



# Current Research in Pharmaceutical Sciences

Available online at [www.crpsonline.com](http://www.crpsonline.com)



ISSN: 2250 – 2688

Received: 21/12/2022

Revised: 26/12/2022

Accepted: 28/12/2022

Published: 08/01/2023

**Pradyumna Ghosal, Shivani**

Department of Pharmaceutical Chemistry,  
School of Science, Hemvati Nandan  
Bahuguna Garhwal University, Srinagar  
Garhwal, (U.K), India 246174

## Correspondence

**Pradyumna Ghosal**

Department of Pharmaceutical Chemistry,  
School of Science, Hemvati Nandan  
Bahuguna Garhwal University, Srinagar  
Garhwal, (U.K), India 246174

Email: [pradyumnaghosal@gmail.com](mailto:pradyumnaghosal@gmail.com)

DOI: 10.24092/CRPS.2022.120403

Website: [www.crpsonline.com](http://www.crpsonline.com)

Quick Response Code:



## ***In Vitro* Evaluation of Some Brands of Diclofenac Sodium Injection Marketed in Greater Noida, Uttar Pradesh, India Using UV-Vis Spectrophotometric Method**

**Pradyumna Ghosal, Shivani**

### ABSTRACT

Quality is of principal subject to human beings in all perspective of life. When it comes to the quality of the pharmaceuticals which are consumed by humans, it is of most extreme significant as they are utilized for the prosperity of the humanity. In this study our objective was to evaluate the experimental *in vitro* study of the commercially obtainable Diclofenac Sodium injection brands which are available in Greater Noida. Ten different ampoules of 75mg/3ml diclofenac sodium injection products randomly collected from retail pharmacies and Govt. Hospital of targeted area in Greater Noida, Uttar Pradesh, India, twenty ampoules 75 mg/3ml have the same batch number of each brand were collected for the analysis. All the analytical methods were done in the quality control laboratories of JBJM Parenteral Pvt Ltd, Greater Noida, Uttar Pradesh, India. The study was carried out by performing various tests which is affiliated with the quality such as general appearance of Diclofenac Sodium injection ampoule, Particulate matter, Average fill volume, pH and content assay through pH Meter (Spectra lab), UV-Vis Spectrophotometer (UV-1900i SHIMADZU). The assay was evaluated by UV-Vis Spectrophotometer at the wavelength of 276nm. The results show that diclofenac sodium injection following IP specification, it can be concluded that all of the 10 brands of the drug passed through UV-Vis spectroscopy method also in pH meter. The Spectroscopy method was successfully applied to evaluate of Diclofenac Sodium injection.

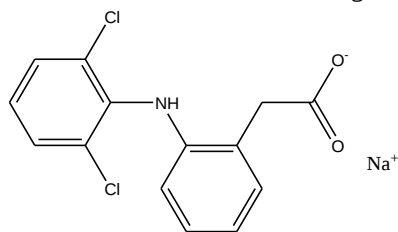
**Key words:** *In vitro* evaluation, Diclofenac sodium injection, UV-Vis Spectroscopy, pH, Analytical method, Pharmaceutical analysis, SHIMADZU, Greater Noida, Spectroscopy, Quality evaluation.

### 1. INTRODUCTION

Quality is of principal subject to human beings in all perspective of life. When it comes to the quality of the pharmaceuticals which are consumed by humans, it is of most extreme significant as they are utilized for the prosperity of the humanity.<sup>1</sup> The Pharmaceutical products must have to undergo various number of tests and total quality control as along with quality assurance before being marketed and consumed by patients and consumers for cure, prevent or treatment of any disease. Both quantitative and qualitative are required for evaluation their quality and assurance it. Now-a-days technology allows scientists to acquire detailed quality evaluation of products.

