

From: Nilam Patel [<mailto:nilamp@glenmark-generics.com>]

Sent: Monday, February 25, 2013 4:38 AM

To: FUEHRING Stefan (SANCO)

Subject: RE: Transporation of Active substance (our ref.: Ares(2013)194516)

Dear Stefan,

We need to understand the meaning of "Appropriately specialized".

Also, we need clarification that if the storage condition of any API is below 25°C than we have to transported the material by maintaining below 25°C only? Or

if we have 6month accelerated stability data (40±2°C), can we transported material by defining standard transportation period at normal temperature (ambient) from customer to vendor?

Regards,

Nilam Patel

[<mailto:nilamp@glenmark-generics.com>]

Sent: Thursday, February 14, 2013 7:51 AM

To: SANCO PHARMACEUTICALS D6

Subject: FW: Transporation of Active substance

Dear Sir/Madam,

We have referred the new draft guideline on "THE PRINCIPLES OF GOOD DISTRIBUTION PRACTICES FOR ACTIVE SUBSTANCES FOR MEDICINAL PRODUCTS FOR HUMAN USE".

It will really help us to understand the storage and distribution requirements of APIs.

As per Section 27 "Active substances requiring controlled temperature storage should also be transported by appropriately specialized means".

Can you please the elaborate the meaning of "Appropriately specialized".

The APIs should be transported with temperature condition same as storage condition? Or

Can we use six month accelerate stability data and after risk assessment , decision can be taken for transportation condition?

Regards,

Nilam Patel

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