



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

NAFDAC Public Assessment Report (NAPAR)

Pregabalin 300 mg capsules

Pregabalin 300 mg

A4-102044

Freshborn Industries Limited

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

PART 1: ABSTRACT

Pregabalin capsules, manufactured at Astamed Healthcare (I) Private Limited, Thane, Maharashtra State, India, was granted marketing authorization by NAFDAC for the treatment of peripheral and central neuropathic pain, generalized anxiety disorder (GAD) on 31 March 2026.

Pregabalin is indicated for treatment of peripheral and central neuropathic pain, generalized anxiety disorder (GAD) and as adjunct therapy for partial seizures.

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 capsules 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 capsules 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.

PART 2: ACCEPTED PRESENTATIONS

Product name	Active ingredients	Pharmaceutical form/description	Packaging	Pack size
Pregabalin capsules	Pregabalin 300 mg	Hard gelatin capsule Hard gelatin capsules with an opaque red cap and white body. They contain white granular powder	Clear colourless plastic (PVC) on aluminium foil blister cards, each containing 10 capsules. Available in cartons of 15 x 10 capsules	15 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



PART 5: SCIENTIFIC DISCUSSION

5.1. About the Product

5.1.1 Name of the product

Pregabalin 300 mg capsules

5.1.2 Therapeutic indication

Pregabalin is indicated for the treatment of peripheral and central neuropathic pain, generalized anxiety disorder (GAD) and as adjunct therapy for partial seizures.

5.1.3 Applicant

Freshborn Industries Limited, 45 Ashogbon Street Idumota, Lagos State.

5.1.4 Pharmaceutical form

Hard gelatin capsules

Hard gelatin capsules with an opaque red cap and white body. They contain white granular powder.

5.1.5 Storage

Store below 30°C. Protected from light & moisture

5.1.6 Shelf life

36 months

5.1.7 Product presentation

Clear colourless plastic (PVC) on aluminium foil blister cards, each containing 10 capsules. Available in cartons of 15 x 10 capsules.

5.2 Drug Substance

5.2.1 Manufacturer

Pregabalin is manufactured by Lee Pharma Limited, 10/G-1, Gaddapotharam (Village) Jinnaram (Mandal), Medak (District) Andhra Pradesh, 502319, India.

The API specifications are pharmacopoeia 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 pregabalin capsules include dicalcium phosphate, maize starch, talcum, magnesium stearate and empty hard gelatin capsules, all being controlled by acceptable specifications.

TSE / BSE free certificates have been provided for the excipients.

5.4 Drug Product

5.4.1 Drug product manufacturer

Stamed Healthcare (I) Private. Limited, Plot No 2 & 3, Phase II Genesis Industrial Complex, Kolgaon, Palghar, Thane: 401 404 Maharashtra State, 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, Lyrica manufactured by Pfizer Inc., Germany.

The product is manufactured by dispensing, sifting, milling, dry mixing and blending, capsule filling and packing. All the manufacturing processes were validated

Comparative dissolution profile was conducted in line with ICH M9 guidelines between the reference product Lyrica (Pfizer) and pregabalin capsules. The profiles in the three BCS media are similar.

5.4.3 Specification

The finished product specification is based on in-house. The finished product specifications include identification, description, dissolution and disintegration time. 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 'Store below 30°C. Protected from light & moisture' have been accepted.

5.6 Conclusion

Based on the assessment of data submitted on quality, the benefit–risk profile of pregabalin capsules was acceptable for the following indication: 'indicated for the treatment of peripheral and central neuropathic pain, generalized anxiety disorder (GAD) and as adjunct therapy for partial seizures', and is included in the list of approved medicinal products by NAFDAC.

PART 6: STEPS TAKEN FOR REGISTRATION

The applicant, Freshborn Industries Limited, 45 Ashogbon Street Idumota, Lagos State submitted application to the National Agency for Food and Drug Administration and Control (NAFDAC), for the registration of pregabalin capsules.

The following are the steps for registration

December 2025	Date of receipt of application
March 2026	Date of conclusion of assessment
March 2023	Date of inspection
31 March 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 capsules