## 1.1 Diclofenac Sodium

Diclofenac is a profoundly powerful and very much endured nonselective NSAID recommended for use in the treatment of acute and chronic painful and inflammatory conditions. The currently available parenteral formulation of diclofenac sodium contains propylene glycol benzyl alcohol as solubilizers (hereafter termed PG-BA diclofenac), but is still relatively insoluble.<sup>9</sup> Diclofenac injection is a nonsteroidal anti-inflammatory drug (NSAID) used to treat adults with mild to moderate pain. It is used alone or given with other opioid (narcotic) pain medicines to treat adults with moderate to severe pain. Opioid analgesics have long been the primary pharmacotherapy for moderate to severe pain after surgery, but are associated with a number of adverse effects, such as respiratory depression, sedation, nausea and vomiting, pruritus, urinary retention and ileus. Such prolonged infusion can slow the onset of analgesia. Chemical structure of Diclofenac Sodium shown in the Figure 1.



**Figure 1: Chemical structure of Diclofenac Sodium**

The mechanism of action of Diclofenac Sodium is inhibition of prostaglandin biosynthesis via nonselective inhibition of cyclo-oxygenase isozymes.

## 1.2 Profile of Diclofenac Sodium Injection

Table 1: Profile of Diclofenac Sodium Injection as per I.P 2018

|                          |                                                                                                                         |
|--------------------------|-------------------------------------------------------------------------------------------------------------------------|
| <b>IUPAC name</b>        | Diclofenac Sodium is sodium 2-[2,6-dichlorophenyl]- amino] phenylacetate                                                |
| <b>Molecular Formula</b> | C <sub>14</sub> H <sub>10</sub> Cl <sub>2</sub> NNaO <sub>2</sub>                                                       |
| <b>Category</b>          | Analgesic and anti-inflammatory                                                                                         |
| <b>Dose</b>              | Intramuscular injection, 25 to 75 mg.                                                                                   |
| <b>Assay</b>             | Diclofenac sodium injection contains not less than 95% and not more than 105% of the stated amount of diclofenac sodium |
| <b>Usual strength</b>    | 25mg per ml                                                                                                             |

## 2. MATERIAL AND METHODOLOGY

### 2.1 Study Area and Period

The study was conducted from June to August, 2022 at the Greater Noida City. Which is situated in the state of Uttar Pradesh, India. Greater Noida city is located at approx. 45km from New Delhi (The Capital of India). The *in vitro* evaluation of Diclofenac Sodium Injection is Carried Out at JBJM Parenteral Pvt. Ltd, Greater Noida.

### 2.2 Study Design

The experimental *in vitro* study design was used to evaluate the *in vitro* analysis of the commercially obtainable Diclofenac Sodium injection brands which are available in Greater Noida. The study was carried out by performing various tests which is affiliated with the quality such as general appearance of Diclofenac Sodium injection ampoule, Particulate matter, Average fill volume, pH and content assay.

### 2.3 Instruments

Instruments used are Desiccator, Analytical Balance (Shimadzu), Digital Ultrasonic Cleaner (Tempstar), pH Meter (Spectra lab), UV- Spectrophotometer (UV-1900i SHIMADZU).

### 2.4 Glassware Used

Volumetric Flask (10ml, 50ml and 100ml), Measuring Cylinder (5ml, 10ml and 100ml), Pipette (1ml, 2ml and 5ml), Funnel, Beaker (100ml, 250ml and 500ml).

### 2.5 Reagents Used

Methanol Gradient Grade (Product code 41060, Batch No. MCM-4408, Molychem Pvt Ltd, Mumbai), Tablet Buffer pH 7.0 (Batch No 6809140821, Thermo Fisher Scientific India Pvt Ltd), Tablet Buffer pH 9.2 (Batch No 6209200120, Thermo Fisher Scientific India Pvt Ltd), Tablet Buffer pH 4.0 (Batch No 6003350919, Thermo Fisher Scientific India Pvt Ltd), Reference Standard Diclofenac Sodium Powder (Cat No. D-002, Lot No. IPRS/49/13, Indian Pharmacopoeia Commission, Government of India).

### 2.6 Collection of Sample

Ten different ampoules of 75mg/3ml diclofenac sodium products randomly collected from retail pharmacies and Govt. Hospital of targeted area in Greater Noida, Uttar Pradesh, India. twenty ampoules 75 mg/3ml have the same batch number of each brand were collected for the analysis. All the analytical methods were done in the quality control laboratories of JBJM Parenteral

Pvt Ltd, Greater Noida, Uttar Pradesh, India. The product information such as Manufacturer name, Batch number, and Marketed company are coded by Special Name for each brand is given in Table 2.

