



## **National Agency for Food & Drug Administration & Control (NAFDAC)**

### **NAFDAC Public Assessment Report (NAPAR)**

**Flow-K 600 mg tablets**

**Potassium chloride 600 mg**

**A4-102039**

**Pinbarth Pharmaceuticals Limited**

This report reflects the scientific assessment for the approval of Flow-K tablets. The product was licenced in March 2026.

## PART 1: ABSTRACT

Flow-K tablets containing potassium chloride, manufactured at Dr. Milton's Laboratories Private Limited, Thirubuvanai, Puducherry, India, was granted marketing authorization by NAFDAC for the management and treatment of hypokalemia on 31 March 2026.

Flow-K tablet is indicated for the management and treatment of hypokalemia.

For details on the uses of this product and for side effects and warnings, see the summary of product characteristics (SmPC), which can be found in the NAFDAC Greenbook.

The marketing authorization of flow-K tablets by NAFDAC is based on the review of the Common Technical Document (CTD) dossier submitted to ascertain the quality, safety, and efficacy.

All accepted presentations of flow-K tablets have been shown in part 2 of this report. The summary of product characteristics (SmPC) and the approved labelling have been presented in part 3 and part 4 respectively.

Scientific discussion on the quality, non-clinical and clinical aspects of flow-K tablets has been presented in part 5 of this report.

The detailed steps taken to approve flow-K tablets by NAFDAC have been presented in part 6 of this report.

No action or steps have been taken following the marketing authorization of flow-K tablets.

## PART 2: ACCEPTED PRESENTATIONS

| Product name          | Active ingredients        | Pharmaceutical form/description                                          | Packaging                                                                                                                               | Pack size       |
|-----------------------|---------------------------|--------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------|-----------------|
| Flow-K 600 mg tablets | Potassium chloride 600 mg | Orange, round, film-coated tablets. The tablets are plain on both sides. | Round, opaque white plastic (HDPE) bottle containing 100 tablets. The bottle has a white, childproof plastic (polypropylene) screw cap. | 1 x 100 tablets |

## PART 3: SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

Refer to the NAFDAC Greenbook URL below for the SmPC

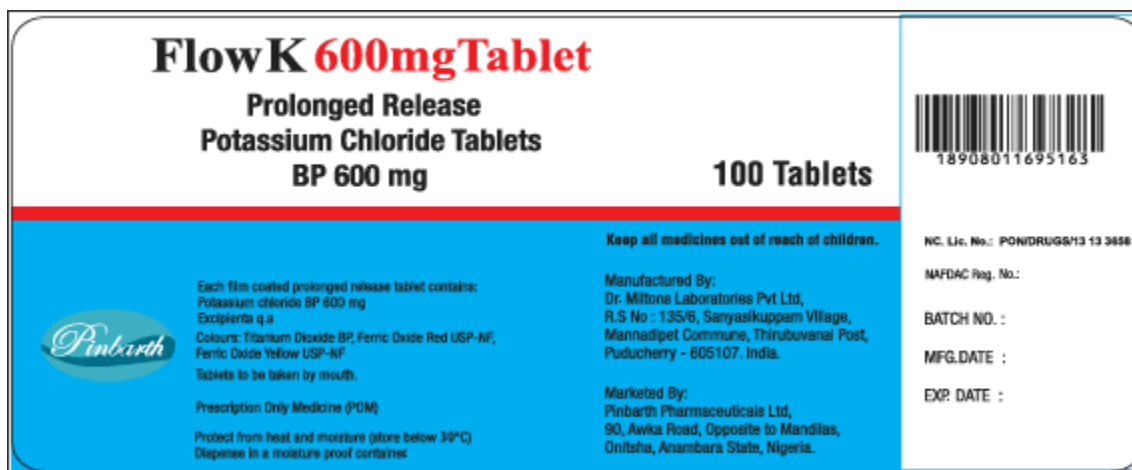
See: <https://greenbook.nafdac.gov.ng/>

## PART 4: LABELLING

### Primary label



### Secondary label



## PART 5: SCIENTIFIC DISCUSSION

### 5.1. About the Product

#### 5.1.1 Name of the product

Flow-K potassium chloride 600 mg tablets

#### 5.1.2 Therapeutic indication

Flow-K tablet is indicated for the management and treatment of hypokalemia.

