

Version 1, March 26, 2020

Relevance of findings for Dihydrotychsterol

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 Dihydrotychsterol. It is not our intention to present the findings less seriously than they are. We made this assessment in good faith. We hope to help you as MAH in your risk assessment.

No rights can be derived from this assessment.

#		Finding (summarized)	Relevance for DHT2
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>Can be considered as a general finding.</i>
	ii		<i>Can be considered as a general finding. This finding mentions unit 13, not directly to the Pilot plant where DHT2 is manufactured.</i>
	iii		<i>Can be considered as a general finding.</i>
	iv		<i>This is considered a general quality issue.</i>
2b			<i>DHT2 is packaged in glass vials and stored in a freezer. No storage of the glass vials containing the product will take place in the drum storage area.</i>
2c			<i>This is considered a general quality issue.</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>DHT2 is not an NCE and therefore pharmacological and toxicological characteristics are known.</i>

3b			<i>DHT2 is manufactured in campaigns in the same Pilot plant. First batch after November 2017 was manufactured in June 2018. The probability for contamination with the mentioned product is minimal.</i>
3c	i		<i>The manner of executing risk assessments is a general issue.</i>
	ii		<i>The production of the mentioned product was executed in the Pilot plant, this is fully applicable to DHT2, no production of DHT2 did take place afterwards.</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 Pilot Plant where the DHT2 is manufactured. However, it may however be a general issue</i>
5		Overall and serious lack of maintenance	<i>The Pilot Plant where DHT2 is manufactured is not specifically mentioned, but bad 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 Dihydrotychsterol	<i>This observation is fully applicable to DHT2</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 DHT2 as well</i>
7b			<i>This may apply to DHT2 as well</i>
8		No cleaning validation was performed in unit 3C.	<i>This observation is not applicable to DHT2</i>