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Reference Material Data Sheet

NP2 High Moisture Nicotine Pouch Reference Product

Data Sheet Number: 2024-NP2-CTRP

Reference values generated on: September 25, 2024

Reference values are valid until: September 25, 2029

Superseded data sheet code: N/A

Description of Material	High moisture nicotine pouch without added flavorings
Lot/Batch Number	NP2 High Moisture Nicotine Pouch
Matrix	Nicotine pouch without cut, ground, powdered, or leaf tobacco
Major starting materials	Fillers, pouch material, nicotine, pH adjuster, stabilizer, water and sweetener

Notes

- Reference values listed below reflect analysis results submitted by a single laboratory using a single method satisfying Clause 5.15 of ISO Guide 34:2009 and statistically evaluated using Approach A in Clause 10.5 of ISO Guide 35:2006.
- The "Reference Uncertainty" listed herein are expanded uncertainties obtained by multiplying the combined standard uncertainty by a constant coverage factor of 3, i.e. $k = 3$.
- The reference values listed herein are reflective of chemical analysis done on an "as is" basis, i.e. the samples were not dried prior to analysis.
- The reference values and uncertainties contained herein will be updated by the valid until date or as needed.
- The manufacturing process included a start-up period of approximately 20 minutes where six heads came online at various time intervals in the production of the nicotine pouches. Due to these time intervals, all samples collected during this start-up period were collapsed to be time 0. Statistical models included time and head nested within time as covariates per the sampling technique.

NP2 High Moisture Nicotine Pouch Reference Values and Uncertainties

Parameter	Reference Value	Reference Uncertainty	Number of accepted data points	Constant Coverage factor
Nicotine (mg/g)	15.4	1.6	123	3
Nicotine (mg/pouch)	10.7	1.1	123	3
pH	9.10	0.10	123	3
Oven Volatiles (%)	47.07	5.38	123	3
Pouch weight (g)	0.6926	0.0503	123	3

INSTRUCTIONS FOR CORRECT USE:

The reference material should be stored in the original packaging or in airtight containers just large enough to contain the sample in a cool, dry place (~4° C) after receipt. If the unopened reference material will not be used within ~2 weeks, it is recommended that the reference material is stored at, or below, -20° C until needed. Allow the unopened reference materials to equilibrate in the refrigerator for a minimum of 24 hours and then at least 1 hour at laboratory conditions prior to use.

HAZARD INFORMATION: Please see Safety Data Sheet for NP2 High Moisture Nicotine Pouch Reference Products. This product is not for human consumption. For experimental purposes only. Not to be offered for sale, sold or distributed to consumers. Not for clinical trials.

HOMOGENEITY: Homogeneity of this material is reflected in the expanded uncertainties disclosed herein.

APPROVING PERSONNEL: This material is approved by **Huihua Ji, Ruth McNees, and Ling Yuan** on behalf of CTRP.