



Maldives Food and Drug Authority

Ministry of Health
Male'
Republic of Maldives

Check List for Fast-track evaluation of COVISHIELD vaccine
(Batch No: 4120Z004)

S. No	Items to be checked	Remarks (Accept/Reject with any comments, if required)
1	Copy of EUA/ Manufacturing License for COVID-19 Vaccines	Acceptable as manufacturing approval for Covishield has been issued from the Food and Drug administration, Pune, India on 20 th August 2020.
2	Copy of Certificate of Pharmaceutical Product (COPP)	Acceptable as permission to manufacture and use Covishield vaccine given By Drugs controller General, Central Licensing Authority, India on 3 rd Jan 2021 for restricted use in emergency situations.
3	Copy of last registration dossier submitted to (NRA) of the origin (soft copy in searchable PDF in CTD format as accepted by WHO/ICH). Mandatory only if product is not WHO-EUL listed or WHO-PQed	Acceptable as Copy of last registration dossier submitted to Indian NRA is provided through We-transfer. Below is the link of the dossier: https://we.tl/t-wKIgLgst4G
4	Status of WHO-EUL listing or WHO-PQ status. Verify the certificates or listing issued by WHO	Acceptable as of the letter submitted to WHO-EUL has been Submitted. 1) Applied for WHO EUL on 13th January 2021 2) Screening of submitted data completed 3) Reviewers list for CMC, Preclinical and Clinical data agreed with WHO 4) Review is ongoing
5	Manufacturer certificates of analysis for three finished product batches	Acceptable as data submitted for 9 batches
6	National Control Laboratory (Country of Origin) release and test reports for three batches	Acceptable as analysis data for 9 batches submitted from the Central Drug Laboratory, Kasauli, India
7	Photo of vaccine presentations, copy of labels of all presentation and packing inserts	Acceptable as all the details submitted and which is in line with the product received as well



8	Undertaking that information shall be provided if there is any change in the status of EUA or manufacturing license in origin country and undertaking to submit a copy of any new CTD submission to origin country NRA or assurance from Govts or other agencies	Acceptable as Declaration from Serum institute of India (SII) submitted
9	For imported COVID-19 Vaccines: <ul style="list-style-type: none"> - List of countries where the vaccine is being used - Number of doses and batches manufactured till date - Importer verification and status- COVAX, UN agency, Government 	Acceptable COVISHIELD is supplied to following countries; <ol style="list-style-type: none"> 1. Bhutan 2. Maldives 3. Nepal 4. Bangladesh 5. Myanmar 6. Mauritius 7. Seychelles 8. Morocco 9. Brazil <ul style="list-style-type: none"> - Number of doses and batches manufactured till date has being submitted - Imported by Government of Maldives.
10	CTD Dossier (if applicable) <ul style="list-style-type: none"> - Table of Contents - Module 2 (Summary) 	Acceptable as the full dossier in the common technical dossier (CTD) format submitted with table of content and modules

