World Health Organization

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In reply please refer to: APIMF374-0/AF/MS

Mr Xuelai Zhou
Vice-General Manager, Regulatory Affairs
Hainan Poly Pharma Co Ltd
Guilinyang Economic Development Area
Haikou 571127
Hainan
Chine (République populaire de)

21 September 2020

Dear Mr Zhou,

WHO Prequalification Unit – Medicines
API Master File Procedure - Letter of Acceptance

Application number: APIMF374-0

Related APIMF dossier: APIMF374

Thank you for your company's APIMF application for Ganciclovir (sodium) - sterile to the WHO Prequalification Unit.

A team of evaluators recently completed the assessment of your APIMF. As a result of this assessment, you are informed that the present APIMF information for Ganciclovir (sodium) - sterile is acceptable.

The API starting materials accepted as a result of this assessment are: [redacted]

Please note that the API starting material represents the point in the preparation of the API where GMP should be applied and detailed in your APIMF. Similarly, this also represents the point where changes to preparation or control of the API should be notified to the WHO including changes to the suppliers of the API starting material.

Please note that the outcome of the assessment of this APIMF is an important step towards the final acceptability of the quality part of any product dossier submitted to the WHO Prequalification Unit.

The attached API Quality Information Summary (API-QIS) is an important component of the APIMF Amendment procedure. Please alert us to possible corrections to the API-QIS immediately.

Information/notification/commitment noted

a. No reprocessing or reworking is conducted by Hainan Poly Pharm Co. Ltd.

b. No blending, no recovery of material and solvents, no recycling of mother liquors and alternative processes is performed by Hainan Poly Pharm Co. Ltd.

ENCL: (1)

c. The applicant committed that once additional analytical data for single maximum impurity and total impurities of starting material N,9-diacetylguanine in future become available, they will [redacted] based on the results.

d. The applicant committed that the method description and validation report for the HPLC method that was used to monitor potential genotoxic impurities [redacted] and API will be included 3.2.S.3.2 of future revisions of the APIMF.

Your cooperation is appreciated.

Yours sincerely,

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