12-4. **AZ** shall provide **DS** with the results of **GMP Inspection** conducted by authorities where **AZ** is the Marketing Authorization holder within one (1) month after the inspection.

(GMP AUDIT)

12-5. **DS** or its **Affiliates** shall assess and qualify and periodically audit **Affiliate** manufacturers or third party contractors related to the **PRODUCT** or **Key Materials** in accordance with procedures of **DS** and its **Affiliates**. **DS** or its **Affiliates** shall provide **AZ** with an audit report including any **CAPA**, if **AZ** requests the report and **Manufacturing Sites** accept to disclose it to **AZ**. If necessary, **DS** and/or its **Affiliates** have a meeting with **AZ** about the results of **GMP Audit**, but ultimately the decision of **DS** and/or its **Affiliates** is respected.

12-6. **AZ** or its **Affiliates** shall assess and qualify **Affiliate's** manufacturers or third party contractors related to packaging, labeling, and/or storage for unlabeled vials of the **PRODUCT**. **AZ** shall provide **DS** with appropriate documentation showing execution of the audit program.

12-7. **AZ** shall have the right to conduct on-site audit to evaluate **DS Affiliate's Manufacturing Sites**. The response(s) to finding(s) in **DS Affiliate's** manufacturers should be discussed by **AZ**, **DS** and its **Affiliate** and the correspondence should be determined in good faith. Regular audit right shall not be exercised by **AZ** more than once per two (2) years. The Audit duration will be mutually agreed upon between DS and AZ, and AZ conducts the audit with maximum two (2) teams and no more than two (2) persons per team. To schedule the regular audit of **DS Affiliate's Manufacturing Sites**, **AZ** shall give **DS** or its **Affiliates** reasonable advance notice, not less than sixty (60) days' notice. In case of "for cause" audit, **DS** or its **Affiliates** will make all reasonable efforts to schedule the audit as soon as possible.

ARTICLE 13. PRODUCT RELEASE DOCUMENTS

13-1. **DS** or its **Affiliates** shall provide **AZ** and its designee the following documents for product release written in English and approved by an authorized person.

a) **Certificate of Analysis (CoA)**: including following items:
   i. **PRODUCT** name
   ii. **Manufacturing Site** name and address

J.M.