

Material Name: Sugar Spheres

Source/Type of Excipient: Mineral Mineral derived Plant Plant derived
 Synthetic Fermentation derived

Other (explain):

Elemental Impurity		Class	Likely to be Present			If Known, Please Identify the Expected Concentration /Units (or Range)	Analytical Method Used (and Limit of Detection if Available)	Comments regarding source of information (i.e.; frequency of testing, process understanding, etc.)
			Yes	No	Unknown			
Arsenic (inorganic)	As	1	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	Unknown <input type="checkbox"/>	< 0,01 mg/Kg	EPA 7000B 2007 + EPA 7062 1994	Annual control
Cadmium	Cd	1	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	Unknown <input type="checkbox"/>	< 0,01 mg/Kg	EPA 7000B 2007 + EPA 7130 1986	Annual control
Mercury (inorganic)	Hg	1	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	Unknown <input type="checkbox"/>	< 0,01 mg/Kg	UNI EN ISO 17294-2 2005	Annual control
Lead	Pb	1	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	Unknown <input type="checkbox"/>	< 0,01 mg/Kg	EPA 7000B 2007 + EPA 7420 1986	Annual control
Cobalt	Co	2A	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	Unknown <input type="checkbox"/>	< 0,02 mg/Kg	EPA 3050B + EPA 7000B 2007	Annual control
Nickel	Ni	2A	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	Unknown <input type="checkbox"/>	< 0,02 mg/Kg	EPA 7000B 2007 + EPA 7520 1986	Annual control
Vanadium	V	2A	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	Unknown <input type="checkbox"/>	< 0,05 mg/Kg	EPA 3050B + EPA 7000B 2007	Annual control
Silver	Ag	2B	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Unknown <input checked="" type="checkbox"/>			
Gold	Au	2B	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Unknown <input checked="" type="checkbox"/>			
Iridium	Ir	2B	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Unknown <input checked="" type="checkbox"/>			
Osmium	Os	2B	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Unknown <input checked="" type="checkbox"/>			
Palladium	Pd	2B	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Unknown <input checked="" type="checkbox"/>			

SEDE LEGALE: VIA PER CERRO, 2 - 20025 LEGNANO (MI) - PARTITA IVA 08017380158 - C.C.I.A.A. 1197238

Elemental Impurity		Class	Likely to be Present			If Known, Please Identify the Expected Concentration /Units (or Range)	Analytical Method Used (and Limit of Detection if Available)	Comments regarding source of information (i.e.; frequency of testing, process understanding, etc.)
			Yes	No	Unknown			
Platinum	Pt	2B	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Unknown <input checked="" type="checkbox"/>			
Rhodium	Rh	2B	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Unknown <input checked="" type="checkbox"/>			
Ruthenium	Ru	2B	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Unknown <input checked="" type="checkbox"/>			
Selenium	Se	2B	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Unknown <input checked="" type="checkbox"/>			
Thallium	Tl	2B	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Unknown <input checked="" type="checkbox"/>			
Barium	Ba	3	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Unknown <input checked="" type="checkbox"/>			
Chromium	Cr	3	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	Unknown <input type="checkbox"/>	0,02 mg/Kg	EPA 7000B 2007 + EPA 7190 1986	Annual control
Copper	Cu	3	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	Unknown <input type="checkbox"/>	< 0,05 mg/Kg	EPA 7000B 2007 + EPA 7210 1986	Annual control
Lithium	Li	3	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	Unknown <input type="checkbox"/>	<0,05 mg/Kg	EPA 7000B 2007 + EPA 7000B 2007	Annual control
Molybdenum	Mo	3	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Unknown <input checked="" type="checkbox"/>			
Antimony	Sb	3	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	Unknown <input type="checkbox"/>	< 0,02 mg/Kg	EPA 7000B 2007 + EPA 7062 1994	Annual control
Tin	Sn	3	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Unknown <input checked="" type="checkbox"/>			

Reference: ICH Q3D Guideline for Elemental Impurities, Step 4 version, December 2014

NOTES: No elemental impurities, metal reagents, metal catalysts are intentionally added or used in the manufacturing process of Sugar Spheres.

Prepared By: QC Giulia Loss _____

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