MANNITOL (STARTING MATERIAL)

	Name	Position	Signature	Date
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1.0 MATERIAL IDENTIFICATION

1.1	Standard Name	Mannitol (Starting Material)
1.2	Alternate Name	Pearlitol PF
1.3	Description	A white powder. Formula, CGH14O6,
1.4	Packaging	Packaging must be intact for goods to be accepted. There must be at least 2 layers of packaging. Material must be received within original packaging - polyethylene bag/ paper bag.
1.5	Dimensions	Not Applicable
1.6	Weight	Not Applicable
1.7	CAS Number	69-65-8.

2.0 APPROVED SUPPLIER

2.1	Supplier	Brenntag Australia Pty Ltd.
2.2	Manufacturer	Roquette Freres. Address: 1, Rue de la Haute Loge, 62136 Lestrem France.
2.3	!> rQ duct Code	Pearlitol, Material Grade PF (Pyrogen Free).

3.0 STORAGE CONDITIONS

Store in a clean place from 15°C to 30°C, protected from moisture.

4.0 HAZARD AND SAFETY

Not considered a hazardous material.

5.0 CERTIFICATES REQUIRED

5.1 Certificate must be batch specific and include a signature (an electronic signature is deemed acceptable).

5.2 Certificate of Analysis (C of A) stating that the batch meets the requirements of the cunent USP and Ph. Eur. for mannitol. Specific tests listed must include at least one identity test. The C of A must contain the address of the site of the manufacturer

9.0 RESULT SHEET

Result Sheet 1 of 4

Lot number_____

TEST NAME	TEST METHOD	SPECIFICATION	RESULT	RESULT RECORD LOCATION	INITIAL /DATE
Appearance	TM-014	White or almost white, crystalline powder or free-flowing granules.			
Identification (by Infrared Absorption)	TM-036	Complies with pharmacopeial mannitol reference spectrum.			
Appearance of solution	TM-014	Clear and colourless.			
Melting Range	TM-037	Between 165°C and 170°c			
Melting Point	TM-037	Between 165°C and 170°c			
Assay	TM-006	98.0% to 101.5% ofD-mannitol (dried substance)			
Related Substances	TM-006	Sorbitol :S2.0%			
		Isomalt (Total of both peaks) :::;0.2%			
		Maltitol :::;0.2%			
		Individual Unidentified Substances :SO. I0%			
		Total Impurities ::::2.0%			
Reducing Sugars	As per the current edition of the Ph. Eur. and USP	Maximum 0.1% (calculated as glucose equivalent)			

Results of tests and inspections are within specification. **Sign**_____**Date** _____

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Result Sheet 3 of 4

Lot Number _____

TEST NAME	TEST METHOD	SPECIFICATION	RESULT	RESULT RECORD LOCATION	INITIAL /DATE
Total Viable Aerobic Count and Prescribed Organisms	Total Viable Aerobic Count **As per current USP/Ph. Eur (harmonised) and FM-210**	$<10^2$ colony forming units per gram			
	Total Combined Yeast/Mould Count **As per current USP/Ph. Eur (harmonised) and FM-210**	$<10^1$ colony forming units per gram			
	Test for *E. Coli* **As per current USP/Ph. Eur (harmonised) and FM-210**	Absence of *Escherichia coli* in 1 gram			
	Test for *Salmonella* **As per current USP/Ph. Eur (harmonised) and FM-210**	Absence of *Salmonella* in I0 grams			
	Tests for S. *aureus* and *P. aeruginosa.* **As per current USP/Ph. Eur (harmonised) and FM-210**	Absence of S. *aureus* and *P. aeruginosa* in I gram			
	Bile Tolerant Gram Negative Bacteria **As per current USP/Ph. Eur (harmonised) and FM-210**	Absence of Bile-Tolerant Gram Negative Bacteria in 1 gram			

Results of tests and inspections are within specification. **Sign**_____**Date** _____

10.0 DOCUMENT CHANGE HISTORY

Version	Date Effective	Section	Description and Rationale
16	01Jul22	2.0	Updated product code. Updated supplier as per CR934.
15	30Nov20	6.1	Added note to also sample the polyethylene plastic bags as per CR850
		Result Sheet 4	Added results table for Polyethylene bag testing as per CR850.
14	06-Nov-20	1.4	Added statement regarding material being received in original packaging as per CR850.
		2.1	Supplier name changed from Axieo to DKSH Performance Materials as per CR919.
		3.0	Added storage condition of 15°C to 30°C as per CR850.
		All	Formatting updated to current template TE-017-07.
13	13-May-19	3.0	Remove statement "should not exceed 30°C as this has been incorrectly stated since version 1 of this document. Product is stored in warehouse at 15°C to 25°C. refer to CRNo.824
		6.1	Remove reference to sampling for water content, as water content is now longer a required test as per CR No.564.
		Result Sheet 1	Remove Assay: D-mannitol anhydrous test as per CR564
		Result Sheet 1	Remove reducing sugars tested as per Ph. Eur 7th Edition and include that remaining Reducing Sugars test is to be compliant with the current edition of USP as well as the Ph. Eur. in accordance with CR No.564.
		Result Sheet 2	Remove the Water Content and Lead test and as per CR564. Remove the Heavy Metals test as per CR789.
12	16-Mar-18	All	Formatting updated to current template TE-017-06. This included adding a new section 4 for hazards and safety.
		Result Sheet 2	Reference to Probe changed to Intertek as per CR762.
		Result Sheet 3	Added detail to test method column for micro tests noting that the methods used are all as per current USP/Ph.Eur (harmonised) for clarity.
11	17-Oct-16	5.1	Reinstatement of water content test as this test will be required for compliance with marketing authorisation for Bronchitol-Pharmaxis Russia, as detailed in CR564.
		Results Sheet 1 and 2	Anhydrous assay specification reinstated as well as water content, Lead limit test and reducing sugars as per Ph. Eur. 7th edition. This is to ensure compliance with marketing authorisation for Bronchitol-Pharmaxis Russia, detailed in CR564.
10	25-Aug-16	2.1	Nuplex Specialties changed to Axieo as per CR606.
		All	Formatting altered due to updated template TE-017-05.

		Result Sheet	In Results Sheet 1 of3 Test Method for Specific Rotation changed from "As per the current edition of the USP" to "as per TM-038" as stated in CR#230.
		Result Sheet	Identification by Infrared Absorption method changed to TM-036 from "as per current USP and Ph. Eur" as stated in CR#252.
		Result Sheet	Microbial tests changed to harmonised method as per CM-09-024-03 and CR#23l.

END OF DOCUMENT