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Reference number: OGYÉI/2359-1/2021

Inspection Report

Inspected site	[redacted]	
Inspection date	On site: 13-15/01/2021 Distant assessment: 08-09/01/2021	
Responsible Authority	National Institute of Pharmacy and Nutrition, Hungary Országos Gyógyszerészeti és Élelmezés-egészségügyi Intézet	
Inspectors	[redacted]	
Introduction	The company is a subsidiary of China National Biotec Group (CNBG) which itself is also a subsidary of the state owned China National Pharmaceutical Group Corp. The company only involved in the manufacturing of vaccines, about 10 vaccines products being manufacturing in E-town site, mainly including Inactivated Poliomyelitis Vaccine Made from Sabin Strains (Vero Cell) (sIPV), Poliomyelitis (Live) Vaccine Type I Type III (Human Diploid Cell) (bOPV), Oral and Yellow Fever Vaccine (YF)	
Aim and type of the inspection	GMP inspection of sterile medicinal products (pre-filled glass srynges, vials) and sterile active substance for human use.	
Scope of the inspection	Bulk of SARS-CoV-2 Vaccine (Vero Cell), inactivated (sterile)	CAS: -
Inspected fields	All fields according to Eudralex Vol. 4: Quality Managements System, Personne, Premise and Equipment, Documentation, Production, Quality Control, Outsourced Manufacturing, Complaints and Recall, Self Inspection	
Non inspected fields	NA	

Participants from the site	[redacted] R) ion on ion (QC) ROD) A) vorkshop 6) agement anagement
Legal base	- Directive 2001/83/EC of the European Parliament and of the Council on the Community code relating to medicinal products for human use - Commission Directive 2003/94/EC laying down the principles and guidelines of good manufacturing practice in respect of medicinal products for human use and investigational medicinal products for human use - Eudralex Volume 4 GMP for human medicinal products

Observations	
General observations	
G.1 Site Master File	Site Master File of COVID-19 Vaccine (Vero Cell), inactivated SOP-02-01-00-007 v.01 (effective date: 23/11/2020) was available for review prior to the inspection.
G.2 Authorisations	The National Medicinal Product Administration issued the manufacturing authorization, on 13/06/2020, license No. 京 20160276 and include the manufacturing of sterile biological products (vaccines). - Sterile dosage forms: small volume liquid (injectables - vial and prefilled srynge, drops); lyophilisates (vial).
G.3 GMP Inspections	GMP inspections of last four years: - WHO (Geneva) 06-10/03/2017
1. Quality Management System	
1.1 Quality Management System	The Quality System, described in the Quality Manual QM-001 (effective date: 16/01/2020) presented the main activities, units and adhered to the GMP standards and requirements.
1.2 Change Control	The changes were controlled according to SOP-03-08-02-001 (effective date: 14/08/2019), the procedure prescribed the evaluation, the definition of required actions and their review prior to the implementation. In 2020 83 changes were initiated in reletion of the manufacture of SARS-CoV-2 Vaccine (Vero Cell), inactivated. During the inspection the following change controls were reviewed: - CC202011157 (initiated on: 02/11/2020) The change control was raised to convert two reserved rooms to storage rooms. The change control was cancelled in favour of the installation of a new filling line. - CC2020003028 (initiated on: 02/03/2020) purchasing a new fridge (<-20°C) to store VVM labels. The initial assessment has been made but the equipment was not purchased until the inspection, therefore the change control was still open.
1.2.1	• According to the SOP-03-08-02-001 procedure the company uses temporary change control, and according to SOP-03-08-01-001 procedure planned deviation which two procedure covers the same field of operation; furthermore, no limitation of the repetation of the same temporary change was present in the procedure. **Deficiency, Eudralex Vol. 4 1.4 (xiii, xiv)**
1.3 Deviation Management	The deviation management was described in SOP-03-08-01-001 (effective date: 02/02/2019), covering the root cause analysis, the assessment of the impact on product quality and the definition of CAPAs where applicable. The deviations were classified as critical, major and minor. The deviations were trended on yearly basis, the report of 2020 was presented along with selected investigations. In 2020 24 deviations were recorded in relation with SARS-CoV-2 Vaccine (Vero Cell), inactivated. During the inspection the 0116-2020-1-017 (initiated on 02/11/2020, closed on: 27/11/2020) in the prefilled syringe filling line 2 equimpment failure have ben occurred during the filling of the 202011148 batch for several times. The machine was in a continuous run mode and making noise.

