

Strain Equivalence Statement

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1. Subject

This statement confirms the equivalence of *Bacillus spizizenii* (formerly *Bacillus subtilis* subsp. *spizizenii*) NCTC 10400 supplied by LotusTech under the brand VerisQ™ to the corresponding ATCC reference strain, for the purpose of **non-therapeutic pharmaceutical quality control testing** under USP, EP and JP general chapters.

2. Strain identification

Organism	<i>Bacillus spizizenii</i> (formerly <i>Bacillus subtilis</i> subsp. <i>spizizenii</i> — name updated per USP-NF Notice, 18 Dec 2025)
UKHSA catalogue no.	NCTC 10400
ATCC equivalent	ATCC 6633
WDCM identifier	WDCM 00003
Other equivalent collections	= CIP 52.62 = NBRC 3134 = NCIMB 8054 = DSM 347

3. Pharmacopoeial citations

United States Pharmacopeia	USP <56>, <61>, <81>, <1117>
European Pharmacopoeia	EP 2.6.12, 2.7.2, 5.1.3
Japanese Pharmacopoeia	JP 4.05
Indicated QC use	Microbial enumeration; antibiotic microbial assay indicator organism; biological indicator (BI) validation; sporicide / sterilization process validation.

4. Statement of equivalence

The strain *Bacillus spizizenii* (formerly *Bacillus subtilis* subsp. *spizizenii*) NCTC 10400 supplied by LotusTech is sourced directly from the UK Health Security Agency Culture Collections (UKHSA — NCTC / NCPF, Porton Down, UK). Through documented pedigree, identical phenotypic and genotypic characteristics, and a common WDCM identifier where applicable, this strain is recognised internationally as equivalent to **ATCC 6633**. Pharmacopoeia users may therefore rely on this strain to satisfy general chapters that specify the corresponding ATCC catalogue number, in accordance with the “or strains shown to be equivalent” allowance in USP <60> / <61> / <62> / <71>, EP 5.1.3, and equivalent JP provisions.

5. Source and traceability

Material is supplied under the Material Licence Agreement BE25 009 between UK Health Security Agency (UKHSA, acting through its Culture Collections) and LotusTech Pty Ltd. Each batch is released with a Certificate of Analysis (CoA)

bearing the original UKHSA accession data, the passage number from the master seed lot, and a traceable batch identifier. Strains are supplied as freeze-dried (lyophilised) ampoules and are released no further than the 5th passage from the master seed lot, in line with USP <1117>, EP 5.1.3 and JP General Information.

6. Limitations of use

The strain is supplied for non-therapeutic pharmaceutical quality control testing only. It is not intended for therapeutic, diagnostic, in-vivo, or human/animal-clinical use, nor for the manufacture of any product administered to humans or animals. Onward transfer or re-distribution of viable material to third parties is prohibited under the terms of BE25 009.

7. Authorisation

This statement is issued under the authority of LotusTech Pty Ltd (Quality Assurance / Regulatory Affairs). The presence of the corporate stamp below constitutes formal authorisation; no manual signature is required.



Issued by

LotusTech Pty Ltd

Quality Assurance / Regulatory Affairs

Date of issue: 01 May 2026

References: UKHSA Culture Collections — "Equivalence with bacterial reference strains"; NCTC equivalents of ATCC strains (NW520304); World Data Centre for Microorganisms (WDCM) global catalogue; USP General Chapters <51>, <60>, <61>, <62>, <71>, <81>, <1117>; EP 2.6.1 / 2.6.12 / 2.6.13 / 5.1.3; JP 4.05 / 4.06.

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