



CERTIFICATION OF SUITABILITY OF MONOGRAPHS
OF THE EUROPEAN PHARMACOPOEIA

Certificate No. RO-CEP 2002-058-Rev 00

1 *Name of the substance:*
2 **DESMOPRESSIN**

3 *Name of holder:*
4 **LIPOTEC SA**
5 Crta Santa Eulàlia 240
6 E - 08902 L'hospitalet De Llobregat (Barcelona)

7 *Site of production:*
8 **LIPOTEC SA**
9 Crta Santa Eulàlia 240
10 E - 08902 L'hospitalet De Llobregat (Barcelona)

11 After examination of the information provided on the manufacturing method and subsequent
12 processes (including purification) for this substance on the site of production mentioned above,
13 E - 08902 L'hospitalet De Llobregat (Barcelona), we certify that the quality of the substance is
14 suitably controlled by the monograph **DESMOPRESSIN** (no. 0712, Ph. Eur. 4th Ed. and any
15 subsequently revised version) and its specifications are controlled by the test(s) mentioned below, based on
16 the analytical procedure(s) given in the monograph, for ex.

**NOT FOR
PUBLIC RELEASE**

17 The following related substances are controlled by the test(s) mentioned above, and their limits are set at :

18 D-Cys-Desmopressin not more than 0.5 %
19 Asp-dehydrated Desmopressin not more than 0.5 %

21 — Test for trifluoroacetic acid by liquid chromatography (Annex 1)
22 Trifluoroacetic acid not more than 0.25 %

23 The submitted dossier must be updated every five years or after any significant modification of
24 the manufacturing method that may alter the quality, safety or efficacy of the product or require
25 changing the specifications of the monograph.

26 Manufacture of the substance shall take place in accordance with the Good Manufacturing
27 Practice and in accordance with the dossier submitted.

28 Failure to comply with these provisions will render this certificate void.