PHARMOBEDIENT

August 24, 2024

Division of Dockets Management
U.S. Food and Drug Administration
Department of Health and Human Services
Room 1061, l-IFA-305
5630 Fishers Lane
Rockville, MD 20852

ANDA Suitability Petition for Diclofenac Potassium Tablets 37.5 mg

Dear Sir/Madam,

The undersigned submits this Suitability Petition pursuant to section 505(j)(2)(C) of the Federal Food, Drug, and Cosmetic Act ("FDC Act") and in accordance with 21 C.F.R. § 10.20, 10.30 and 314.93, to request that the Commissioner of the U.S. Food and Drug Administration ("FDA") declare that the drug product, Diclofenac Potassium Tablets, 37.5 mg is suitable for submission in an Abbreviated New Drug Application ("ANDA").

A. Action Requested:

The Suitability Petition requests that the FDA determine and declare that Diclofenac Potassium Tablets, 37.5 mg is suitable for submission in an Abbreviated New DrugApplication (ANDA). This Suitability Petition pursuant to Section 505(j)(2)(C) of the FDC Act and 21C.F.R. §314.93, is the appropriate mechanism for securing FDA authorization to submit anANDA for a drug product that differs in dosage form from the Reference Listed Drug (RLD).

The Reference Listed Drug (RLD) upon which this petition is based is CATAFLAM immediate-release tablets from NOVARTIS PHARMACEUTICAL CORP, which FDA approved on Nov 24, 1993 under NDA # N020142. CATAFLAM is discontinued and **Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**.

The relevant copy of the pages from the current Electronic Edition of the Approved Drug Products with Therapeutic Equivalence Evaluations (Orange Book) for CATAFLAM is provided as **Attachment 1**. The RLD labeling obtained from Drugs@FDA is also provided as **Attachment 2**.

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Approval of this Suitability Petition would allow the sponsor to submit Diclofenac Potassium Tablets, 37.5 mg as an ANDA.

B. Statement of Grounds:

Reference Standard (RS) drug listed is # A075463 of RK PHARMA INC and is marketed in a 50 mg strength tablet as identified in the Orange Book. Diclofenac Potassium Tablets, USP 50 mg, the RS for the proposed drug product, containing 50 mg of Diclofenac Potassium, as film-coated immediate-release tablets, is a Nonsteroidal Anti-Inflammatory Drug (NSAID) indicated for the following:

- For treatment of primary dysmenorrhea
- For relief of mild to moderate pain
- For relief of the signs and symptoms of osteoarthritis
- For relief of the signs and symptoms of rheumatoid arthritis

A copy of the most recent labeling for RS under ANDA # 075463 (Revised January 10, 2023) is provided as **Attachment 3**.

The dosing recommendation in the RS package insert states the following under "Dosage and Administration":

> Use the lowest effective dose for the shortest duration consistent with individual patient treatment goals (see WARNINGS; Gastrointestinal Bleeding, Ulceration, and Perforation).
>
> After observing the response to initial therapy with diclofenac potassium tablets, the dose and frequency should be adjusted to suit an individual patient's needs.
>
> For treatment of pain or primary dysmenorrhea the recommended dosage is 50 mg three times a day. With experience, physicians may find that in some patients an initial dose of 100 mg of diclofenac potassium tablets, followed by 50 mg doses, will provide better relief.
>
> For the relief of osteoarthritis the recommended dosage is 100-150 mg/day in divided doses, 50 mg twice a day or three times a day.

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For the relief of rheumatoid arthritis the recommended dosage is 150-200 mg/day in divided doses, 50 mg three times a day or four times a day.

The proposed drug product also contains diclofenac potassium in a tablet dosage form, but in a 37.5 mg strength. The petition is thus seeking a change in tablet strength to 37.5 mg from that of the RLD (25 mg and 50 mg). The availability of a new 37.5 mg tablet strength will provide a prescribing physician with the ability to prescribe the lowest effective dose and the flexbility to meet individual patient treatment need.

Table 1 presents the comparison between approved marketed and proposed drug product.

Table 1 - Comparison of Approved Drug Products to Proposed Drug Product

Product Name	Reference Standard (RS) and RLD Drug Products	Diclofenac Potassium Tablets by Pharmobedient Pharmaceuticals, LLC
Drug Substance	Diclofenac Potassium, USP	
Dosage Strengths	25 and 50 mg	
Dosage Form	Tablets	Tablets
Route of Administration	Oral	
Indication	• For treatment of primary dysmenorrhea • For relief of mild to moderate pain • For relief of the signs and symptoms of osteoarthritis • For relief of the signs and symptoms of rheumatoid arthritis	

Note: - *Formulation development of tablet will be done to meet all the quality and regulatory requirements.*

The proposed labeling for Pharmobedient's Diclofenac Potassium Tablets is provided as **Attachment 4;** with the changes annotated in track changes from the FDA approved labeling of the Immediate Release Tablets. The only differences between the two products'labeling are those related to the *product strength*.

The tablets formulation of Diclofenac Potassium will be developed by Pharmobedient to obtain immediate-release oral dosage form bioequivalent to Reference Standard (RS) drug - Diclofenac Potassium Tablets by RK PHARMA INC, that enhances and promotes therapeutic convenience, adherence and compliance:

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Considering the formulation release properties and the desired bioequivalence to the RS formulation, the bioavailability of the proposed 37.5 mg dosage strength of tablets shall be studied against the 50 mg dosage strength of RK PHARMA's Diclofenac Potassium Tablets. Thus, within the scope of the proposed ANDA approach, the proposed drug shall demonstrate bioequivalence (90% CI) against the RS in the two bioavailability studies (fasting and fed conditions) required by the Office of Generic Drug (OGD) Product-Specific Guidance for Generic Drug Development for bioequivalencestudies of Diclofenac Potassium tablets, as provided in **Attachment 5**.

Therefore, the petitioner's request for the Commissioner to find that a change in dosage strength from 25 mg and 50 mg to 37.5 mg should raise no questions of safety or effectiveness, and the Agency should approve the petition.

C. Environmental Impact
The petitioner claims a categorical exclusion under 21 CFR 25.31.

D. Economic Impact
The petitioner does not believe that this is applicable in this case, but will agree to provide such an analysis, if requested by the Agency.

E. Certification
The undersigned certifies that to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner, which are unfavorable to the petition.

During the course of the review of this Suitability Petition, if there are any questions or comments, please do not hesitate to contact undersigned.

Sincerely,

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