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

Public Assessment Report (PAR)

Vitamin B-complex injection

Thiamine hydrochloride BP 25 mg, riboflavin sodium phosphate BP 2 mg, pyridoxine hydrochloride BP 2.5 mg, nicotinamide BP 50 mg, D-panthenol USP 5 mg

NRN: A4-101368

Dom Dike Pharmaceutical Company Limited

This report reflects the scientific assessment for the approval of Vitamin B-complex injection**.** The product was licenced in June 2025.

PART 1: ABSTRACT

Vitamin B complex, a parenteral preparation containing essential water-soluble B vitamins, manufactured at Dom Dike Pharmaceutical Company Limited was granted marketing authorization by NAFDAC on 25 June 2025 for the prevention and treatment of vitamin B deficiencies.

Vitamin B complex injection is indicated for treatment of vitamin B-complex deficiency states and during convalescence from illness.

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 Vitamin B complex injection 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 Vitamin B complex 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 and clinical aspects of Vitamin B complex has been presented in part 5 of this report.

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

No action or steps have been taken following the marketing authorization of Vitamin B complex.

PART 2: ACCEPTED PRESENTATIONS

Product Name	Active Ingredients	Pharmaceutical Form/Description	Packaging	Pack size
Vitamin B complex injection	Thiamine Hydrochloride BP 25 mg, riboflavin sodium phosphate BP 2 mg, pyridoxine hydrochloride BP 2.5 mg, nicotinamide BP 50 mg and D-panthenol USP 5 mg	Injection solution. Yellowish colored solution.	Amber glass vials USP Type-I.	10 x 10 mL, 50 x 10 mL

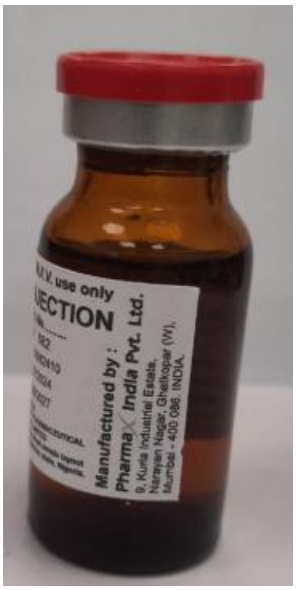
PART 3: SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

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

Vitamin B-complex injection.

5.1.2 Therapeutic indication

For treatment of vitamin B-complex deficiency states and during convalescence from illness.

5.1.3 Manufacturer/applicant

Manufactured by Pharmax India Private Limited, 9 Kurla Industrial Estate off Narayan Nagar Ghatkopar (W), Mumbai - 400 086 Maharashtra state, India. The local applicant is Dom Dike Pharmaceutical Company Limited, F11/6 Agbo Edo Market Nnewi, Anambra, Nigeria.

5.1.4 Pharmaceutical form

Injection

Yellowish coloured solution

5.1.5 Storage

Do not store above 30°C.

5.1.6 Shelf life

24 months

5.1.7 Product presentation

Amber colour glass vials packed in printed carton.

5.2 Drug Substance

5.2.1 Manufacturer

1. Thiamine Hydrochloride BP: Prachi Pharmaceuticals Private Limited, 11/1 Rakhangi Mahal Acharya Donde Marg Opp Wadia Childern's Hospital Parel; Mumbai - 400012, India.
2. Riboflavin Sodium Phosphate BP: Hubei Guangji Pharamaceuticals Co, Limited, Jiangdi Road, Wuxue City, Hubei Province, China.
3. Nicotinamide BP: Aarti Drugs Limited, Mahendra Industrial Estate, Ground Floor, Plot No. 109-D, Road No.29, Sion East Mumbai, Maharashtra 400022.
4. Pyridoxine Hydrochloride BP: Zhejiang Tianxin Pharmaceutical Co. Limited, No.215 Fengze Road Tiantai, Zhejiang -317200, China.
5. D-Panthenol USP: Zhejiang Hangzhou Xinfu Pharmaceutical Co, Limited, No. 50 Qinshan Jincheng, Linian, Hangzhou, Zhejiang 311300, P.R. China

The API specifications include tests for description, identification (IR and HPLC), pH, related substances, assay, water content, sulphated ash, optical rotation, heavy metals, colour test, solubility, sulphates, loss on drying, appearance, melting point, and reaction with ammonia.

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 Vitamin B-Complex Injection include benzyl alcohol, polysorbate 80, sodium chloride, sodium hydroxide, disodium EDTA, and water for injections. The active ingredients are compatible with the used.

5.4 Drug Product

5.4.1 Drug product manufacturer

Pharmax India Private Limited, 9 Kurla Industrial Estate Off Narayan Nagar Ghatkopar (W), Mumbai - 400 086 Maharashtra state, India

5.4.2 Pharmaceutical development

The development of Vitamin B-Complex injection and the associated manufacturing process used knowledge from various developmental experiments. This comprised knowledge on the variability with respect to physiochemical and functional properties in all excipients used in the **f**ormulation design.

5.4.3 Specification

The finished product specification is based on in-house methods. The finished product specifications include identification, description, pH, sterility, particulate matter assay and extractable volume. The test procedures have been adequately validated.

5.4.4 Stability

Stability studies have been conducted at 30°C/75%RH as long-term storage conditions and 40°±2°C/75% ±5% RH for six months at accelerated conditions in the packaging intended for marketing of the product. The product proved to be quite stable at these conditions, with no apparent negative trend. Based on the data submitted, the proposed shelf life of 24 months and 'Do not store above 30°C' have been accepted.

5.5 Conclusion

Based on the assessment of data on quality, safety, and efficacy, the benefit–risk profile of Vitamin B-complex injection was considered acceptable for the following indication: treatment of vitamin B-complex deficiency states and during convalescence from illness. The product is therefore included in the list of approved medicinal products by NAFDAC.

PART 6: STEPS TAKEN FOR REGISTRATION

The manufacturer, Pharmax India Private Limited, 9 Kurla Industrial Estate off Narayan Nagar Ghatkopar (W), Mumbai - 400 086 Maharashtra State, India. Submitted application to the National Agency for Food and Drug Administration and Control (NAFDAC), for the registration of Vitamin B- complex injection.

The following are the steps for the registration of Vitamin B

21 August 2024	Date of receipt of application
26 May 2025	Date of conclusion of assessment
23 December 2024	Date of inspection
25 June 2025	Date of issuance of Marketing Authorization

PART 7: STEPS TAKEN FOLLOWING REGISTRATION

No action or steps have been taken following marketing authorization of Vitamin B complex injection.