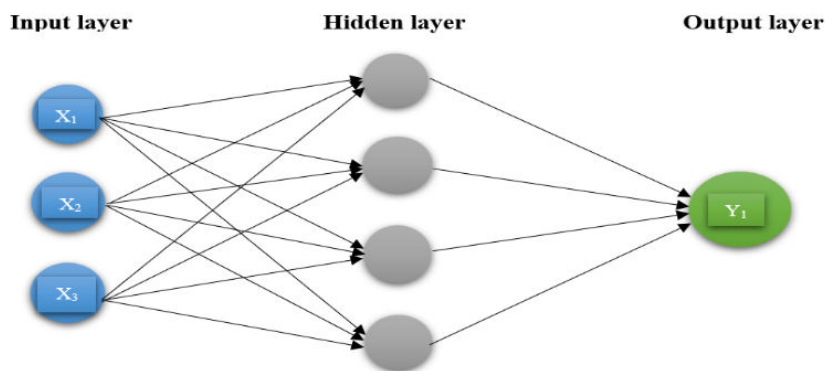
There are mainly 2 types, they are:

i. Single layer feed forward networks:

The simplest type of neural network is a single-layer perceptron network, which has one layer of outputs and numerous weights that directly feed inputs into outputs. This is how the simplest feedforward network may be thought of.

ii. Multilayer feed forward networks:

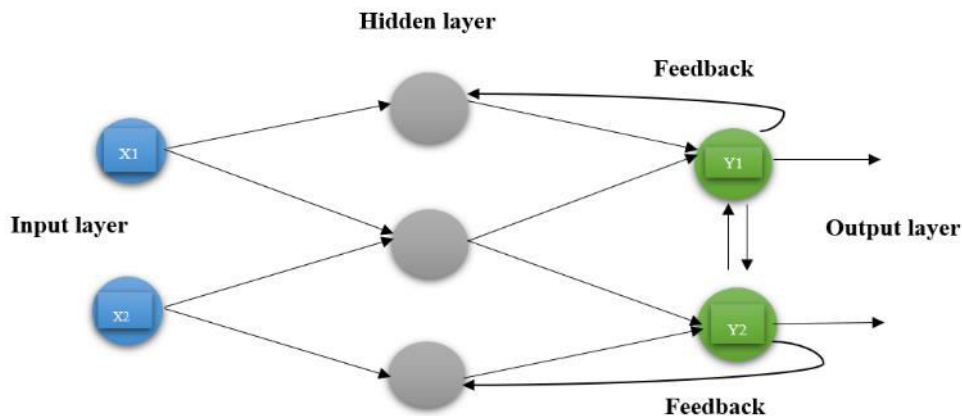
Data and equations from input and output data travel in a single path in a multi-layer feedback neural net called an integration of perceptrons. The neural net contains a number of layers of perceptrons. A single input layer and a perceptron output layer make up the most basic neural network.



(Fig 2: Structure of Feedforward network)

b. **Feed Back Propagation Network:**

The Feed-Back ANN systems make use of content addressable memory. By contrasting a network's output with the output that is wanted and anticipated, neural networks can be learned utilising a feedback loop. The weights of the connections between the network units are changed and modified using the difference between these two outputs.



(Fig 3: Structure of Feedback network)

IV. DEVELOPMENT OF AN ANN MODEL

The numerous parameters that must be chosen in order to create a neural network model for every application show that significant trial and error is involved in the design process. The flow diagram represents the many phases involved in creating a neural network schematically.

STEP 1:

Variable Selection: A suitable variable selection process is used to choose the input variables crucial for modelling the variables under consideration.

STEP 2:

Formation of training, testing, validation: To discover the pattern in the data, a training set is used. A trained network's capacity for generalisation is assessed using a testing set. Validation set checks the training network's performance.

STEP 3:

Neural network architecture: The architecture of a neural network specifies its structure, including the number of output nodes, hidden layers, and hidden nodes.

STEP 4:

Evaluation criteria: The sum of squared errors is the error function that neural networks minimise the most frequently. Various software programmes also include least absolute deviations, least fourth powers, asymmetric least squares, and percentage differences as additional error functions.

