

Version 1, March 26, 2020

## Relevance of findings for Cholesterol HP

This document should be read with the inspection report of the EDQM. You can download it [here](#).

In this document we indicate the relevance of a finding for the product Cholesterol HP. It is not our intention to present the findings less seriously than they are. We made this assessment in good faith, in order to help you as MAH in your risk assessment.

No rights can be derived from this assessment.

#		Finding (summarized)	Relevance for Cholesterol HP
1		Lack of QA-oversight and/or technical knowledge	<i>This finding is actually a conclusion that can be drawn from the other 8 major findings and is therefore regarded as critical.</i>
2		The firm's approach to materials management was considered as not in compliance	
2a	i		<i>This finding is generally applicable.</i>
	ii		<i>This finding is generally applicable.</i>
	iii		<i>Not applicable to Unit 6B where the Cholesterol HP is manufactured</i>
	iv		<i>No materials from this warehouse are used in the manufacture of Cholesterol HP.</i>
2b		<i>Cholesterol HP or its starting material (Cholesteryl acetate) are not stored in the Drum storage. Cholesterol HP is stored in the final product warehouse Temperature is controlled at 20 – 25°C</i>	
2c		<i>No catalysts are used in the manufacturing process of Cholesterol HP</i>	
2d		<i>This is applicable to the whole site</i>	
2e		<i>This is applicable to the whole site</i>	
3		Risks associated with the introduction of new chemical entities/products/API's	
3a			<i>Cholesterol an NCE and therefore pharmacological and toxicological characteristics are known</i>
3b			<i>Cholesterol HP is neither manufactured in the dedicated facility for the mentioned substance nor in the Pilot Plant PP-RG-05, therefore no risk for contamination</i>
3c	i		<i>The manner of executing risk assessments is a general issue.</i>

	ii		<i>The production of the mentioned substance was executed in the Pilot plant, not applicable to Unit 6B where Cholesterol HP is manufactured</i>
	iii		<i>This maybe a general issue</i>
4		Observations with regard to the recovery of solvents	<i>This finding relates to unit 5, not directly to the Unit 6B where the Cholesterol HP is manufactured. It may however be a general issue</i>
5		Overall and serious lack of maintenance	<i>Unit 6B where Cholesterol HP is manufactured is not specifically mentioned, but poor maintenance is a general problem.</i>
5a			
5b			
5c			
5d			
5e	i		
	ii		
	iii		
6		Observations with regard to the process validation activities related to Dihydrotachysterol	<i>This observation is not applicable to Cholesterol HP.</i>
7		The cleaning of sampling and dispensing rooms in warehouse 1 where open material was handled were considered as not in compliance.	
7a			<i>This may apply to Cholesterol HP as well</i>
7b			<i>This may apply to Cholesterol HP as well</i>
8		No cleaning validation was performed in unit 3C.	<i>This observation is not applicable to Cholesterol HP</i>