Table 2: List of collected samples

| S. no | Product code | Label Claim  | Filled Volume | Manufacturing Date | Expiry Date   | Country |
|-------|--------------|--------------|---------------|--------------------|---------------|---------|
| 1     | DIC 01       | 75mg/<br>3ml | 3 ml          | July/<br>2021      | June/<br>2023 | India   |
| 2     | DIC 02       | 75mg/<br>3ml | 3 ml          | Feb/<br>2021       | Jan/<br>2023  | India   |
| 3     | DIC 03       | 75mg/<br>3ml | 3 ml          | Sept/<br>2021      | Aug/<br>2023  | India   |
| 4     | DIC 04       | 75mg/<br>3ml | 3 ml          | March/<br>2021     | Feb/<br>2023  | India   |
| 5     | DIC 05       | 75mg/<br>3ml | 3 ml          | Dec/<br>2021       | Nov/<br>2023  | India   |
| 6     | DIC 06       | 75mg/<br>3ml | 3 ml          | Dec/<br>2021       | Nov/<br>2023  | India   |
| 7     | DIC 07       | 75mg/<br>3ml | 3 ml          | March/<br>2021     | Feb/<br>2023  | India   |
| 8     | DIC 08       | 75mg/<br>3ml | 3 ml          | Dec/<br>2021       | Nov/<br>2023  | India   |
| 9     | DIC 09       | 75mg/<br>3ml | 3 ml          | March/<br>2021     | Feb/<br>2023  | India   |
| 10    | DIC 10       | 75mg/<br>3ml | 3 ml          | March/<br>2021     | Feb/<br>2023  | India   |

## 2.7 Practical Method

The methods employed for the purpose of this study are the pH and UV-Vis Spectrophotometer. To assess the quality and performance of the batches of a brand in comparison with one another, different tests should be taken. And this is the case with Diclofenac Sodium Injection, which were submitted to compendial and non-compendial tests to establish a formal comparison based on the analysis of studied parameters.<sup>2</sup>

## 2.8 Physical and Pharmaceutical Tests

These tests include general appearance of Diclofenac Sodium injection ampoule, Particulate matter, Average fill volume, pH and Assay.

### 2.8.1 General Appearance of Diclofenac Sodium Injection Ampoule

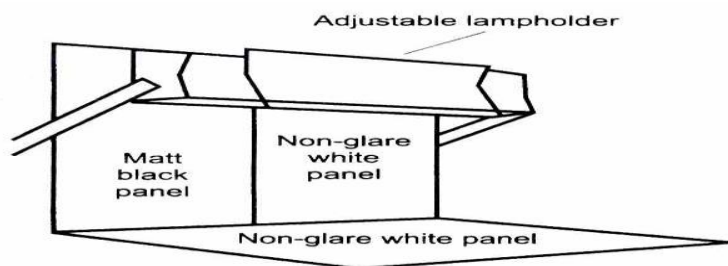
Five ampoules were randomly selected from each brand and individually inspected by bare eyes to confirm their color of the liquid, shape of each individual ampoule, quality of sealing etc. Result of general appearance of Diclofenac Sodium injection ampoule shown in Table 7.

### 2.8.2 Particulate Matter Test

Particulate contamination of injections consists of foreign particle or matter, mobile undissolved particles, other than gas bubbles unintentionally present in the solutions. The test is carried out with observation by inspection with the naked or bare eye. The method is very simple where take 10 ampoule/ container randomly and remove any labels on the ampoule/ container, wash and dry the outside. Gently shake, stir or transpose the ampoule/ container ensuring that air bubbles are not introduced, and observe for about 5seconds in front of the white panel. Repeat the procedure in front of the black panel. Record the presence of any particles. Repeat the procedure for a further 9 ampoules/ container.<sup>9</sup> Result of Particulate matter test given in Table 8.



