

केन्द्रीय मुहर विभाग -2

संदर्भ :- के मू वी-2/16 : 16112

27 09 2022

विषय: IS 16112 : 2013 के amendment no. 3 & amendment no. 4 के अनुपालन के दिशा निर्देश

यह उपरोक्त विषय के संदर्भ में है।

सक्षम अधिकारी द्वारा अनुमोदित दिशा निर्देश अनुपालन हेतु संलग्न है।

सभी क्षेत्रीय/शाखा कार्यालयों से अनुरोध है की दिशा निर्देशों का तत्काल प्रभाव से अनुपालन सुनिश्चित करें।

(ज्ञान प्रकाश)

वैज्ञानिक- सी

प्रमुख (के मू वी 2)

सभी क्षेत्रीय/शाखा कार्यालय/प्रयोगशालाओं/PCD/LRMD

CENTRAL MARKS DEPARTMENT-2

Our Ref: CMD-2/16 : 16112

27 09 2022

Subject : Guidelines for implementation of amendment no. 3 & amendment no. 4 to IS 16112 : 2013

This has reference to the subject mentioned above.

The Competent Authority has approved the enclosed Guidelines for implementation.

All ROs/BOs are requested to ensure the implementation of the above Guidelines with immediate effect.

(Gyan Prakash)
Scientist C

Head (CMD-2)

All ROs/BOs/Labs/PCD/LRMD

CENTRAL MARKS DEPARTMENT-2

Our Ref: CMD-2/16 : 16112

27-09-2022

Subject: Guidelines for implementation of Amendment No. 3 & Amendment No. 4 to IS 16112 : 2013 Beta Picoline - Specification

1. Amendment No. 3 & Amendment No. 4 to IS 16112 : 2013 have been published. The last date for implementation of the amendments is 01 November 2022.
2. All BOs shall inform the Applicants and Licensees under their jurisdiction about implementation of the above amendments within a week of issuance of these guidelines.
3. The significant changes in the standard through these amendments as listed in the Table are given for the purpose of general guidance. BOs shall ensure that the product conforms to all the requirements, as applicable, as per the amendments.

Clause	Change
Page 2, Annex - A, clause A-2.3	<p>Through amendment no- 3, the specification for the capillary column of Gas Chromatograph used for determination of beta picoline and its impurities as per method given in Annex A, has been modified (Specification for capillary column was also modified vide amendment no.- 2, however some information was missing in amendment no-2, now amendment no 3 has been published to provide complete details of the column).</p> <p>The following note has also been added:</p> <p>NOTE — The above gas chromatographic conditions are suggestive. However any GC having different columns (packed/Capillary having different length/diameter/film thickness) and different carrier gas (He, H2 or N2), with different calibration technique (internal standard, external standard, area normalization) may be used, provided standardization/calibrations are done after setting up chromatographic conditions for required resolution.'</p>
Page 1, Table 1, SI No. (iv)	<p>Through amendment no. 4, the requirement for Gamma Picoline content has been modified (increased to 0.8 max from 0.4 max)</p>

4. The existing Product Manual has been revised to incorporate the amendments and it is being circulated separately through BIS website, as Product Manual Doc : PM/ 16112/ 2 September 2022.
5. Specification for the capillary column of Gas Chromatograph used for determination of beta picoline and its impurities has been modified however through note it is

informed that Gas chromatographic conditions are suggestive and any GC having different chromatographic conditions may be used, provided standardization/calibrations are done after setting up chromatographic conditions for required resolution. Further requirement of Gamma Picoline content has been relaxed.

6. In view of above, no evidence of conformity needs to be obtained from applicants/licensees. However, All BOs shall inform the Applicants and Licensees under their jurisdiction about implementation of these amendments within a week of issuance of these guidelines

(Gyan Prakash)
Sc C, CMD-2

Head (CMD II)

DDG (Certification)