	Root causes: thorn cable switched the machine into continuous run mode, CAPA: replace the thorn cable, during the inspection of the supplier it was found that the filled srynge trays hit into each other. This additional issue relates to a software setting issue for which the supplier has been contacted.
1.4 Validation Policy Validatin master plan	The validation policy of the site has been described in the SOP-05-03-01-001 (effective date: 02/07/2020) procedure. The manufacturing processes needed to be revalidated once in every 5 years if no change in the manufacturing process has been occurred. The analytical methods were only revalidated if there was a change in the method.
1.4.1	• The SOP-05-03-01-001 (effective date: 02/07/2020) did not distinguish the periodic review and revalidation in case of software validation; furthermore the periodic review of the analytical methods were not regulated. **Deficiency, Eudralex Vol. 4 Annex 11 11**
1.5 Finished Product Release	The finished productof the SARS-CoV-2 Vaccine was released by the QP according to SOP-03-07-00-023 (effective date: 01/01/2021) procedure. The batch documentation, the analytical records, all related data and documents were reviewed by dedicated QA staff. The QP can only relase the batch when the official relase has been arrived from the authorities.
1.5.1	• The CoA issued by the QP did not containe the declaration regarding the manufacturing conditions and the compliance to the MA. **Deficiency, Eudralex Vol. 4 Annex 16 General principles**
1.6 Product Quality Review	The product quality reviews were prepared on annual bases according to EF-SOP-03-08-05-001 procedure, considering the parameters indicated in the EU GMP. For the vaccine no PQR was prepared (no commercial production performed in 2020) As an example the PQR for WFI was reviewed.
1.6.1	• The PQRs did not contain the evaluation of stability data, the trend analysis or its outcome. The OOT results were not continuously assessed, only yearly once during the product quality review. **Deficiency, Eudralex Vol. 4 1.10 (vii), 6.9, 6.27**
1.7 Risk Management	The risk management was described in SOP-03-08-03-001 (effective date: 14/09/2020) procedure, and it was based on ICH Q9 guideline. The FMEA (1-10 scoring) and the matrix method.
1.7.1	• The matrix risk assessment method described in the SOP-03-08-03-001 (effective date: 14/09/2020) procedure was not scientifically justified. The same overall RPN could be major and medium risk at the same time. **Deficiency, Eudralex Vol. 4 1.13 (i)**
1.8 Supplier Qualification	The suppliers were qualified according to SOP-03-02-00-002 (effective date: 10/06/2019) procedure. The raw material and excipient suppliers and the primary packaging material manufacturers of sterile products underwent a qualification consisting of questionnaire testing of three lots, validation, and the validation batches were involved into the stability study. The suppliers were categorised based up on the material into 4 categories: I (low risk, e.g.: raw materials for the media); II (low risk, e.g.: materials with pharmacopeia specification); III (medium risk) and IV (high risk). The category I and II suppliers were audited once in every 5 years, the category III once in every 3 years and the category IV once in every 2 years. The vendors of non

	active ingredients and other packaging materials were approved based on the questionnaire, the results of 3 lots and the initial on-site audit The list of suppliers under qualification and approved suppliers was maintained and checked routinely. The list of approved vendors was presented.
1.9 Computerised Systems	All of the softwares used on site were validated according to the VMP. During the inspection, the software validation of the SCADA computerised system (SATP-209-209-UT-EMS-001) was reviewed. The validation contained the testing of the user rights and user groups (administrator, technical and operators) together with the audit trail functions. The Excel spreadsheets, used at the QC laboratory, were also validated.
1.10 Data integrity	Data integrity was regulated on site by GL-02-003 procedure.
1.10.1	• There is no guidance how to evaluate the company electronic and paper based systems. The work on DI management not started yet. **Deficiency, Eudralex Vol. 4 Annex 11 1, 4.1, 4.6, 5, 7, 11, 12**
2. Personnel	
2.1 Personnel	The number of employees related to the SARS-CoV-2 Vaccine production was distributed between the main units as follows. Department — Staff Production — 240 QC — 114 QA — 44 Total headcount of the site — 1150
2.2 Organisational Structure	The organisational chart ORG-00 (effective date: 17/06/2020) was presented the relationship between the quality and production functions. There was adequate separation of manufacturing and quality reporting lines described in the site organisation chart. The IT department was part of the endineering department which was independent from both the quality and the production departments.
2.3 Job Description	During the inspection the job descriptions, which were present in annexes of the job description procedure, of the production worker (JD-31-10), QC analyst (JD-04-128), QA reviewer (JD-03-25) and the QP (JD-00-02) were reviewed.The job descriptions were part of the training of every worker.
2.4 Training	The training policy was decribed in SOP-03-08-17-001 (effective date: 01/04/2020) procedure. Every employee must receive at least 40 lessons of training annually. The effectiveness of the training was avaluated by written test and oral examination and the acceptance level was set to 80%. During the inspection the training plans for 2020 and for 2021 were reviewed together with the training records of the selected worker (JIA Zhiyan).
2.4.1	• The training procedure (SOP-03-08-17-001) did not have any precaution in place regarding the retraining of the employees returning to the company from a longer leave. **Comment**

