



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

NAFDAC Public Assessment Report (NAPAR)

Pregabalin 75 mg capsules

Pregabalin 75 mg

A4-101968

Simpec Pharmaceutical Limited

This report reflects the scientific assessment for the approval of Pregabalin capsules. The product was licenced in February 2026.

PART 1: ABSTRACT

Pregabalin capsule, manufactured at Rathod Pharmachem India, was granted marketing authorization by NAFDAC for the treatment of neuropathy, adjunctive therapy for partial seizures and generalized anxiety disorder on 26 February 2026.

Pregabalin capsule is indicated for neuropathic pain, partial seizures, and generalized anxiety disorder.

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

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

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

PART 2: ACCEPTED PRESENTATIONS

Product name	Active ingredients	Pharmaceutical form/description	Packaging	Pack size
Pregabalin 75 mg capsule	Pregabalin 75 mg	Hard gelatin capsules Hard gelatin capsules with an opaque white cap and red body. They contain white hard white granules	Clear colourless plastic (PVC) on aluminium foil blister cards, each containing 14 capsules	1 x 14 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



PART 5: SCIENTIFIC DISCUSSION

5.1. About the Product

5.1.1 Name of the product

Pregabalin 75 mg capsule

5.1.2 Therapeutic indication

Pregabalin capsule is indicated for the treatment of peripheral and neuropathic pains, as adjunctive therapy for partial seizures for generalized anxiety disorder.

5.1.3 Applicant

Simpec Pharmaceutical Limited, 3 Akusu lane, Sapele North, Aniocha, Delta State.

5.1.4 Pharmaceutical form

Hard gelatin capsule

Hard gelatin capsules with an opaque white cap and red body. They contain white hard white granules

5.1.5 Storage

Do not store above 30°C. Protect from sunlight

5.1.6 Shelf life

36 months

5.1.7 Product presentation

Clear colourless plastic (PVC) on aluminium foil blister cards, each containing 14 capsules

5.2 Drug Substance

5.2.1 Manufacturer

The active pharmaceutical ingredient pregabalin capsule is manufactured by Divis Laboratories Limited. (Unit - 2) Chipada, Annaram post – 531 162 Bheenunipatmam mandal Vishakhapatnam, Andhra Pradesh, India.

The API specifications are pharmacopeial based.

Stability testing was conducted according to the requirements of NAFDAC.

5.3 Other ingredients

Other ingredients used in the formulation of pregabalin capsule include maize starch, lactose monohydrate, MCCP, di calcium phosphate, talcum, magnesium stearate, arosil, sodium lauryl sulphate, sodium starch glycolate and E.H.G capsule all being controlled by acceptable specifications.

None of the excipients are derived from human or animal origin.

5.4.1 Drug product manufacturer

The drug product is manufactured by Rathod Pharmachem, plot no.117, Philadara, Ghandevi – Khareal, Ta.Ghandevi, India.

5.4.2 Pharmaceutical development

The objective of the pharmaceutical development is to develop a safe, efficacious, and high-quality solid oral dosage form that is similar to the market innovator product, Lyrica by Pfizer. Inc., USA, while ensuring consistent delivery of the intended therapeutic effect.

The manufacturing method used were wet granulation, dispensing, sifting & mixing, blending and lubrication. All the manufacturing methods were validated.

Comparative dissolution profile was conducted in line with ICH M9 guidelines between the reference product Lyrica pregabalin capsule (Pfizer Inc., New York, NY, United States of America.) and Pregabalin capsules. The profile in the three BCS media is similar.

5.4.3 Specification

The finished product specification is based on British pharmacopeia monograph. The finished product specifications include description, identification, average weight, assay, dissolution, related substances, locking strength, dissolution time, weight of 20 filled capsules. 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 30°C and Do not store above 30°C. Protect from sunlight have been accepted.

5.5 Conclusion

Based on the assessment of data the benefit–risk profile of Pregabalin capsule was acceptable for the following indication: ' the treatment of peripheral and neuropathic pains, as adjunctive therapy for partial seizures for generalized anxiety disorder ', and is included in the list of approved medicinal products by NAFDAC.

PART 6: STEPS TAKEN FOR REGISTRATION

The applicant, Simpec Pharmaceutical Limited, 3 Akusu lane, Sapele North, Aniocha,Delta State,Nigeria submitted application to the National Agency for Food and Drug Administration and Control (NAFDAC), for the registration of pregabalin 75 mg capsule.

The following are the steps for registration

August 2025	Date of receipt of application
January 2026	Date of conclusion of assessment
September 2025	Date of inspection
26 February 2026	Date of issuance of Marketing Authorization

PART 7: STEPS TAKEN FOLLOWING REGISTRATION

No action or steps have been taken following marketing authorization of Pregabalin capsule.