IPAC-RS
International Pharmaceutical Aerosol Consortium on Regulation & Science

IPAC-RS Comments on "NASAL PREPARATIONS, Nasalia"

Reference: PA/PH/Exp. 12/T (23) 6 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 1, Lines 31-33	Preparations for administration to the injured nose, particularly when the mucosa is damaged, or prior to surgery are sterile and, unless otherwise justified and authorised, free from preservatives and supplied in single-dose containers.	Preparations for administration to an injured nose, particularly when the mucosa is damaged, or prior to surgery are sterile and, unless otherwise justified and authorised, free from preservatives and supplied in single-dose containers.	It seems that "an" is a better pronoun. Use of "the" implies that the document only applies to an injured nose. It is possible that I am attempting to change what may be common European English to what I believe would be common US English.	Minor
Page 1, Lines 45-47	During the development of nasal preparations whose formulation contains a preservative, the need for and the efficacy of the chosen preservative shall be demonstrated to the satisfaction of the competent authority.	During the development of nasal preparations whose formulation contains a preservative, the need for and the efficacy of the chosen preservative shall be demonstrated to the satisfaction of the appropriate authority.	I think, at least publicly, "authorities" are assumed to be competent.	Minor
Page 2, Line 27.5	Sterility (2.6.1). Where the label states that the preparation is sterile, it complies with the test.		What test? Implied is test(s) specified in 2.6.1 but the language is unclear.	Regular

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Page 4, Lines 11-18	Unless otherwise justified and authorised, the preparation complies with the test if 9 out of the 10 results lie between 75 per cent and 125 per cent of the average 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 but within the range of 65 per cent to 135 per cent, repeat the test for 2 additional containers (30 values in total). Not more than 3 of the 30 values lie outside the range of 75 per cent to 125 per cent and no value lies outside the range of 65 per cent to 135 per cent. Unless otherwise authorised, the average value must be between 85 per cent and 115 per cent of the label claim for delivered dose.	~~Unless otherwise justified and authorised, the preparation complies with the test if 9 out of the 10 results lie between 75 per cent and 125 per cent of the average 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 but within the range of 65 per cent to 135 per cent, repeat the test for 2 additional containers (30 values in total). Not more than 3 of the 30 values lie outside the range of 75 per cent to 125 per cent and no value lies outside the range of 65 per cent to 135 per cent. Unless otherwise authorised, the average value must be between 85 per cent and 115 per cent of the label claim for delivered dose.~~	This exact language is already in 2.5.54 Uniformity of Delivered Dose of Inhalation and Nasal Preparations, so does not need to be here.	Major
Page 4, Lines 30-37	If 2 or 3 values lie outside the range of 75 per cent to 125 per cent but within the range of 65 per cent to 135 per cent, repeat the test for 2 additional containers (30 values au total). Not more than 3 of the 30 values lie outside the range of 75 per cent to 125 per cent and no value lies outside the range of 65 per cent to 135 per cent. Unless otherwise authorised, the average value must be between 85 per cent and 115 per cent of the target delivered mass.	~~If 2 or 3 values lie outside the range of 75 per cent to 125 per cent but within the range of 65 per cent to 135 per cent, repeat the test for 2 additional containers (30 values au total). Not more than 3 of the 30 values lie outside the range of 75 per cent to 125 per cent and no value lies outside the range of 65 per cent to 135 per cent. Unless otherwise authorised, the average value must be between 85 per cent and 115 per cent of the target delivered mass.~~	This exact language is already in 2.5.54 Uniformity of Delivered Dose of Inhalation and Nasal Preparations, so does not need to be here.	Major
Page 5, line 47 – Page 6, Line 11	Unless otherwise justified and authorised, the preparation complies with the test if 9 out of the 10 results lie between 75 per cent and 125 per cent of the average value	~~Unless otherwise justified and authorised, the preparation complies with the test if 9 out of the 10 results lie between 75 per cent and 125 per cent of the average value~~	This exact language is already in 2.5.54 Uniformity of Delivered Dose of Inhalation and Nasal Preparations, so does not need to be here.	Major

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	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 but within the range of 65 per cent to 135 per cent, repeat the test for 2 additional containers (30 values in total). Not more than 3 of the 30 values lie outside the range of 75 per cent to 125 per cent and no value lies outside the range of 65 per cent to 135 per cent. In justified and authorised cases, these ranges may be extended but no value may be less than 50 per cent or more 150 per cent of the average value. Unless otherwise authorised, the average value must be between 85 per cent and 115 per cent of the label claim for delivered dose.	~~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 but within the range of 65 per cent to 135 per cent, repeat the test for 2 additional containers (30 values in total). Not more than 3 of the 30 values lie outside the range of 75 per cent to 125 per cent and no value lies outside the range of 65 per cent to 135 per cent.~~ ~~In justified and authorised cases, these ranges may be extended but no value may be less than 50 per cent or more 150 per cent of the average value.~~ ~~Unless otherwise authorised, the average value must be between 85 per cent and 115 per cent of the label claim for delivered dose.~~		