2.5 Personnel Hygiene & Gowning	The medical examination was regulated in the SOP-08-05-00-001 (effective date: 20/05/2020) procedure, it was required before employing then once a year. The last medical check up of the selected worker (JIA Zhiyan, carried out on: 18/12/2020) has been reviewed. The garment was cleaned according to SOP-07-04-00-009 (effective date: 28/04/2019) procedure, sterilized for sterile manufacturing and inspected visually before use.
2.5.1	• No limit has been established fot the number of the washing of the garments (for area B) in SOP-07-04-00-009 (effective date: 28/04/2019) procedure; furthermore the number of the washings were not followed, nor documented. **Deficiency, Eudralex Vol. 4 Annex 1 41, 45**
3. Premise and Equipment	
3.1 Production areas	The manufacturing of the Bulk of SARS-CoV-2 Vaccine (Vero Cell), inactivated (sterile) took place at a completely separated 209 building. In the building the final upstream step, the virus harvesting, inactivation, purification and the preparation of the intermediate of the finished pharmaceutical product manufacturing steps were carried out. The area, where the active virus was handled, was isolated, only the dedicated personnel, dressed into special gowning, which were equipped with special biological air filters, were allowed to enter. All of the measuring equipment were connected into a building management system and the area was under surveillance by controllable (movement and magnification) CCTV system. The Area was equipped with two 300L bioreactors for harvesting. The upkeep of the working cellbank and the first part of the upstream was carried out in the 3rd floor of the 104 building. Prefilled syringe manufacturing was carried out on the 1st floor of the 107 building. The filling machine was located under a LAF, which was qualified as grade A with a grade B background. Vialable and non vialable particals were monitored continuously during the manufacturing operation. The Vial filling was also carried out in building 107 with the same layout as the prefilled srynge manufacturing. Both filling machine were connected to the secondary packaging area of building 107.
3.2 HVAC System	The AHU 103-UT-HVAC-011, which supplied the grade B environment of the second floor vial filling machine located in building 103, contained cooling/heating and de-humidifying units, G3 pre-filters, F5 and F7 fine filters, and terminal H14 terminal HEPA filters. The requalification of the HVAC systems were carried out annually. During the inspection the RVR-103UT-HVAC-011-2020-01 (effective date: 15/12/2020) revalidation contained air axchange rate, leak test, smoke test, recovery, pressure differential, temperature, and humidity particle count (air sampling and settle plate).
3.3 Water System	Purified water was produced in 2 basic phases. The first phase was the preparation of the treated water by multi grade and carbon filtration followed by RO and EDI treatment. Only the conductivity was monitored with the limit of 0.5 µS/cm. The PW was used only for the manufacturing of WFI. The WFI was produced by the distillation of PW. The operation of water system was presented during the tour, along with the related logbooks.

