



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

NAFDAC Public Assessment Report (NAPAR)

Pregabalin 75 mg capsules

Pregabalin 75 mg

A4-102038

Afrigenics Pharmaceuticals Limited

This report reflects the scientific assessment for the approval of pregabalin capsules. The product was licenced in March 2026.
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PART 1: ABSTRACT

Pregabalin capsules manufactured at Bafna Pharmaceuticals Limited, Grantlyon, Chennai, India, was granted marketing authorization by NAFDAC for the treatment of generalised anxiety disorder on 31 March 2026.

Pregabalin is indicated for the treatment of generalised anxiety disorder and also as adjunctive therapy in adults with partial seizures with or without secondary generalization.

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 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 75 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 3×10 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



PART 5: SCIENTIFIC DISCUSSION

5.1. About the Product

5.1.1 Name of the product

Pregabalin 75 mg capsules

5.1.2 Therapeutic indication

Pregabalin is indicated for the treatment of generalised anxiety disorder and also as adjunctive therapy in adults with partial seizures with or without secondary generalization.

5.1.3 Applicant

Afrigenics Pharmaceuticals Limited, No 2, Iringa Street, Wuse Zone 6, Abuja, Nigeria.

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

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

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 3x10 capsules

5.2 Drug Substance

5.2.1 Manufacturer

Pregabalin is manufactured by Reine Lifescience, Plot No. 5901, Kanoria Chemical Road, Nr. Par Drugs, GIDC Estate, Ankleshwar – 393002. Dist. Bharuch (Gujarat) India.

The API specifications are pharmacopoeial and in-house based.

Stability testing was conducted according to the requirements of NAFDAC.

5.3 Other ingredients

Other ingredients used in the formulation of pregabalin capsules include maize starch, mannitol, purified talc and empty hard gelatin capsules, all being pharmacopoeial controlled.

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

5.4 Drug Product

5.4.1 Drug product manufacturer

Bafna Pharmaceuticals Limited, Unit II No.147, Madhavaram Redhills High Road, Grantlyon, Vadakarai Post, Chennai - 600 052, 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 profile in the three BCS media is similar.

5.4.3 Specification

The finished product specification is based on in-house. The finished product specifications include description, identification, assay, average weight, uniformity of weight, disintegration time, dissolution rate and microbial counts. 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, the benefit–risk profile of pregabalin was acceptable for the following indication: 'for the treatment of generalised anxiety disorder and also as adjunctive therapy in adults with partial seizures with or without secondary generalization' and is included in the list of approved medicinal products by NAFDAC.

PART 6: STEPS TAKEN FOR REGISTRATION

The applicant, Afrigenics Pharmaceuticals Limited, No 2, Iringa Street, Wuse Zone 6, Abuja, Nigeria, submitted application to the National Agency for Food and Drug Administration and Control (NAFDAC), for the registration of pregabalin.

The following are the steps for registration

August 2026	Date of receipt of application
March 2026	Date of conclusion of assessment
July 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.