V. ANNs IN PHARMACEUTICAL FORMULATION AND DEVELOPMENT

Even though it produced successful outcomes, ANNs were not well-liked among pharmaceutical researchers until the start of the twenty-first century. The absence of infrastructure, ignorance of the algorithms and programming languages used by ANNs, lack of confidence in the new system of process development, etc. may all be contributing factors. However, starting in 2001, other pharmaceutical researchers became interested in the area and created unique methods and software to address various facets of the creation of pharmaceutical products and processes.

5.1 ANN's in modelling and optimization of pharmaceutical formulation^[9]:

Numerous formulation elements and process variables go into creating a pharmaceutical formulation. Establishing mathematical relationships between the formulation variables and the subsequent responses and optimising the formulation conditions are key components of quantitative model-based pharmaceutical formulation. The problem of competing objectives arises when a formulation system has many purposes because the optimum formulation conditions for one property may not necessarily be acceptable for other qualities. To create an ideal formulation system, effective modelling and optimization approaches are therefore required.

5.2 ANN in tablet manufacturing^[10]:

Aksu and associates *et al.*, used ANNs in the direct compression method of tablet manufacture. They deduced from the analysis that ANNs save quite a significant amount of time and that the pharmaceutical business does not use them as frequently as other industries do. The links between the properties of input materials and output properties were described using the commercial software package FormRules. Another for-profit software programme, INForm, was used with the essential inputs.

Their study's goals included improving the formulation of the ramipril tablet and developing knowledge and design spaces a novel method for developing pharmaceutical products using an ANN programme and genetic programming. It was proven following the optimization that the investigated formulation fell within the design space. Additionally, they found that it was possible to learn more about the knowledge area through experiments employing hydroxypropyl methylcellulose and lubricants in proportions other than those utilised in the current study because the knowledge and the design areas were too close to one another.

For design area studies, it's crucial to determine the values that could produce a model in addition to how the formulation affects the tablet's properties. This study benefited greatly from the use of several computer programmes in terms of assessing the accuracy of the results. This held true particularly for programmes that produced an equation at the conclusion.

5.3 ANN's in optimization of emulsion^[11]:

Kumar et al., reported in order to optimise the fatty alcohol concentration during the creation of an o/w emulsion using ANNs. Their study's goal was to use ANNs to create a stable o/w emulsion by optimising the concentration of a fatty alcohol as well as an internal phase. According to the study, ANN predictions were precise and enabled measurement of the relative relevance of the inputs. Additionally, they discovered that it was feasible to generate output values that were relatively near to experimental values by altering the network structure and settings. The predicted values of the ANN model and the actual output values were contrasted. The percentage of response variability was represented by R^2 values; the model's R^2 value of 0.84 indicated adequate modelling, which is backed by the correlation coefficient's value of 0.9445.

5.4 ANN's for prediction of in- vitro dissolution profile^[12]:

It's remarkable that the use of ANNs in the creation of pharmaceutical products and processes began with the prediction of drug dissolution profiles for various formulations rather than with the investigation of fundamental steps in the product development process. In order to distinguish between different formulation types and maybe provide an approximation of the dissolution behaviour in vivo, dissolution testing allows one to analyse the drug release behaviour of pharmaceutical dosage forms in vitro. Dissolution testing is frequently employed in quality control studies, including those that examine batch-to-batch uniformity, stability, and the detection of manufacturing errors.

Leaneet al., predicted in-vitro predictions of sustained-release (SR) minitabiet dissolving using artificial neural networks (ANN). With the use of ANNs, they investigated the relative significance of several formulation and process parameters regulating the in vitro dissolution from enteric-coated SR minitabiet. They estimated the relative significance of the various formulation and processing variables in determining the minitabiet dissolving rate using input feature selection (IFS) algorithms. Their research also included the use of genetic algorithms in addition to forward and backward stepwise algorithms. A backpropagation approach was utilised in the study to test whether the IFS process had correctly located any unnecessary inputs before training the ANNs. They discovered that the importance of the numerous formulation and processing variables in determining the release of medication from minitabiet was consistently ranked by IFS.