Figure 2 (a): Apparatus for visible particle



**Figure 2 (b): Apparatus for visible particle (Source Self and Indian Pharmacopeia Vol II 2018)**

### 2.8.3 Average Fill Volume

The methodology of to investigate average fill volume of the ampoule, ten ampoules/containers were randomly selected from each brand and individually shake the ampoule and drawn the liquid in 3ml syringe and pour into 5ml measuring cylinder to calculate the fill volume of the liquid. The mean and standard variation in volume were calculated for average fill volume by using the following formula and Result of average fill volume given in Table 5.

$$\text{Average fill volume} = \frac{\text{Total volume of liquid of ten ampoules}}{10}$$

### 2.8.4 pH

#### 2.8.4.1 Preparation of Buffer Solution and Calibration of pH Meter

Table 3: Preparation method of pH buffer

| S. No | pH     | Preparation                                                                                                                                                       |
|-------|--------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1     | 7.0 pH | Dissolve one tablet in 100ml volumetric flask and up to 50% distilled water and sonicate to completely dissolve the tablet, then make it up with distilled water. |
| 2     | 4.0 pH | Dissolve one tablet in 100ml volumetric flask and up to 50% distilled water and sonicate to completely dissolve the tablet, then make it up with distilled water. |
| 3     | 9.2 pH | Dissolve one tablet in 100ml volumetric flask and up to 50% distilled water and sonicate to completely dissolve the tablet, then make it up with distilled water. |

pH meter calibration is a necessary step of using a pH meter because of how the electrode changes over time. The methodology of calibrating a pH meter, at first the electrode was cleaned up by distilled water the calibrating with buffer 7.0 pH, 4.0 pH and 9.2 pH respectively.

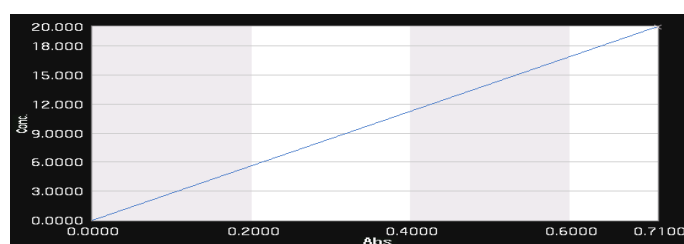
#### 2.8.4.2 Calculating the pH of the Ampoules/ Containers of Each Brand

The methodology of to investigate pH of the ampoule, five ampoules/containers were randomly selected from each brand and individually shake the ampoule and pour the liquid into a beaker and dip the electrode to calculate the pH of Diclofenac Sodium Injection. Result by Calculating the pH of ampoules given in Table 6.

#### 2.8.5 Assay of Diclofenac Sodium Injection Using UV-Vis Spectrophotometer

##### 2.8.5.1 Preparation of Standard Reference Solution

The reference standard solution solutions were prepared by equivalent weighed 50mg reference standard Diclofenac Sodium Powder (Cat No. D-002, Lot No. IPRS/49/13, Indian Pharmacopeia Commission, Government of India) as assay 0.9965 mg per mg on as is basis was dissolved in 50ml volumetric flask with Methanol Gradient Grade (Product code 41060, Batch No. MCM-4408, Molychem Pvt Ltd, Mumbai) and sonicate it for 30mins to make completely dissolve and make up the 50ml volumetric flask with Methanol Gradient Grade (Product code 41060, Batch No. MCM-4408, Molychem Pvt Ltd, Mumbai) the mixture was mixed well and filtered through a filter paper into clean beaker. After filtration, 1ml of dissolved solution is pipetted out and transfer to each clean and dry 50ml volumetric flask and Methanol Gradient Grade (Product code 41060, Batch No. MCM-4408, Molychem Pvt Ltd, Mumbai) was poured and again sonicated for few minutes then make it up the volumetric flask by Methanol Gradient Grade (Product code 41060, Batch No. MCM-4408, Molychem Pvt Ltd, Mumbai) to make 20 ppm reference standard solution.<sup>3,4,5</sup> Standard curve of Diclofenac Sodium Reference solution given in Figure 3.