	During the inspection the operation [SAP17026W351-OQ (protocol effective date: 22/05/2018, report effective date: 15/04/2020)] and the performance [PQR-209-UT-WFI-001 (effective date: 05/06/2020), Phase 1 report date: 10/05/2020, Phase II report date: 25/05/2020, Phase III was on/going during the inspection] qualification were reviewed.
3.3.1	• The remote/control testing has not been carried out, no justification was available in the SAP17026W351-OQ (effective date: 22/05/2018) qualification documentation although the OQ protocol require it. **Deficiency, Eudralex Vol. 4 Annex 15 2.7**
3.4 Other Utilities	Compressed air used in the building of 103 was getting in direct contact with the product. During the inspection the performance qualification documentation of the compressed air has been reviewed: - Protocol: PQP-103-UT-PAD-001-2020-01 - Report: PQR-103-UT-PAD-001-2020-01 During the qualification the system was tested for exemption of oil and the viable and non viable particle count limits were set to meet the specification for class A clean area. The system contained a 0.22µm end filter before entering the clean area.
3.5 Environmental Monitoring	The microbiological environment was monitored according to SOP-04-08-04-001 (effective date: 11/12/2020) procedure - EM monitoring of sterile areas - Particle count monitoring - continuously in grade A, B daily, C weekly, D monthly in operation. - Active and passive air monitoring - continuously in grade A (settle), once a shift grade A active air, B daily, C weekly, D monthly in operation. - Surface micro sampling: grade A once a shift, B daily, C weekly, D monthly. - Personnel monitoring: grade A once a shift, B daily The sampling points of sterile areas were determined in risk assessment which was part of the SOP, the layouts indicating the sampling points for the 103 building. The EM results were compilled together quarterly and include the prevous quarter's results as well. During the inspection the environmental monitoring of the 107 building 2nd floor filling room for 2020 2nd and 3rd quarter (EF-SOP-04-08-02-001-001 (signed of 13/09/2020) has been reviewed.
3.6 Warehouse & Material Management	The finished products were stored at the cold warehouse (2-8°C) located at the 103 building. The warhouse was fully automatic and it was capable to hold up to 5500 palets. The packaging section of the warehouse was also controlled to keep the cold supply chain. The quarantine batches were stored in the warehouse under logical separation until the market release of the batch by the QP. The security of the logical quarantine has been checked and challenged by the inspector during the inspection.
3.7 Equipment & Qualification	The list of production equipment was present in a SMF annex. During the inspection the following equipment qualifiactions were reviewed: - Vial filling machine: RVR-103-D-FIL-001-2020-01 (speed: 400 vial/ minute). - Prefilled syringe filling machine (building 107): RVR-107-IF-3FSM-001-2020-01 (24/05/2020-06/06/2020, speed: 600 syringe/ minute

3.8 Cleaning & cleaning validation	The production took place in dedicated production line. The line cleaning was performed after every batch. During the inspection the following cleaning validations were reviewed: - Protocol CVP-41-00 - Report CVR-41-007 report approved on 05/09/2020. CIP and SIP sytems was in place. Cheking of the effectiveness of the cleaning was done by rince and swab sampling and tested by TOC (limit: 40 ppm, LoD: 2 ppm), endotoxin, conductivity. - Cleaning validation of filling machine ID107392FSM01 (room 71F309) WFI 30-40 °C, then standing in 0.4M NaOH for 4hours, then WFI 70-80 °C 5minutes 3 times then sonication and finally test of rince and swab samples by TOC
4. Documentation	
4.1 Documentation System	The documentation system was managed electronically in the "Colorful Butterfly" system according to SOP-03-01-00-014 (effective date: 16/11/2020) prosecure. The SOPs were prepared according to SOP-03-01-00-002 procedure and the numbering was made according to SOP-03-01-00-003 procedure. The procedures were prepared, printed and approved by the responsible emlpolees. After the approval the electronic version was uploaded to the system. The system stamp evey exported document with the exportation date and the name of the person, who exported it. The document archiving was carried ot according to SOP-03-01-00-004 (effective date: 28/08/2020) procedure. The batch related documentatnion was keept for 5 year, the longest shelf-life was 3 years of any of the products. The documentation which was present in the current MAs were keept until the MA was active.
5. Production	
5.1 Manufacturing, Batch Records, Process Validation	The working Vero cells were thawed and cultivated in monolayer cell factories (CFs), and then passaged to 10-layer CFs for cultivation, then transferred to 40-layer CFs for cultivation followed by the transfer to a 40-L bioreactor in building 104. The cells were transferred to the 300-L bioreactor located in building 209. The Vero cells are inoculated with SARS-Co V-2 working virus seeds. The harvest is filtered through a 5.0μm filter to remove the cell debris to obtain a clear solution which is transferred to the harvest tank. In the 1000-L tank for inactivation by β-propiolactone. The inactivated virus passed through an ultrafiltration and than concentrated by using membrane method. After the concentration a nuclease soulution was added to destroy any residual DNA and followed by a second ultra filtration and a 0.2μm sterile filtration. During the inspection the batch record for the Bulck Batch NCOV20200070347, the final bulck batch NCOV2020007901 and the filling batch 202012347 were reviewed. from the final product 160108 vials were manufactured with a filling volume of 0.6 ml / vial of which 500 vials were taken as sample. The manufacturing process was validated stepvise, although a validation summary was also prepared.

