REPUBLIC OF LEBANON
MINISTRY OF PUBLIC HEALTH

الجمهورية اللبنانية
وزارة الصحة العامة

Self Assessment Quality Module 3: Part S

February 2022

Section	*Quality Part Module 3 Part S: Drug Substance*	*To complete*	*Remarks*
3.2. S	**Drug Substance (name of the active ingredient, manufacturer):**		
3.2. S.1	**General Information (name of drug substance, manufacturer).**	Open Part	
3.2. S.1.1	Nomenclature.	Open Part	The manufacturer should provide a full description of this section
3.2. S.1.2	Structure.	Open Part	The manufacturer should provide a full description of this section
3.2. S.1.3	General Properties.	Open Part	The manufacturer should provide a full description of this section
3.2. S.2	**Manufacture (name, manufacturer):**		
3.2. S.2.1	Manufacturer(s).	Open Part	The manufacturer should provide a full description of this section
3.2. S.2.2	Description of Manufacturing Process & process controls.	The manufacturer should provide a full description of this section (as open part). If the detailed information is submitted as a closed part, a brief description should be provided with the Certificate of European Pharmacopoeia-CEP » or the « Certificate of Suitability-COS »	The manufacturer should provide a full description of this section (as open part). If the detailed information is submitted as a closed part, a brief description should be provided with the Certificate of European Pharmacopoeia-CEP » or the «Certificate of Suitability-COS»

3.2. S.2.3	Control of Materials	Open Part/Closed Part	It could be submitted either as open or closed part. If it was submitted as closed part, the manufacturer should provide: the Certificate of European Pharmacopoeia-CEP » or the « Certificate of Suitability-COS »
3.2. S.2.4	Control of Critical Steps & intermediates.	The manufacturer should provide a full description of this section (as open part). If the detailed information is submitted as a closed part, a brief description should be provided with the Certificate of European Pharmacopoeia-CEP » or the « Certificate of Suitability-COS »	The manufacturer should provide a full description of this section (as open part). If the detailed information is submitted as a closed part, a brief description should be provided with the Certificate of European Pharmacopoeia-CEP » or the « Certificate of Suitability-COS »
3.2. S.2.5	Process Validation.	Open Part/Closed Part	It could be submitted either as open or closed part. If it was submitted as closed part, the manufacturer should provide: the Certificate of European Pharmacopoeia-CEP » or the « Certificate of Suitability-COS »
3.2. S.2.6	Manufacturing Process Development	Open Part/Closed Part	It could be submitted either as open or closed part. If it was submitted as closed part, the manufacturer should provide: the Certificate of European Pharmacopoeia-CEP » or the « Certificate of Suitability-COS »

3.2. S.3	**Characterization (name, manufacturer)**		
3.2. S.3.1	Elucidation of Structure and other Characteristics (name, manufacturer)	Open Part	The manufacturer should provide a full description of this section
3.2. S.3.2	Impurities (name, manufacturer)	The manufacturer should provide a full description of this section (as open part). If the detailed information is submitted as a closed part, a brief description should be provided with the Certificate of European Pharmacopoeia-CEP » or the « Certificate of Suitability-COS »	The manufacturer should provide a full description in this section (as open part). If the detailed information is submitted as a closed part, a brief description should be provided with the Certificate of European Pharmacopoeia-CEP » or the « Certificate of Suitability-COS »
3.2. S.4	**Control of Drug Substance (name, manufacturer)**		
3.2. S.4.1	Specification.	Open Part	The manufacturer should provide a full description of this section
3.2. S.4.2	Analytical Procedures.	Open Part	The manufacturer should provide a full description of this section
3.2. S.4.3	Validation of Analytical Procedures.	Open Part	The manufacturer should provide a full description of this section
3.2. S.4.4	Batch Analysis.	Open Part	The manufacturer should provide a full description of this section
3.2. S.4.5	Justification of Specification	The manufacturer should provide a full description of this section (as open part). If the detailed information is submitted as a closed part, a brief description should	The manufacturer should provide a full description in this section (as open part). If the detailed information is submitted as a closed part, a brief description should

		be provided with the Certificate of European Pharmacopoeia-CEP » or the « Certificate of Suitability-COS »	be provided with the Certificate of European Pharmacopoeia-CEP » or the « Certificate of Suitability-COS »
3.2. S.5	**Reference Standards or Materials (name, manufacturer).**	Open Part	The manufacturer should provide a full description in this section (as open part). If the detailed information is submitted as a closed part, a brief description should be provided with the Certificate of European Pharmacopoeia-CEP » or the « Certificate of Suitability-COS »
3.2. S.6	**Container Closure System (name, manufacturer)**	Open Part	Even if the COS is submitted, the manufacturer should provide a full description of this section
3.2. S.7	**Stability (name, manufacturer)**	Open Part	Even if the COS is submitted, the manufacturer should provide a full description of this section
3.2. S.7.1	Stability Summary and Conclusions.	Open Part	Even if the COS is submitted, the manufacturer should provide a full description of this section
3.2. S.7.2	Post-approval Stability protocol & Commitments.	Open Part	Even if the COS is submitted, the manufacturer should provide a full description of this section
3.2. S.7.3	Stability Data	Open Part	Even if the COS is submitted, the manufacturer should provide a full description of this section