2.7.6 Synopses of Individual Studies

2.7.6.1 Produktieve hoest: tijm of broomhexine? Een dubbelblind gerandomiseerd onderzoek [Productive cough: Thyme or bromhexine? A double-blind randomised investigation] Knols et al 1994.

Name of Sponsor/Company: -		Individual Study Table Referring to Part of the Dossier **module 5**	*(For National Authority Use only)*
Name of Finished Product: -		Volume:	
Name of active substance: **Thyme syrup**		Page:	
Title of Study:	**Produktieve hoest: tijm of broomhexine? Een dubbelblind gerandomiseerd ondersoek**		
Investigators:	**Knols G, Stal PC, Van Ree JW**		
Study centre (s):	**5 medicinal practices**		
Publication (reference)	**(8)**		
Studied period (years):	**Between December 1992 and March 1993**	Phase of development:	
Objectives:	**Effect of treatment on symptoms of productive cough**		
Methodology:	**Randomised, double-blind, comparative study**		
Number of patients (planned and analyzed):	**60**		
Diagnosis and main criteria for inclusion:	**Complaints associated with productive cough**		
Test product, dose and mode of administration, batch number:	**Thyme syrup syrup (no details regarding DER, extraction solvent and amount of herbal preparation in the syrup).** **Oral administration, 3 x 10 ml daily.**		
Duration of treatment:	**5 days**		
Reference therapy, dose and mode of administration, batch number	**Bromhexine forte** **No further information on dose and mode of administration**		
Criteria for evaluation: Efficacy: Safety:	**Subjective evaluation of symptoms associated with productive cough** **Not mentioned**		
Statistical methods:	**Not available**		
Results Efficacy: Safety:	**In both groups similar improvements. Improvement in smoking subjects seem to be delayed.** **Not mentioned**		

2.7.6.2 Company report cited in an ESCOP monograph

Name of Sponsor/Company: **Dentinox Gesellschaft KG, Berlin**	Individual Study Table Referring to Part of the Dossier **module 5**	*(For National Authority Use only)*
Name of Finished Product: **Hustagil® Thymian Hustensaft**	Volume:	
Name of active substance: **Thyme syrup**	Page:	

Title of Study:	**Integrierter Abschlussbericht vom 04.12.1997 für Dentinox Gesellschaft KG, Berlin. Anwendung von Hustagil® Thymian Hustensaft bei Kindern mit Erkältungskrankheiten der oberen Luftwege oder mit Beschwerden der Bronchitis.**	
Investigators:	**Not mentioned**	
Study centre (s):	**Not specified**	
Publication (reference)	**Report is cited in (2)**	
Studied period (years):	**Not specified**	Phase of development:
Objectives:	**Effect of treatment on intensity of cough**	
Methodology:	**Randomised, double-blind, multicenter study**	
Number of patients (planned and analyzed):	**154**	
Diagnosis and main criteria for inclusion:	**Children withbronchial catarrh or bronchitis**	
Test product, dose and mode of administration, batch number:	**Thyme syrup syrup (containing 97.6 mg of thyme fluid extract (2-2.5:1) per ml). Oral administration, 15-30 ml daily.**	
Duration of treatment:	**7-14 days (mean 7.9 days)**	
Reference therapy, dose and mode of administration, batch number	-	
Criteria for evaluation:		
Efficacy:	**Assessment of cough intensity (criteria for evaluation not mentioned).**	
Safety:	**Not mentioned**	
Statistical methods:	**Not available**	
Results		
Efficacy:	**Compared to the start of the treatment an improvement in the intensity of coughing was reported in 93.5% of patients.**	
Safety:	**Not mentioned**	