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M E B

Medicines Evaluation Board

Graadt van Roggenweg 500 | 3531 AH Utrecht | The Netherlands CORRESPONDENCE ADDRESS P.O. Box 8275 | 3503 RG Utrecht | The Netherlands +31 (0)88 224 80 00 | www.cbg-meb.nl

Request for timeslot for national Marketing Authorisation Application for homeopathic medicinal product for human use

Proposed Product Name:		
Pharmaceutical Form(s):		
Active substance(s):		
ATC code:		
Proposed indication(s):		
Legal basis of application:		
Art. 14 Art. 16(1) Art. 16(2)		
		(1-)
Duplicate/multiple applications will be submitted: Yes No		
Indicate the number of duplicates:		
Name(s) and address(es) of the		Has a Ph.Eur. Certificate of suitability (CEP)
manufacturer(s) of active substance:		been issued for the active substance and/or will
manaractarcity of active substance.		an Active Substance Master File (ASMF) be
		used?
1)		
1)		☐ CEP ☐ ASMF ☐ N/A
2)		☐ CEP ☐ ASMF ☐ N/A
3)		CEP ASMF N/A
Name(s) and address(es) of the		Does the manufacturer of the finished product
manufacturer(s) of finished product:		have an EU GMP certificate?
1)		Yes No
2)		Yes No
,		
3)		Yes No
Applicant's preferred submission date (month/year):		
Scientific advice received:		
If yes, provide details (from which	ch MS, scope and	d outcome):
Applicant:		
Authorised contact person:		
Address:		
Phone:		
E-mail address:		
Date:		