

Cleaner with Chematic .

Technical Brief for : CLEANING OF EUDRAGIT®

Date : February 2009

Subject : **Cleaning Process Recommendations for the
Cleaning of Eudragit®**

Dober has been providing pharmaceutical, biopharmaceutical, medical device, nutraceutical and food marketplaces with Chematic® detergents that excel in the removal of hard to clean residues. The detergents offered by Dober have been validated to be highly effective in the cleaning of Eudragit® based polymers marketed by EVONIK.

The table that follows includes a number of detergents and cleaning recommendations already developed by Dober, for the Eudragit® polymers. When combined with other excipients that are intended to modify pharmaceutical dissolution, these recommendations may need to be altered. Please contact Dober Group at +1-800-323-4983 (or +1-630-410-7300) to learn more about our free Application Cleaning Methodology services and how Dober can help you determine the correct cleaning conditions for any application.

Eudragit® Type	Typical Eudragit® Products	Recommended Dober Detergent	Recommended Process Parameters			
			CIP Spray Applications 15 minutes *		Manual Cleaning 15 minutes *	
			Concentration	Temperature	Concentration	Temperature
Eudragit® L	<ul style="list-style-type: none"> L-100 L-100-55 L-30-55 	Chematic® 82 or 82Euro	2 - 10% v/v	60 - 70°C	2% v/v	50 - 60°C
Eudragit® S	<ul style="list-style-type: none"> S-100 	Chematic® 82 or 82Euro	2 - 10% v/v	60 - 70°C	2% v/v	50 - 60°C
Eudragit® RL	<ul style="list-style-type: none"> RL100 RLPO RL30D 	Chematic® 9301†	10% v/v	70°C	**	**
			Hot post rinse 70 - 80°C			
Eudragit® RS	<ul style="list-style-type: none"> RS100 RSPO 	Chematic® 9301†	10% v/v	70°C	**	**
			Hot post rinse 70 - 80°C			
	<ul style="list-style-type: none"> RS30D 	Chematic® 453	10% v/v	70°C	**	**
Eudragit®	<ul style="list-style-type: none"> NE30D 	Chematic® 485	CIP Version of Chematic® 485 under development (end of 2009)		10% v/v	50-60°C
					Cold post rinse 15-30°C	

Note: All concentrations are dependent upon application.

* times may need to be adjusted based upon temperature employed and soil deposition.

** manual cleaning to be undertaken with care based on necessity for high temperatures and concentrations

† Also available, Chematic® 9301-D -- a modified version of Chematic® 9301 with higher levels of solvent for difficult excipients added to Eudragit®

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