They were ranked consistently in both release process indexes. Removal of inputs deemed to be less relevant during the ANNs' subsequent training enhanced network performance. The several formulation and processing variables that affected the release rate of the drug from minitabiet may be ranked according to their relative importance using ANNs. This is possible for all significant phases of the release process. They determined from the ANN's subsequent training that eliminating less important inputs from the procedure increased the ANN's performance.

5.5 ANNs in Minimization of the Capping Tendency by Tableting Process Optimization^[13]:

Belicet al. discussed about how to optimise the tableting process while minimising the capping propensity by using ANNs and fuzzy models. Their research's goal was to determine how tablet capping propensities were affected by particle size and tableting machine variables such main pressure, pre-pressure, and tableting speed. The impact of particle size and tableting machine settings on the capping coefficient was modelled using ANN and fuzzy models. The viability of using regularly measured quantities to forecast tablet quality was examined. The findings demonstrated that while trial and error methods cannot entirely be replaced, model-based expert systems based on modern routinely measured variables can greatly improve them. The modelling outcomes also indicate that it is advantageous to employ a variety of modelling techniques to assess the accuracy of model prediction when it is not feasible to gather a sufficient number of measurements to identify the model in question.

5.6 ANNs in Prediction of the In Vitro Permeability of Drugs^[14]:

Paixaoet al. used ANNs to predict the in vitro permeability measured in Caco-2 cells. They gathered the in vitro Log Papp values for 296 various medications from published studies of drug absorption in Caco-2 cells for the investigation. Examples of medications absorbed passively via the paracellular or transcellular pathway were provided, along with instances of active transport by various transporters. In the study, examples of medications with efflux mechanisms were also included. Log Papp values were divided into a training group of 192 drugs for network



optimization and a testing group of an additional 59 drugs for early stop and internal validation. As a result, the training group and testing group, respectively, had correlations of 0.843 and 0.702 and root mean square errors (RMSE) of 0.546 and 0.791. An additional 45 medications were used for external validation, with a correlation of 0.774 and RMSE of 0.601.

The specified molecular descriptors stored information about the molecules' size, shape, flexibility, electronegativity, lipophilicity, and other properties that are related to medication absorption. Because it enables the in-silico assessment of the in vitro Caco-2 apparent permeability, they came to the conclusion that the ANN model may be a useful tool for prediction and simulation in the drug development process.

VI. ANN's SOFTWARE

Almost everyone has access to the vast amount of ANN technology. These systems are already widely used in the pharmaceutical industry and are expected to grow in popularity. Examples of these ANN-based applications that are used to design or analyse various formulations are provided.

ANN's Software	Description
MATLAB ^[15]	Software for neural network construction, design, visualisation, and simulation is available through the Artificial Neural Toolkit. Neural networks are utilised in situations where systematic analysis is challenging, such as pattern recognition and nonlinear detection and regulation of structures. Although MATLAB is primarily designed for numeric computation, symbolic computation capabilities are accessible through an optional toolbox that uses the MuPAD symbolic engine. Graphical multi-domain simulation and model-based design for embedded and dynamic systems are added via an additional programme called Simulink.
STATISTICA 10 ^[16]	The STATISTICA Artificial Neural Networks; C and PMML code generators contain a vast array of statistics, marking settings, network designs, and training algorithms (Predictive Model Markup Language). The generator of C code is an addition.
Pythia – The Neural Network designer ^[17]	A neural network goes through two stages, the "learning process" and the "regeneration phase," respectively. During the training phase, sample data containing all inputs and desired outputs is analysed to maximise network performance, which entails lowering the variability.
Neuro solutions© 6.07 ^[18]	The primary programme for the building of neural networks is called Neuro Technologies. It combines a modular, icon-based network architectural interface with cutting-edge learning techniques like Levenberg-Marquardt and backpropagation over time. Other significant capabilities include programmatic management using OLE Automation from Visual Basic, the production of C++ source code, customised components by DLLs, and neuro-fuzzy designs. We advise you to also download a free test copy in order to fully comprehend the software. After you've gone through the extensive selection of live examples, you should attempt building and training a neural network with your own data.
Neural Works Professional II/PLUS ^[19]	The industry standard for intricate neural network manufacturing environments is Neural Works® Technical II/PLUS. UNIX, Linux, and Windows operating systems can run Professional II/PLUS on a variety of hardware architectures; data and network files are exchangeable in every way. An installation and user manual specific to the platform, a tutorial, a neural computation guide, basic and specialised reference manuals, and installation and user guides are all included in the Technical II/PLUS kit's comprehensive documentation of the entire phase of developing and implementing neural networks.
Stuttgart Neural-Network Simulator ^[20]	<ul style="list-style-type: none"> • For feed forward networks, back propagation (BP) • Reverse Transmission • Swift prop • Back percolation • RProp • Modified functions of the radial base (RBF)