### **5.1.3 Applicant**

Pinbarth Pharmaceuticals Limited, No 90, Awka Road, Onitsha, Anambra State, Nigeria.

### **5.1.4 Pharmaceutical form**

Tablet

Orange, round, film- coated tablets. The tablets are plain on both sides.

### **5.1.5 Storage**

Do not store above 30°C. Store in the original packaging.

### **5.1.6 Shelf life**

36 months

### **5.1.7 Product presentation**

Round, opaque white plastic (HDPE) bottle containing 100 tablets. The bottle has a white, childproof plastic (polypropylene) screw cap.

## **5.2 Drug Substance**

### **5.2.1 Manufacturer**

Potassium chloride is manufactured by Anish Chemicals Chitra Gujarat Industrial Development Corporation, Bhavnagar, Gujarat

The API specifications are pharmacopoeial based.

Stability testing was conducted according to the requirements of NAFDAC.

## **5.3 Other ingredients**

Other ingredients used in the formulation of flow-K tablets include hydrogenated castor oil, microcrystalline cellulose, magnesium stearate, methacrylic acid & methyl methacrylate copolymer 1:2, lactose monohydrate, talc, polyethylene glycol 400, titanium dioxide, colorcoat MB4S-H II 7100321 A (Orange), insta glow IG-001, isopropyl alcohol, methylene chloride, all being pharmacopoeial controlled.

## **5.4 Drug Product**

### **5.4.1 Drug product manufacturer**

Dr. Milton's Laboratories Private Limited, 135/6, Sanyasikuppam village, Thirubuvanai (post), Mannadipet Commune, Puducherry, India.

### **5.4.2 Pharmaceutical development**

The objective of the pharmaceutical development is to manufacture a generic which is stable, deliver the intended performance, safe and bioequivalent in term of efficacy to the reference product, Slow-K tablets manufactured by CIBA laboratories, Switzerland.

The product is manufactured by dry mixing, wet granulation, sieving, lubrication, compression, and packing. All the manufacturing processes were validated.

Comparative dissolution profile was conducted in line with ICH M9 guidelines between the reference product Slow-K tablets (Norvatis) and Flow-K tablets. The profile in the three BCS media are similar.

### 5.4.3 Specification

The finished product specification is based on pharmacopoeial. The finished product specifications include description, identification, microbial limits and stability testing. The test procedures have been adequately validated.

### 5.4.4 Stability

Stability studies have been conducted at 30°C/75%RH at long-term storage conditions and for six months at accelerated conditions in the packaging intended for marketing the product. The product proved to be quite stable in these conditions, with no apparent negative trend. Based on the data submitted, the proposed shelf life of 36 months and 'Do not store above 30°C. Store in the original packaging' have been accepted.

### 5.6 Conclusion

Based on the assessment of data submitted on quality, safety and efficacy, the benefit–risk profile of flow-K tablets was acceptable for the following indication: 'for the management and treatment and hypokalemia', and is included in the list of approved medicinal products by NAFDAC.

## PART 6: STEPS TAKEN FOR REGISTRATION

The applicant, Pinbarth Pharmaceuticals Limited, No. 90, Awka Road, Onitsha, Anambra State, Nigeria, submitted application to the National Agency for Food and Drug Administration and Control (NAFDAC), for the registration of flow-K tablets

The following are the steps for registration

|                      |                                             |
|----------------------|---------------------------------------------|
| October 2024         | Date of receipt of application              |
| October 2025         | Date of conclusion of assessment            |
| October 2025         | Date of inspection                          |
| <b>31 March 2026</b> | Date of issuance of Marketing Authorization |

## PART 7: STEPS TAKEN FOLLOWING REGISTRATION

No action or steps have been taken following marketing authorization of Flow-K tablets.