



Circular No.87/ 2024

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25 -06-2024

نتقدم بثقة
Moving Forward
with Confidence

رؤية عمان
2040
Oman Vision

To All:

Drug Stores

Pharmaceutical Consultancy Services Companies

Local Pharmaceutical Industries

After compliments,

Sub: High risk excipients (Glycerin, Propylene Glycol, Maltitol Solution, Hydrogenated Starch Hydrolysate, Sorbitol Solution).

With reference to the above mentioned subjected, this is to inform you that you are requested to update the products file (pharmaceutical/Health/Herbal/Medical device), with regard to the part related to the control of these excipients (from all approved sources) to include the following:

1. Limit of acceptance for the impurities (Ethylene glycol and Diethylene Glycol) in these excipient specifications.
2. A validated analytical procedure for determination of the said impurities.
3. Batch analysis certificates for these excipients from all the sources as per the updated specifications.
4. To update the dossier with any variation related to the source(s), specifications and analytical procedure of these excipients.

In addition, whenever these excipients constitute a high percentage of the finished product composition formula, to update the specifications of the finished product with limit of acceptance for the said impurities with supportive validated analytical procedure.

Yours faithfully,

Dr. Mohammed Hamdan Al Rubaie
Director General



Cc:

- All directors in DSC
- All Section Heads in DG office.



DSC
مركز سلامة الدواء
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