Brain-Maker v3.7 ^[21]	The Brain Maker Neural Network Program enables you to utilise your programme for a variety of purposes, including pattern identification, medical diagnosis, industry and sales forecasting, estimation of markets, shares, products, and futures, and sports disability. almost every position requiring special insight. Brief papers about a few of our clients and their Brain Builder software can be found in the menu on the left.
Neuroshell Predictor ^[22]	Using well-known forecasting techniques, NeuroShell Predictor is a straightforward, step-by-step procedure that scans your current data for potential future trends. Even though it has the most advanced prediction algorithms currently available, it is made to be incredibly effective with little human input. To make access to and from other programmes simple, the software can read and write text files. The NeuroShell Predictor's usage of common text files makes integration with other software easier. By identifying patterns in your data file, the NeuroShell Predictor gains the ability to forecast the future. You can choose the columns from your data file that will be used as inputs for the model and the output column that will hold the values you are attempting to forecast using the predictor.
Neuroph ^[23]	By offering a Java neural network framework and GUI interface that facilitates designing, training, and storing neural networks, Neuroph makes the process of developing neural networks more straightforward. The Neuroph is a fantastic option for you if you are just getting started with neural networks and want to see how they operate without getting bogged down in complex theory and implementation, or if you need them right away for a research project. The neural network framework is compact, well-documented, simple to use, and incredibly adaptable.
Neural Designer ^[24]	Neural Designer is software for machine learning that is based on neural networks, one of the primary areas of research in artificial intelligence. It has a graphical user interface that makes it easier to enter data and comprehend results. Data analytics performed by Neural Designer include descriptive, diagnostic, predictive, and prescriptive analytics. It uses deep architectures with numerous non-linear layers and includes tools for autoencoding, time series analysis, pattern recognition, and function regression. Neural Designer receives a data set as its input, and it outputs a predictive model. An explicit mathematical phrase that represents the outcome can be exported to any computer language or operating system.
NeuroXL Predictor ^[25]	The NeuroXL Predictor interface is simple to use, doesn't require a deep understanding of neural networks, and effortlessly integrates with Microsoft Excel. A wide range of jobs, including stock price prediction, sales forecasting, and sports score prediction, benefit from the software's increased precision and accuracy. Threshold, Hyperbolic tangent, Zero-based log-sigmoid, Log-sigmoid, and Bipolar sigmoid are the five transmission functions that can now be used. Additionally, the trained network can be saved and then loaded as needed.

VII. CONCLUSION

These discussions have made it abundantly evident that ANNs are effective tools for developing pharmaceutical processes and products. Because they can handle sophisticated pattern recognition issues, ANNs have recently attracted a lot of attention for their potential usage in the pharmaceutical industry. However, ANNs offer an opportunity to predictably use the data from earlier investigations of a comparable nature. A trained ANN can predict the dissolving profile of a tablet formulation extremely easily and with a high degree of confidence when other computer programmes are unable to do so from the raw data, such as the amount of tablet binder, disintegrant, binding time, tablet hardness, etc. We believe there is scope for further improvement in the use of ANNs in drug development.

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