**Figure 3: Standard curve of Diclofenac Sodium reference solution**

### 2.8.5.2 Preparation of Test Solution (Assayed Solution)

The sample solutions were prepared by use two diclofenac sodium ampoules from each brand product were emptied into individual ten small beakers. All the ten samples were labelled using marker pen and masking tape. Then 2 ml (50mg) solution was pipette out and transferred to each 50ml volumetric flask and Methanol Gradient Grade (Product code 41060, Batch No. MCM-4408, Molychem Pvt Ltd, Mumbai) was poured and sonicated for 30 mins to dissolve the drug molecule and make it up the volumetric flask by Methanol Gradient Grade (Product code 41060, Batch No. MCM-4408, Molychem Pvt Ltd, Mumbai). The mixture in respective volumetric flask was mixed properly and filtered through a filter paper into clean beakers. After filtration 1ml of respective solution is pipetted out and transfer to each clean and dry 50ml volumetric flask and Methanol Gradient Grade (Product code 41060, Batch No. MCM-4408, Molychem Pvt Ltd, Mumbai) was poured and again sonicated for few minutes then make it up the volumetric flask by Methanol Gradient Grade (Product code 41060, Batch No. MCM-4408, Molychem Pvt Ltd, Mumbai) to make 20 ppm test solution.<sup>6,7,8,10</sup>

### 2.8.5.3 Assay Test

Using the previous prepared solutions of diclofenac sodium reference and samples, and measured by calibrated UV-Vis Spectrophotometer (UV-1900i SHIMADZU) at 276 nm.<sup>11</sup> The assay percent of each sample recorded as shown in Table 9 by using the formula.

$$\text{Assay (\% content)} = \frac{A}{AA} \times \frac{B}{BB} \times \frac{C}{CC} \times \frac{D}{DD} \times \frac{E}{EE} \times \frac{F}{100} \times 100$$

Table 4: Aberration of words used in assay test (% content)

|    |                                                                   |
|----|-------------------------------------------------------------------|
| A  | Absorbance of test sample                                         |
| AA | Absorbance of reference standard sample                           |
| B  | Weight of reference standard sample in mg                         |
| BB | Volume of methanol for dissolving reference standard sample in ml |
| C  | Volume of pipetted solution of reference standard sample in ml    |
| CC | Volume of methanol in ml for dissolving pipetted solution         |
| D  | Volume of methanol for dissolving test solution in ml             |
| DD | Weight of test sample in mg                                       |
| E  | Volume of methanol in ml for dissolving pipetted solution in ml   |
| EE | Volume of pipetted solution of test sample in ml                  |
| F  | Potency of reference standard sample                              |

The assay mg content of each sample recorded as shown in (Table 10) by using the formula.

$$\text{Assay (\% content)} \times \text{Label Claim}$$

$$\text{Assay (mg content): } \frac{\text{Assay (\% content)} \times \text{Label Claim}}{100}$$

## 2.9 Data Analysis

The differences in practical data for the different marketed Diclofenac Sodium Injection were compared using Microsoft Office 2019 and Lab Solution software.

## 3. RESULT

*In Vitro* evaluation of some brands of Diclofenac Sodium injection marketed in Greater Noida, Uttar Pradesh, India Using UV-Vis Spectrophotometric method a fundamental analytical methodology in the pharmaceutical industry. This methodology allows quality assurance of liquid dosages forms for parenteral administration.

### 3.1 Result of Average Fill Volume

Table 5: Result of average fill of Diclofenac Sodium injection ampoule

| S. No | Product code | Limit     | Result |
|-------|--------------|-----------|--------|
| 1     | DIC 01       | 3.0 – 3.5 | 3.1    |
| 2     | DIC 02       | 3.0 – 3.5 | 3.0    |
| 3     | DIC 03       | 3.0 – 3.5 | 3.0    |
| 4     | DIC 04       | 3.0 – 3.5 | 3.0    |
| 5     | DIC 05       | 3.0 – 3.5 | 3.1    |
| 6     | DIC 06       | 3.0 – 3.5 | 3.0    |
| 7     | DIC 07       | 3.0 – 3.5 | 3.0    |
| 8     | DIC 08       | 3.0 – 3.5 | 3.1    |
| 9     | DIC 09       | 3.0 – 3.5 | 3.1    |
| 10    | DIC 10       | 3.0 – 3.5 | 3.1    |

