



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

NAFDAC Public Assessment Report (NAPAR)

Pinnacle pregabalin 150 mg capsules

Pregabalin 150 mg

A4-102124

Pinnacle Health Pharmaceutical and Stores Limited

This report reflects the scientific assessment for the approval of pregabalin capsule. The product was licenced in May 2026.

PART 1: ABSTRACT

Pinnacle pregabalin capsules, manufactured at Globela Pharma Private Limited, Surat, Gujarat, India. was granted marketing authorization by NAFDAC for the treatment of partial seizures in adults on 26 May 2026.

Pinnacle pregabalin is indicated for the treatment of peripheral and central neuropathic pain in adults.

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 pinnacle pregabalin 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 pinnacle pregabalin 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 pinnacle pregabalin has been presented in part 5 of this report.

The detailed steps taken to approve pinnacle pregabalin by NAFDAC have been presented in part 6 of this report.

No action or steps have been taken following the marketing authorization of pinnacle pregabalin.

PART 2: ACCEPTED PRESENTATIONS

Product name	Active ingredients	Pharmaceutical form/description	Packaging	Pack size
Pinnacle pregabalin 150 mg capsules	Pregabalin 150 mg	Hard gelatin capsule Hard gelatin capsules with an opaque red cap and body. They contain a white to off white powder.	Aluminium on Aluminium blister cards, each containing 10 capsules. Available in cartons of 3 x 10 capsules.	3 x 10 capsules

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



5.1.2 Therapeutic indication

Pinnacle pregabalin is indicated for the treatment of peripheral and central neuropathic pain in adults, also as an adjunctive therapy in adults with partial seizures with or without secondary generalization and for the treatment of generalised anxiety disorder in adults.

5.1.3 Applicant

Pinnacle Health Pharmaceutical and Stores Limited, No. 16/18 Nuru Oniwo Aguda, Surulere, Lagos, Nigeria.

5.1.4 Pharmaceutical form

Hard gelatin capsule

Hard gelatin capsules with an opaque red cap and body. They contain a white to off white powder.

5.1.5 Storage

Store below 30°C. Protect from sunlight and moisture.

5.1.6 Shelf life

36 months

5.1.7 Product presentation

Aluminium on Aluminium blister cards, each containing 10 capsules. Available in cartons of 3 x 10 capsules.

5.2 Drug Substance

5.2.1 Manufacturer

The active ingredient, pregabalin is manufactured by CTX Lifesciences Private Limited, Block No. 251-252 Sachin- Magdalla Road, GIDC, Sachin, Surat – 394 230, Gujarat, India

The API specifications are both pharmacopoeial and in-house based.

Stability testing was conducted according to the requirements of NAFDAC. The proposed re-test period is justified based on the stability results when the API is stored in line with the storage statement.

5.3 Other ingredients

Other ingredients used in the formulation of pinnacle pregabalin include lactose anhydrous, maize starch, purified talc all being pharmacopoeial controlled and an E.H.G Scarlet/ Scarlet size “2” capsule being in-house controlled.

5.4 Drug Product

5.4.1 Drug product manufacturer

Globela Pharma Private Limited, 357-358, Road No.-3, Sachin G.I.D.C, Surat, Gujarat, India.

5.4.2 Pharmaceutical development

The objective of pharmaceutical development is to manufacture a generic which is stable, deliver the intended performance, safe and bioequivalent in terms of efficacy to the reference product, Lyrica capsule manufactured by Pfizer Inc. USA.

The manufacturing method used was dry mixing followed by lubrication, capsule filling, polishing and blister packaging of capsules. All the manufacturing processes were validated.

5.4.3 Specification

The finished product specification is in-house based. The finished product specifications include description, identification test, weight of 20 capsules, average weight of capsules, uniformity of weight, weight of 20 empty capsules, average weight of empty capsules, average net weight, disintegration time, dissolution test, related substances, assay, microbial limit test. The test procedures have been adequately validated.

5.4.4 Stability

Stability studies have been conducted at 30°C/75% RH 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 'Store below 30°C, protect from sunlight and moisture' have been accepted.

5.5 Conclusion

Based on the assessment of data submitted, the benefit–risk profile of pinnacle pregabalin was acceptable for the following indication: 'for the treatment of peripheral and central neuropathic pain in adults, also as an adjunctive therapy in adults with partial seizures with or without secondary generalization and for the treatment of generalised anxiety disorder in adults' and is included in the list of approved medicinal products by NAFDAC.

PART 6: STEPS TAKEN FOR REGISTRATION

The applicant, Pinnacle Health Pharmaceutical & Stores Limited, No. 16/18 Nuru Oniwo Aguda, Surulere Lagos, Nigeria, submitted application to the National Agency for Food and Drug Administration and Control (NAFDAC), for the registration of pinnacle pregabalin.

The following are the steps for registration

May 2025	Date of receipt of application
October 2024	Date of conclusion of assessment
March 2026	Date of inspection
26 May 2026	Date of issuance of Marketing Authorization

PART 7: STEPS TAKEN FOLLOWING REGISTRATION

No action or steps have been taken following marketing authorization of Pinnacle pregabalin capsules.