

IPAC-RS Comments on PhEur “PREPARATIONS FOR INHALATION”

Reference: PA/PH/Exp. INH/T (23) 7 ANP

The International Pharmaceutical Aerosol Consortium on Regulation & Science (IPAC-RS, details at <https://www.ipacrs.org/>) seeks to advance the science, and especially the regulatory science, of orally inhaled and nasal drug products; and as such, is pleased to share the following comments. Members of IPAC-RS are listed at <https://www.ipacrs.org/about2>.

Location	Original Language	Proposed Changed Language	Justification of Proposed Change	Importance
Page 4, Lines 41-44	Uniformity of delivered dose, intra-inhaler testing (2.9.54). Pressurised metered-dose inhalers comply with the test.		Comply with which test? Presumably this means comply with 2.9.54 but language could be clarified.	Minor
Page 6, Lines 25-33	<p>The average of the delivered doses is used as the reference value for the limits of acceptance.</p> <p>Unless otherwise justified and authorised, the preparation complies with the test if 9 out of 10 results lie between 75 per cent and 125 per cent of the reference value and all lie between 65 per cent and 135 per cent. If 2 or 3 values lie outside the range of 75 per cent to 125 per cent of the reference value, repeat the test for 2 additional inhalers (30 values in total). Not more than 3 of the 30 values lie outside the range of 75 per cent to 125 per cent of the reference value and no value lies outside the range of 65 per cent to 135 per cent of the reference value.</p>	<p>The average of the delivered doses is used as the reference value for the limits of acceptance.</p> <p>Unless otherwise justified and authorised, the preparation complies with the test if 9 out of 10 results lie between 75 per cent and 125 per cent of the reference value and all lie between 65 per cent and 135 per cent. If 2 or 3 values lie outside the range of 75 per cent to 125 per cent of the reference value, repeat the test for 2 additional inhalers (30 values in total). Not more than 3 of the 30 values lie outside the range of 75 per cent to 125 per cent of the reference value and no value lies outside the range of 65 per cent to 135 per cent of the reference value.</p>	Text is duplicate of text from 2.5.54 so does not need to appear here.	Major

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	Unless otherwise authorised, the average of the delivered doses must be between 85 per cent and 115 per cent of the label claim for delivered dose.	Unless otherwise authorised, the average of the delivered doses must be between 85 per cent and 115 per cent of the label claim for delivered dose.		
Page 7, Line 45 – Page 8, line 6	<p>The average of the delivered doses is used as the reference value for the limits of acceptance.</p> <p>Unless otherwise justified and authorised, the preparation complies with the test if 9 out of 10 results lie between 75 per cent and 125 per cent of the reference value and all lie between 65 per cent and 135 per cent. If 2 or 3 values lie outside the range of 75 per cent to 125 per cent of the reference value, repeat the test for 2 additional inhalers (30 values in total). Not more than 3 of the 30 values lie outside the range of 75 per cent to 125 per cent of the reference value and no value lies outside the range of 65 per cent to 135 per cent of the reference value.</p> <p>Unless otherwise authorised, the average of the delivered doses must be between 85 per cent and 115 per cent of the label claim for delivered dose.</p>	<p>The average of the delivered doses is used as the reference value for the limits of acceptance.</p> <p>Unless otherwise justified and authorised, the preparation complies with the test if 9 out of 10 results lie between 75 per cent and 125 per cent of the reference value and all lie between 65 per cent and 135 per cent. If 2 or 3 values lie outside the range of 75 per cent to 125 per cent of the reference value, repeat the test for 2 additional inhalers (30 values in total). Not more than 3 of the 30 values lie outside the range of 75 per cent to 125 per cent of the reference value and no value lies outside the range of 65 per cent to 135 per cent of the reference value.</p> <p>Unless otherwise authorised, the average of the delivered doses must be between 85 per cent and 115 per cent of the label claim for delivered dose.</p>	Text is duplicate of text from 2.5.54 so does not need to appear here.	Major
Page 10, Line 40 – Page 11, Line 3	<p>The average of the delivered doses is used as the reference value for the limits of acceptance.</p> <p>Unless otherwise justified and authorised, the preparation complies with the test if 9 out of 10 results lie between 75 per cent and 125 per cent of the reference value and all lie between 65 per cent and 135 per cent. If 2 or 3 values lie outside the range of 75 per cent to 125 per cent of the</p>	<p>The average of the delivered doses is used as the reference value for the limits of acceptance.</p> <p>Unless otherwise justified and authorised, the preparation complies with the test if 9 out of 10 results lie between 75 per cent and 125 per cent of the reference value and all lie between 65 per cent and 135 per cent. If 2 or 3 values lie outside the range of 75 per cent to 125 per cent of the</p>	Text is duplicate of text from 2.5.54 so does not need to appear here.	Major

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