### 3.2 Result of pH

Table 6: Result of pH of Diclofenac Sodium injection ampoule

| S. No | Product code | Limit     | Result |
|-------|--------------|-----------|--------|
| 1     | DIC 01       | 8.1 – 9.0 | 8.42   |
| 2     | DIC 02       | 8.1 – 9.0 | 8.38   |
| 3     | DIC 03       | 8.1 – 9.0 | 8.48   |
| 4     | DIC 04       | 8.1 – 9.0 | 8.60   |
| 5     | DIC 05       | 8.1 – 9.0 | 8.51   |
| 6     | DIC 06       | 8.1 – 9.0 | 8.39   |
| 7     | DIC 07       | 8.1 – 9.0 | 8.53   |
| 8     | DIC 08       | 8.1 – 9.0 | 8.56   |
| 9     | DIC 09       | 8.1 – 9.0 | 8.34   |
| 10    | DIC 10       | 8.1 – 9.0 | 8.59   |

### 3.3 Result of General Appearance

Table 7: Result of general appearance of Diclofenac Sodium injection ampoule

| S. No | Product code | Result                                                                                                    |
|-------|--------------|-----------------------------------------------------------------------------------------------------------|
| 1     | DIC 01       | A Slightly faint colorless to liquid, filled in clear glass ampoule of 3ml with blue color ring on neck.  |
| 2     | DIC 02       | A Slightly faint colorless liquid, filled in clear glass ampoule of 3ml with blue color ring on neck.     |
| 3     | DIC 03       | A Slightly faint colorless liquid, filled in clear glass ampoule of 3ml with blue color dot on neck.      |
| 4     | DIC 04       | A Slightly faint colorless liquid, filled in clear glass ampoule of 3ml with blue color dot on neck.      |
| 5     | DIC 05       | A Slightly faint colorless liquid, filled in clear glass ampoule of 3ml with blue color ring on neck.     |
| 6     | DIC 06       | A Slightly faint colorless liquid, filled in clear glass ampoule of 3ml with blue color dot on neck.      |
| 7     | DIC 07       | A Slightly faint colorless to liquid, filled in clear glass ampoule of 3ml with green color ring on neck. |
| 8     | DIC 08       | A Slightly faint colorless to liquid, filled in clear glass ampoule of 3ml with blue color ring on neck.  |
| 9     | DIC 09       | A Slightly faint colorless liquid, filled in clear glass ampoule of 3ml with blue color dot on neck.      |
| 10    | DIC 10       | A Slightly faint colorless liquid, filled in clear glass ampoule of 3ml with green coloring on neck.      |

### 3.4 Result of Particulate Matter Test

Table 8: Result of Particulate matter test of Diclofenac Sodium injection ampoule

| S. No | Product code | Result                                                                                                                      |
|-------|--------------|-----------------------------------------------------------------------------------------------------------------------------|
| 1     | DIC 01       | A clear liquid which free from foreign particle and other mobile undissolved particles which can be detected by naked eyes. |
| 2     | DIC 02       | A clear liquid which free from foreign particle and other mobile undissolved particles which can be detected by naked eyes. |
| 3     | DIC 03       | A clear liquid which free from foreign particle and other mobile undissolved particles which can be detected by naked eyes. |
| 4     | DIC 04       | A clear liquid which free from foreign particle and other mobile undissolved particles which can be detected by naked eyes. |
| 5     | DIC 05       | A clear liquid which free from foreign particle and other mobile undissolved particles which can be detected by naked eyes. |
| 6     | DIC 06       | A clear liquid which free from foreign particle and other mobile undissolved particles which can be detected by naked eyes. |
| 7     | DIC 07       | A clear liquid which free from foreign particle and other mobile undissolved particles which can be detected by naked eyes. |
| 8     | DIC 08       | A clear liquid which free from foreign particle and other mobile undissolved particles which can be detected by naked eyes. |
| 9     | DIC 09       | A clear liquid which free from foreign particle and other mobile undissolved particles which can be detected by naked eyes. |
| 10    | DIC 10       | A clear liquid which free from foreign particle and other mobile undissolved particles which can be detected by naked eyes. |

