



To,
The Director,
National Pharmaceutical Regulatory Agency (NPRA),
Malaysia

Date: February 08, 2023

Subject: Clarification to justify the purpose of QR code in the outer carton

Name of the Product: BENZOSED - Midazolam BP 5 mg/mL solution for Injection or Infusion, 3 ml and 10 ml

Dear Sir/Madam,

We would like to clarify that the purpose of QR code on outer carton of BENZOSED, 3ml and 10ml is for monitoring inventory of the product, such as batch number, expiry date and manufacturing date. The QR code is NOT for linkage to any website.

We assure the NPRA, Malaysia that QR code on outer carton is as per APPENDIX 19: GENERAL LABELLING REQUIREMENTS of Drug Registration Guidance Document (DRGD) Third Edition, Third Revision July 2022.

We request kind authority to accept above clarification and grant us approval for BENZOSED - Midazolam BP 5 mg/mL solution for Injection or Infusion, 3 ml and 10 ml.

For, Troikaa Pharmaceuticals Limited


08/02/23



Suresh Gami

Sr. Manager - Regulatory Affairs

Troikaa Pharmaceuticals Ltd.

(Formerly Known as : Troikaa Exports Pvt. Ltd.)

Regd. Office : 'Commerce House - 1', Satya Marg, Bodakdev, Ahmedabad-380 054. Ph.: (079) 26856242/43/44/45, Fax: 26856246

Corporate Identity Number: U24100GJ1994PLC022162, Email: troikaa@troikaapharma.com Website: www.troikaa.com

WORKS- 1 : Thol, Dist. Mehsana, Pin : 382 728, Gujarat, India. Phone : (02764) 274304, 274326, 274475, 274353 Tele-Fax : (02764) 274684

WORKS- 2 : C-1, Sara Industrial Estate, Selaqui, Dehradun-248 197, Uttarakhand, India. Phone : 0135-2699146, 2698819 Fax : 0135-2698059

WORKS- 3 : Survey No. 2019, 2022, 2023, 2033 & 2035, Near Khetiya Nagdev Mandir, Sanand- Viramgam Highway, Village: Virochannagar

Ta.: Sanand Dist.: Ahmedabad, Pin : 382170