	During the inspection the process validation documentation was reviewed: Process summary: Protocol (PVP-41-003-9) Report (PVR-41-003-4) Inactivation step: Protocol (PVP-41-003-15) bulck step: Protocol (PVP-41-003-16) final bulk step: Protocol PVP-041-003-16
5.1.1	• The manufacturing process validations were deffcient in the following ways: a) No information was present regarding the qualification status of the equipment used during the validation b) Every process parameter was considered as critical. Therfore no risk assessment was performed for the determination of the critical parameters c) Several target parameter were considered as critical parameters (e.g filter to be used 0.2 μm) **Deficiency, Eudralex Vol. 4 Annex 15 5.7, 5.9**
5.2 Aseptic Process Simulation	The aseptic processes were simulated according to "General Protocol for Media Fill" No media fill failure had ever been reported, the last media fill records were presented. - Media fill was performed for all aseptic operations. During the inspection the media fill documentation for the srynge filling operation was reviewed: For the syringe filling operation 30 000 syringe were filled with TSB media for media fill (real batch size: 160000-180000). A worst case set up was also used e.g.: 4 workers allowed work in the room at any time, during the media fill there were 7 present.
5.3 Site Tour	The working cellbank was stored in a liquid nitrogen container at the 4P0128 cold (2-8°C) storage room in building 104. The liquid nitrogen container did not bear any identification during the wisit of the area, but it was corrected during the inspection. The WC201814201 working vero cells were stored and used for the production of the SARS-CoV-2 Vaccine. During the inpection in the 2020057, 2020058, 2021001, 2021002, 2021005, 2021006, 2021009 and 2021010 vero cell batches wer under manufacturing in the area. The IPC was carried out in the room 4P0107 by the 104872COB01 automatic IPC equipment. The transportation of the vero cell from the 104 bulding into the 209 took place in sterilised 50L plastic container in case of 50L batch or in case of a 10L batch in the 10L bioreactorwhich were packed into 2 PE bags place into a plastic container in which an isolation layer was also added.
5.3.1	• No ID was present on the 50L plastic sterile container, used to transport the Vero Cells from building 104 to 209. **Deficiency, Eudralex Vol. 4 Part II 5.13**
5.3.2	• During the site tour several pressure gauges were found lower pressure reading than the specified minimum limit, furthermore at many gauges the limit was not indicated. **Deficiency, Eudralex Vol. 4 3.12**
5.3.3	• To enter the CNC area of the building 209 it was required to gown up like class D area. During the gowning, the only handwashing took place before the change of the footwear or appling the shoe covers. **Comment**

5.4 Re-process & Re-work	The re-process was described in SOP-07-01-00-009 (effective date: 13/05/2019) procedure. The reprocessing was only allowed at the secondary packaging of the finished product. No reworking was allowed on site
6. Quality Control	
6.1 General Presentation	The laboratory used paper based documentation, hence no LIMS system was in place at the QC laboratory, although it was planned to be introduced in the near future. Samples were documented in sample log book. The laboratory consisted of chemical and microbiological laboratories, retain samples, and stability samples stores. The chemical control laboratories were equipped to analyse raw materials, packaging materials, bulk and finished products. The analytical tests were performed according to approved specifications, method descriptions and documented on product specific records, prepared according to the specification and method, provided by the quality assurance for each batch. Method descriptions were available in the laboratory (paper based). The covid vaccine test was described in the SOP-04-01-034—every test item was included. Logbook and calibration was available for every equipemet. The last calibaration onf the osmometer was carried out on 12/01/2021. The pH meter was calibrated daily by using 3 buffer solutions.
6.2 Method Validation	The analytical methods were validated according to the VMP. During the inspection the following analytical method validations were reviewed: - β lactam residue determination (β-propio lakton) protocol: MVP-219, report MVR-219: limit 5 ppm, LoQ= 2.5 ppm, SST: RSD LT 10% - Elisa method validation : protocol: MVP-242, report MVR-242 LoQ= LT 12,5 ng/ml RSD LT 10 % - Effectivity verification of inactivation of the virus: MVP-187 – repeatability checked
6.3 OOS/OOT	The Out of Specification results were handled according to SOP-04-03-00-009-010 procedure. The flow chart and the check list were included in the protocol. Resampling was possible—not determined the exact condition of resampling. As an example the OOS-105PW-2020-010 (TOC for WFI) was reviewed.
6.3.1	• The investigation of OOS-105PW22020-010 (TOC for WFI) did not followed the SOP-04-03-00-009-010 Procedure. No phase-I investigation was carried out before a resampling was performed. **Deficiency, Eudralex Vol. 4 6.9**
6.4 Retain samples	Retain samples were taken and stored under the approved conditions from all released manufacturing batches. Yearly inspection was performed. The retain sample store, the register and selected samples were presented.
6.5 Stability Study	The stability batches were stored in qualified chambers according to the prescribed conditions of ICH Q2 guide. Analysed according to protocols prescribing the testing points, parameters, and requirements.
6.6 Equipment & Qualification	All QC equipement was qualified in the laboratory. ThepH meter, osmometer, spectrophotometers were qualified on annual bases. The qualification operations were present in the equipment logbooks.The last qualification of the osmometer has been performed on 12/01/2021.