### 3.5 Result of Assay Test

#### 3.5.2 Result of assay test in mg content

##### 3.5.1 Result of Assay Test in (%) Content

Table 9: Result of assay (% content) of Diclofenac Sodium injection ampoule

| S. No | Product code | Limit            | Concentration | Absorbance at 276 nm | Result (%) |
|-------|--------------|------------------|---------------|----------------------|------------|
| 0     | Ref. Std     | -                | 20            | 0.710                | -          |
| 1     | DIC 01       | 95.0 % - 105.0 % | 20            | 0.709                | 99.78827   |
| 2     | DIC 02       | 95.0 % - 105.0 % | 20            | 0.713                | 100.3513   |
| 3     | DIC 03       | 95.0 % - 105.0 % | 20            | 0.703                | 98.9438    |
| 4     | DIC 04       | 95.0 % - 105.0 % | 20            | 0.710                | 99.92902   |
| 5     | DIC 05       | 95.0 % - 105.0 % | 20            | 0.712                | 100.2105   |
| 6     | DIC 06       | 95.0 % - 105.0 % | 20            | 0.707                | 99.50678   |
| 7     | DIC 07       | 95.0 % - 105.0 % | 20            | 0.708                | 99.64753   |
| 8     | DIC 08       | 95.0 % - 105.0 % | 20            | 0.711                | 100.0698   |
| 9     | DIC 09       | 95.0 % - 105.0 % | 20            | 0.712                | 100.2105   |
| 10    | DIC 10       | 95.0 % - 105.0 % | 20            | 0.710                | 99.92902   |

Table 10: Result of assay (mg content) of Diclofenac Sodium injection ampoule

| S. No | Product code | Limit               | Result (%) | Result (mg content)/75mg |
|-------|--------------|---------------------|------------|--------------------------|
| 1     | DIC 01       | 71.25 mg – 78.75 mg | 99.78827   | 74.84121/75mg            |
| 2     | DIC 02       | 71.25 mg – 78.75 mg | 100.3513   | 75.26344/75mg            |
| 3     | DIC 03       | 71.25 mg – 78.75 mg | 98.9438    | 74.20785/75mg            |
| 4     | DIC 04       | 71.25 mg – 78.75 mg | 99.92902   | 74.94677/75mg            |
| 5     | DIC 05       | 71.25 mg – 78.75 mg | 100.2105   | 75.15788/75mg            |
| 6     | DIC 06       | 71.25 mg – 78.75 mg | 99.50678   | 74.63009/75mg            |
| 7     | DIC 07       | 71.25 mg – 78.75 mg | 99.64753   | 74.73565/75mg            |
| 8     | DIC 08       | 71.25 mg – 78.75 mg | 100.0698   | 75.05232/75mg            |
| 9     | DIC 09       | 71.25 mg – 78.75 mg | 100.2105   | 75.15788/75mg            |
| 10    | DIC 10       | 71.25 mg – 78.75 mg | 99.92902   | 74.94677/75mg            |

