



09 August 2023

LOC/2023/MAL/NOVOMIN TAB-078(1)

Centre of Product & Cosmetic Evaluation (PPPK)
National Pharmaceutical Regulatory Agency
Lot 36, Jalan Universiti,
46200 Petaling Jaya,
Selangor.

COMMITMENT FOR POST APPROVAL VARIATION SUBMISSION

Product	Active Ingredient	Registration No.
Novomin Tablet 50mg	Dimehydrinate 50mg	MAL19870329AZ

With reference to the above mentioned, please be informed that we commit to submit the variation to update of patient information leaflet (MiV-PA3) after the variation minor change in the manufacturing process (MiV-N12), change of in-process control in drug product (MiV-PA20), administration changes of drug product labelling (MiV-N19) and additional of API source (MaV-3a) have been approved by NPRA.

Therefore, we sincerely hope that you will approve our variation application in order for us to submit the committed variation in a timely manner.

Thank you for your consideration.

Yours sincerely,

XEPA-SOUL PATTINSON (MALAYSIA) SDN BHD

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Lee Xui Kin
Regulatory Affairs Manager

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