September 2022

Public assessment summary report

Name of the Finished Pharmaceutical Product	Diclofenac Sodium Injection 75 mg/2 ml
Manufacturer of the Finished Product	**Cisen Pharmaceauticals co., ltd** Tongji Tech-Industrial Garden, Jining High&New Technology Industries Development Zone, Jining, Shandong Province, P.R. China
Active Pharmaceutical Ingredient(s) (API)	Diclofenac Sodium

1. Introduction

Based on in depth review of quality, safety and efficacy data, the authority granted a marketing authorization for Diclofenac Sodium Injection 75 mg/2 ml, manufactured by Cisen Pharmaceauticals co., ltd, China . The active ingredient of Diclofenac Sodium Injection 75 mg/2 ml is Diclofenac Sodium. Diclofenac is in a class of medications called Non-steroidal anti-inflammatory drugs (NSAIDs).
ATC code M01AB.

The product is indicated for:

The treatment of painful condition, such as kidney stone pain, osteoarthritis (degeneration of joints) and rheumatoid arthritis (inflammation of joints), back pain, gout) formation of crystals in joints), injuries and fractures in children aged over 12 years, adults and older patients.

A compressive description of the indications and posology is given in the SmPC.

2. Assessment of quality

Active pharmaceutical Ingredient (API)

INN name: Diclofenac sodium
Chemical name: *Sodium 2-[(2, 6-dichlorophenyl) amino] phenyl] acetate*

The active substance is white or almost white crystalline powder. It is sparingly soluble in water, freely soluble in ethanol and insoluble in chloroform.

The proposed manufacturing process has been adequately described; critical steps and accompanying in-process controls have been defined to ensure quality of the final compound.

In-process controls performed during the synthesis are suitable to control the reaction progress. Appropriate specifications for starting materials, solvents and reagents have been established.

Evidence of the structure has been confirmed by various methods. Potential impurities originating from starting materials, intermediates, by-products, and degradation products have been discussed in relation to their origin and potential carry-over into the final drug substance. Residual solvents and heavy metals are routinely controlled.

The substance complies with the requirements of the Ethiopian medicine registration guideline for potential impurities.
The specifications reflect all relevant quality attributes of the active substance and were found to be adequate to control the quality of the drug substance. Testing methods are adequately drawn up and sufficiently validated. The reference materials used by the active substance manufacturer and the drug product manufacturer for the control of the substance are adequately characterised. Batch analysis data justify the limits, indicate the good performance of testing methods and demonstrate the batch to batch consistency of the production.

Stability data have been obtained. The data show the substance to be stable. Based on the data submitted appropriate retest periods and storage conditions have been set.
GMP compliance of the API manufacture is demonstrated by document review.

Finished pharmaceutical product (FPP)

Pharmaceutical development and manufacture:

The aim of the pharmaceutical development was to develop Diclofenac Sodium Injection 75 mg/2 ml generic version to the reference innovator product.
A satisfactory package of data on development pharmaceutics has been presented. Brief discussion on reasons for inclusion and quantity of excipients has been provided.
The compositions and the pharmaceutical tests evaluated during development of the final Formulation is included in the documentation.

As a result of development studies product with the following composition, appearance and

Packaging was obtained. The used excipients were: Lidocaine Hydrochloride, 1, 2-Propylene Glycol Polyethylene Glycol-400 Sodium Sulfite, EDTA-2Na Water for Injections. All excipients used comply with their respective CP2015 monographs.

Diclofenac Sodium Injection 75 mg/2 ml is a Colorless or almost colorless solution for injection.

With regard to impurity profile, the product is shown to be similar to the reference product. A description and flow chart of the manufacturing method has been provided. Appropriate in-process controls are included in the manufacturing process. Satisfactory batch formulae were also presented. GMP compliance of the manufacturing site has been demonstrated.

Specifications:

The finished product specification is satisfactory. The acceptance criteria have been justified with respect to conventional pharmaceutical requirements as prescribed in the relevant dosage form monograph of CP2015. Appropriate control strategy was selected. The test methods have been described and have been adequately validated, as appropriate. Batch data have been provided and complied with the specification. Certificates of analysis for three productions are presented. Certificates of analysis were also provided for the working standard used.

The container closure system
Diclofenac Sodium Injection 75 mg/2 ml is a Colorless or almost colorless solution for injection packaged in USP type 1 brown glass ampoules with 10X2ml pack sizes

Stability testing:
It is confirmed that the finished product stability studies were conducted in the container closure system proposed for the marketing of the product in accordance with the current medicine registration guideline of Ethiopia.
Based on the stability study results, a shelf-life of 36 months with storage conditions "*Store in tightly closed containers, at Controlled Room Temperature 20 to 25°C. Do not freeze. Protect from light"* was proposed. The product stability testing data support the current shelf life and storage conditions of the product. Therefore, shelf life and storage statement were considered acceptable Diclofenac Sodium Injection 75 mg/2 ml

3. Assessment of bioequivalence

Evidence for bioequivalence study for parentral dosage forms is not required as per the Ethiopian medicine registration guideline.

4. Conclusion

Based on assessment of data on quality, safety and efficacy of the product, it is considered that the benefit–risk profile of Diclofenac Sodium Injection 75 mg/2 ml manufactured by Cisen Pharmaceauticals co., ltd, China. is acceptable for the following indication(s) in:
The treatment of painful condition, such as kidney stone pain, osteoarthritis (degeneration of joints) and rheumatoid arthritis (inflammation of joints), back pain, gout) formation of crystals in joints), injuries and fractures in children aged over 12 years, adults and older patients.