#### 4. DISCUSSION

To assure that drugs produce the required therapeutic effect also keeping away from toxicities due to overdose, it is very important that the content of the medicine should meet the specification limit as stated in the monograph. According to IP, the percentage content of diclofenac sodium injection should be limited within the range of 95%-105%, out of the ten marketed brands of diclofenac sodium injection in Greater Noida, Uttar Pradesh, were evaluated, from the result obtained using UV-Vis Spectrophotometer of DIC 01 (99.78827%), DIC 02 (100.3513%), DIC 03 (98.9438%), DIC 04 (99.92902%), DIC 05 (100.2105%), DIC 06 (99.50678%), DIC 07 (99.64753%), DIC 08 (100.0698%), DIC 09 (100.2105%) and DIC 10 (99.92902%) are all within the I.P. Specified limit. According to I.P., the pH of diclofenac sodium injection be in limit of 8.1 to 9, here out of the ten marketed brands of diclofenac sodium injection in Greater Noida, Uttar Pradesh, were evaluated, from the result obtained using pH meter of DIC 01 (pH 8.42), DIC 02 (pH 8.38), DIC 03 (pH 8.48), DIC 04 (pH 8.60), DIC 05 (pH 8.51), DIC 06 (pH 8.39), DIC 07 (pH 8.53), DIC 08 (pH 8.56), DIC 09 (pH 8.34) and DIC 10 (pH 8.59) are all within the I.P. Specified limit also average fill volume of each branded diclofenac sodium ampoules were within limit. The general appearance of all branded samples and the particulate matter of all examine diclofenac sodium ampoules which collected for evaluation were obtaining very good result.

#### 5. CONCLUSION

For diclofenac sodium injection following IP specification, it can be concluded that all of the 10 brands of the drug passed through UV-Vis spectroscopy method also in pH meter. The Spectroscopy method was successfully applied to evaluate of Diclofenac Sodium injection.

#### ACKNOWLEDGMENT

I'd like to thank JBJM Parenterals Pvt Ltd, Greater Noida, Uttar Pradesh, India for the analytical and laboratory support.

#### REFERENCES

- Balekundri A, Mannur V. Quality control of the traditional herbs and herbal products: A Review. *Future Journal of Pharmaceutical Sciences*. 2020;6(1).
- Abebe K, Beressa TB, Yimer BT. *In vitro* Evaluations of Quality Control Parameters of Paracetamol Tablets Marketed in Gondar City, Northwest Ethiopia. *Drug, Healthcare and Patient Safety*. 2020;12: 273–279.
- Kadam PV, Bhingare CL, Nikam RY, Pawar SA. Development and validation of UV Spectrophotometric method for the estimation of Curcumin in cream formulation. *Pharmaceutical Methods*. 2013; 4(2):43–45.
- Anand K, Pandey A. Validation Study of Steroidal Drugs (Dexamethasone and Betamethasone) By U.V. Spectrophotometric Method. *Asian Journal of Pharmaceutical and Clinical Research*. 2018;11(7):501.
- Mendez AS, Steppe M, Schapoval EE. Validation of HPLC and UV spectrophotometric methods for the determination of meropenem in pharmaceutical dosage form. *Journal of Pharmaceutical and Biomedical Analysis*. 2003;33(5):947–954.
- Al-Meshal MA, Ramadan MA, Lotfi KM, Shibl AM. *J. Clin. Pharm. Therap.* 1995; 20:159-163.
- Audu SA, Ahmed AM, Sani AETMA, RafatOjuolape AR, Sani AKS, Bukola ARR, Zakama S, Mohammed I. Comparative Quantitative Analysis of Different Brands of 300 mg Aspirin Tablet Marketed in Maiduguri Metropolitan Council. *Journal of Chemical and Pharmaceutical Research*. 2012;4(8):4038- 4051
- Gelsema WJ, de Ligny CL, Remijnse AG, Blijleven HA. pH-Measurements in alcohol-water mixtures, using aqueous standard buffer solutions for calibration. *Recueil Des Travaux Chimiquesdes Pays-Bas*. 2010; 85(7): 647–660.
- Indian Pharmacopoeia, Vol. I, II & III, Government of India, Ministry of Health and family Welfare, Controller of Publications, Delhi (2018) Vol-II.
- Willard H, Merritt L, Dean JA, Settle FA, *Instrumental methods of analysis*, 7th Ed, CBS Publishers & Distributor, New Delhi, (1986) 580-655.
- Al-Khawlani QM, Alzomor AKK, Al-Mekhlafi AG. *In Vitro* Quality Evaluation of Ten Diclofenac Sodium Ampoule Brands in Yemen, Peer Review Under Responsibility of Life Science Informatics Publications. 2018;4(5):451.