Unit: Stability

Summary Sheet for New Registration

Type of Registration	**New (decree)**
Type of Product	**Biological- (Imported or local) (reference or non-reference)**
Applicant Name	
License Holder /Marketing Authorization holder	
Manufacturer of Active substance:	
Manufacturer of Finished Product:	
Manufacturer of Diluent	
1ry Packager	
2ry Packager	
Batch Releaser	
Stability Performed by	**Active substance:** **Finished product:** **Diluent:**
Trade Name	
Active Ingredient	**Finished product:** **Diluent:**
Dosage Form	
Physical Characters of Active substance:	
Physical Characters of Finished Product:	**-If Powder then mention: 1- before reconstitution and 2-After reconstitution** **-If powder & solvent then mention: 1-powder alone 2-solvent alone 3-After reconstitution**
Shelf Life of Active substance:	
Shelf Life of Finished Product:	
Storage Conditions of Active substance:	
Storage Conditions of Finished Product:	
Precautions +Incompatibilities (if	

العنـــــــــــوان: 51 شارع وزارة الزراعة، العجوزة – الجيزة
البـريـد الإلـكـتـرونـي: المكتب الفني / bio.tech@edaegypt.gov.eg، المكتب الإداري /bio.admin@edaegypt.gov.eg
التـــلـيـــفـــــون: 0237484988
موقع الهيئة: www.edaegypt.gov.eg

available)	
Pack of Active substance:	
Pack of Finished Product +Diluent:	
Contact E-mail	

Summary of Stability Study:

The stability study data should be filled in the following table (Separate table for DS/ DP/ Diluent):

Type of study (long or accelerated or stress)/In-use/Photostability	Batch no.	Man. site	Manufacturing date	Duration of study (available submitted data)	Storage conditions	Batch scale (pilot or production)

العنـــــــــــوان: 51 شارع وزارة الزراعة، العجوزة – الجيزة
البريد الإلكتروني: المكتب الفني / bio.tech@edaegypt.gov.eg، المكتب الإداري /bio.admin@edaegypt.gov.eg
التـــلـيـــفـــــون: 0237484988
موقع الهيئة: www.edaegypt.gov.eg