



# Bal Pharma Limited

## COVER LETTER

To:

**INFARMED – Autoridade Nacional do Medicamento e Produtos de Saúde, I.P.**  
Departamento de Medicamentos de Uso Humano  
Parque de Saúde de Lisboa  
Av. do Brasil nº. 53  
1749 – 004 Lisboa  
Portugal

February 03, 2025

**SUB:** Submission of update to Active Substance Master File of Topiramate Applicant Part:  
BPL/TOP-I/AP/09/2025 and Restricted Part: BPL/TOP-I/RP/08/2025.

Dear Sir,

The submission of the Active Substance Master File of drug substance Topiramate in support of the Marketing Authorization application;

**ASMF Holder: Bal Pharma Limited**

Lakshmi Narayan Complex, 5<sup>th</sup> Floor,  
Palace Road, Bengaluru – 560 052, INDIA

**Active Substance Manufacturer / Manufacturing site(s)**

**Bal Pharma Limited**  
Unit II, 61B, Bommasandra Industrial Area,  
Bengaluru – 560 099, INDIA

The aforementioned Active Substance Master File holder hereby submits INFARMED – Autoridade Nacional do Medicamento e Produtos de Saúde, I.P, to refer to and review the above-mentioned Active Substance Master File in support of the following Marketing Authorisation Application(s) or Marketing Authorisation Variation(s) submitted by J.J.Bishop Health a.s. , Czech Republic

Name of Product:	Name Marketing Authorisation Holder:
Topiramato J.J. Bishop Decentralized procedure : DCP nº PT/H/2988/001-003/DC	J.J.Bishop Health a.s. Rybná 682/14 110 00 Prague 1, Czech Republic

Kindly acknowledge the receipt and inform the undersigned if you need any clarification in this regard.

Yours Sincerely,

For Bal Pharma Limited,

Nabajit Sarma  
Associate Vice President

CORPORATE OFFICE : 5th Floor, Lakshmi Narayan Complex, 10/1, Palace Road, Bengaluru - 560 052, India

Ph. : 91 - 80 - 41379500 Fax : 91 - 80 - 22354057 / 58

Email : [info@balpharma.com](mailto:info@balpharma.com) Website : [www.balpharma.com](http://www.balpharma.com)

CIN # L85110KA1987PLC008368

REGD. OFFICE & FACTORY : 21 & 22, Bommasandra Industrial Area, Bengaluru - 560 099. Ph. : 080 - 41570811 / 13 / 19 Fax : 41570820