Shelf Life of Zephex®134a & Re-testing

1. Introduction

1.1. Overview

Zephex®134a that is provided within a package or ISO tank, has a shelf life which extends to 60 months (five years) from the date of manufacture. The date of manufacture is stated on the Certificate of Analysis (CofA) for the material being supplied.

Koura has conducted stability trials, in accelerated conditions at temperatures up to 60°C for 60 months, to provide evidence for this shelf life. The stability trials have been completed in both carbon steel and stainless steel, as Koura provides packages made from both materials.

1.2. Based on Data from ICH Stability Protocols

The stability protocols are followed from the methods as in the ICH Guidelines 'Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients'.

It should be noted that these guidelines are in line for pharmaceutical end products, although Zephex®134a is classified as an excipient.

The full data is contained within the Drug Master File (DMF) for Zephex®134a, which is provided as part of the manufacturer's Marketing Authorisation (MA) application within Europe. A summary of these protocols and the associated data can be found in the Koura document 'Stability Studies for Zephex®134a'.

2. 'Extension' of Shelf Life

2.1. Requests

On occasion, it is queried that a pharmaceutical manufacturer wishes to use Zephex®134a in their product, post the shelf life of the Zephex®134a.

Koura **cannot** authorise the extension of shelf life of Zephex®134a product, due to having stability data up to a maximum of 60 months as explained in the introduction. Any extension of

shelf life must be assessed and justified by the customer within their own quality system.

If a customer requires data to confirm that the Zephex®134a is within specification at the five-year period or beyond, then testing support may be available. This testing service can only perform limited testing and needs to be assessed based on the state of the package/product.

For example:

- Original package supplied by Koura or another package/storage unit.
- Tag seals broken or still secured.
- An amount of the product has been removed or none removed from the package.

Koura can assist in the assessment of which testing can be completed, to provide supporting data to the customer. Koura will not provide a pass/fail result, although will report the analytical tests undertaken. The customer has the original product Certificate of Analysis and can compare the results and draw their own conclusion on the useability of the Zephex® 134a, based on the limited testing that was performed.

Koura cannot authorise the analytical data provided as an extension of shelf life.
It is the responsibility of the end-product manufacturer, to ensure that the Zephex®134a is suitable for use at or beyond the five-year period. This information may be sought by the end product manufacturer taking advice from the regulatory body for the region where the product will be placed on the market.

2.2. Sampling

The process of taking samples that are representative and suitable for analysis, involves a risk-based approach that needs to be adopted by the customer. Koura can offer assistance in this process. Koura will not determine the 'pass' or 'fail' status of a sample of Zephex®134a, this must be assessed by the customer.

Samples will be taken at the customer's site from the vessel it currently occupies. The sampling assessment, based on the points in 2.1, should be completed by the customer.

Due to the risk of taking a non-representative sample, it is highly recommended that sampling should be completed by trained Koura personnel, using Koura approved equipment. This may or may not be able to be completed by Koura and is dependent on specific circumstances. A charge will be applied for this service.

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