National Institute for Quality- and Organizational Development in Healthcare and Medicines

Union Format for Registration of Manufacturer, Importer or Distributor of Active Substances to be used as Starting Materials in Medicinal Products for Human Use

1. Registration Number	:	OGYI/28943-2/2014
2. Name or corporate name of registrant	:	CycloLab Cyclodextrin R&D Laboratory Ltd.
3. Permanent or legal address of registrant	:	Illatos út 7., Budapest, 1097, Hungary
4. Address(es) of site(s) where registered activities take place	:	Illatos út 7., Budapest, 1097, Hungary
5. National legal basis of registration	:	Act XCV of 2005 on Medicinal Products for Human Use
6. Name of responsible officer of the competent authority of the member state validating the registration	:	Confidential
7. Signature	:	
8. Date	:	2014-07-24

This registration form is valid only when presented with all pages. The authenticity of this registration form may be verified in the Union database or with the validating authority.

The registration holder referred to in section 2 shall communicate annually to the competent authority an inventory of the changes which have taken place as regards the information provided in this registration form. Any changes that may have an impact on the quality or safety of the listed active substances must be notified immediately.

SCOPE OF REGISTRATION

Name and address of the site: CycloLab Cyclodextrin R&D Laboratory Ltd., Illatos út 7., Budapest, 1097, Hungary

1. MANUFACTURING OPERATIONS

Active Substance : SULPHOBUTYLETHER BETA CYCLODEXTRIN SODIUM
(182410-00-0)

A	**Manufacture of Active Substance by Chemical Synthesis**
	A.1 Manufacture of active substance intermediates *A.2 Manufacture of crude active substance* *A.3 Salt formation / Purification steps* .
E	**General Finishing Steps**
	E.1 Physical processing steps . *E.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)* *E.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)*
F	**Quality Control Testing**
	F.1 Physical / Chemical testing *F.2 Microbiological testing excluding sterility testing*

Active Substance : DIMETHYL-β-CYCLODEXTRIN
(51166-71-3)

A	**Manufacture of Active Substance by Chemical Synthesis**
	A.1 Manufacture of active substance intermediates *A.2 Manufacture of crude active substance* *A.3 Salt formation / Purification steps* .
E	**General Finishing Steps**
	E.1 Physical processing steps . *E.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)* *E.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)*
F	**Quality Control Testing**
	F.1 Physical / Chemical testing *F.2 Microbiological testing excluding sterility testing*