

Date: 6th March, 2024

To
The Manager
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National Stock Exchange of India Ltd.
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Symbol: SAKAR

SUB: Sakar's oncology (anti-cancer) unit receives EU GMP approval

Dear All,

It gives us immense pleasure to announce that Sakar Healthcare Ltd., ONCOLOGY (anti-cancer) unit has received EU GMP approval dated 5th March 2024 with a validity of three years from audited date.

The research-driven API-integrated oncology formulation (liquid injections, lyophilised injections, tablets, capsules, granules) manufacturing unit located at Bavla, near Ahmedabad, Gujarat has been a state-of-the-art manufacturing unit with equipment hand-picked from across the globe. The European Agency audit team inspected the manufacturing blocks of Oral Solid Dosage (Tablet, Capsule, Granules) and Injection (Liquid, Lyophilised) with packaging and storage compliances in last quarter of calendar year 2023 and has granted the approval.

The WHO GMP approved vertically integrated ONCOLOGY unit of SAKAR has been selling products nationally since few quarters. Meanwhile the dedicated technical team has made slow and steady advancements. 30 generic anti-cancer molecules has been developed at in-house labs and the technology transferred successfully to manufacturing units for commercial scale up. In regulatory part:

- Oral Solid Dosage: 9 product CTD dossiers have been developed for submission, with Bioequivalence studies (completed for 3, ongoing for 6), Process validation and Stability data
- Injections: 8 product CTD dossiers have been made ready for submission supported by Process Validation batches and Stability studies
- Of the 12 oncology APIs developed in this segment, 11 has been granted Written Confirmation that allows export of the API to the European Union


Now with EU GMP certification and in-house preparedness Sakar will have distinctive advantages:

- Register & Export oncology products to EU as Marketing Authorisation Holder or as a CDMO
- Expand export opportunity to high-regulated markets of Canada, Mexico, Colombia, Brazil, South Africa, PICs, GCC, MENA, APAC region- apart from continent of Africa
- Sign business contracts under discussion, submit dossiers and supply against Marketing Authorisations (MAs) hold by partners or in Sakar name
- The target market size increases manifolds that ensures healthy business growth opportunity
- Fully integrated unit will offer competitive advantage with regards to offers and continuity

This is for your information, records and meeting the disclosure requirements under the SEBI (Listing Obligations and Disclosure Requirements) Regulations, 2015, as amended from time to time.

Yours faithfully,

for SAKAR HEALTHCARE LIMITED


BHARAT SONI
COMPANY SECRETARY

