

Certification of Substances Department

JOYANG LABORATORIES

Mr Shaoding GUO
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China-224 300 Yancheng, Jiangsu
Province

CEP_RZ_PH_2021-210-1362033

Strasbourg, 7 May 2021

MFE / aam

By electronic communication

ACKNOWLEDGEMENT OF RECEIPT

Re: CEP 2021-210 / Tacrolimus monohydrate

Dear Mr GUO,

We acknowledge receipt of the confidential dossier for **Tacrolimus monohydrate** that you submitted for a certificate of suitability to the monographs of the European Pharmacopoeia.

- Reference number : **CEP 2021-210** (it should be mentioned in any correspondence)
- Type of application : Double - TSE
- Comment: *Please note that since material with TSE risk is used in the process, your CEP has been reclassified as Double. However, since the animal material is covered by a valid CEP, no additional fees will be charged.*

The timetable can start and the data will be assessed within **5 months**.

The dossier will be dealt with in accordance with the procedure described in Resolution AP-CSP (07) 1 and in particular, will be kept and assessed under conditions that guarantee the confidentiality of the submitted data.

For any question regarding this application, please contact us using the following e-mail address:
cep@edqm.eu

Yours faithfully,

Certification of Substances Department