6.7 Microbiology	At the microbiology laboratory the environmental monitoring, sterility and growth promotion testing has been carried out. The media was prepared at the microbiology labotatory, sterilised in an autoclave at 121°C for 20 minutes and subject to growth promotion testing in every case.
7. Outsourced Activities	
7.1 Manufacturing & Quality Control	The company uses 5 companies to carry out some QC tests of the API and the finished products. The management of the outsourced activities were regulated by SOP-03-08-13-001 (effective date: 29/09/2020) procedure. During the inspection the contract with the National Institutes for Food and Drug Control (signed on 18/08/2020, for the full testing of the Vero working cell) was reviewed.
7.1.1	• The contract with National Institutes for Food and Drug Control (signed on 18/08/2020) did not contain the following: - The right audit the contract acceptor - Any regulation on subcontracting **Deficiency, Eudralex Vol. 4 7.11, 7.17**
8. Complaints and Product Recall	
8.1 Complaints	The customer complaints were handled according to SOP-03-08-10-001 (effective date: 14/05/2020) procedure. The trending for 2019 was presented and in 2020 due to the pandemic situation no complaint has been reported. During the inspection the following complaint handling was reviewed: 2019010(YF)002, reported on: 08/07/2019, related to the 20170803 and 20170804 Yellow fever vaccine batches dissolution of the lyophilised powder was slow. The finished product specification did not contain specification for the dissolution time; hence the complaint was rejected on 30/09/2019, but the batch was later replaced.
8.2 Recall	The recall was carried out according to SOP-03-08-11-002 (effective date: 13/12/2019) procedure. Three leves of recalls has been established: Level I (serious risk to the patients, notification of authorities / customers within 24 hours, documentation and progress report within 1 day); Level II (risk to the patient, 2 days) and Level III (other reasons, no risk to the patient; 7 days). A mock recall was performed once in every two years. During the inspection the last mock recall documentation (initiated on: 05/06/2019, closed on: 29/08/2019) was reviewed.
9. Self-Inspection	
9.1 Self Inspection	Self-inspection was performed according to SOP-03-02-00-001 (effective date: 26/03/2020) procedure, each department was audited once a year. The plan and fulfillment of 2020 was presented along with the report of QC (24/12/2020). 1 minor observation was mentioned, CAPAs were implemented. The 2021 self inspection plan was not approved on the morning of 13/01/2021 which was agains the firm's own procedure which required to prepare the plan until 31 December. It was corrected during the inspection and it was approved on the afternoon of 13 /01/2021.

9.1.1	• The self-inspection procedure [SOP-03-02-00-001 (effective date: 26/03/2020)] did not require that the self auditor to be independent from the audited department. **Deficiency, Eudralex Vol. 4 9.2**

Summary

The inspection findings were as follows.

No critical GMP deficiency was identified.

Major deficiencies: -

Deficiencies: 1.2.1, 1.4.1, 1.5.1, 1.6.1, 1.7.1, 1.10.1, 2.5.1, 3.3.1, 5.1.1, 5.3.1, 5.3.2, 6.3.1, 7.1.1, 9.1.1

Comments: 2.4.1, 5.3.3

You are requested to submit corrective and preventive actions on the observations supported by proper documentation by 3 March 2021.
The decision on the issuance of the GMP certificate will be taken based on the submitted CAPAs.
The institute has the right to check the implementation of CAPA's on site before and after the issuance of the GMP certificate.

3 February 2021

[redacted]