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In reply please refer to: HA765-0/MS/FV

Your reference:

Mrs Sandhya Jadhav
Macleods Pharmaceuticals Ltd
R&D Center Mumbai
Mahakali Caves Road, Shanti Nagar
Andheri (East) / Mumbai 400093
Mumbai
Maharashtra
Inde

6 October 2020

Dear Mrs Jadhav,

**WHO Prequalification Unit– Medicines
FPP Prequalification – Assessment completed – Efficacy & Safety**

Application number: HA765-0

Thank you for submitting the data and information requested for the assessment of the product dossier for the WHO Prequalification Unit – Medicines.

A team of evaluators recently assessed the dossier:

- **HA765 - Dolutegravir (Sodium) Tablet, Dispersible 10mg**

As a result of this assessment, you are informed that the efficacy/safety part of the dossier is considered acceptable. Please note that the outcome of the assessment of quality part of the dossier may affect the final acceptability of the efficacy/safety part of the dossier.

Your cooperation is appreciated.

Yours sincerely,

Dr Matthias Stahl
Team Lead, Medicines Assessment Team
Prequalification Unit
Regulation and Prequalification Department