

Azithromycin PFS Formulation and Short Manufacturing Process

Product Name: Azithromycin PFS

Concentration: Azithromycin USP 200 mg / 5 ml

Batch Size (Kg): 40.00 kg

Batch Quantity (Phial): 2000 bottles

Master Formula

Item No.	Name of Raw Materials	Specification	Unit	Theoretical Amount	Functions
1	Azithromycin Dihydrate (Micronized)	USP	Kg	**2.940	Active
2	Xanthan Gum	USP	Kg	0.160	Excipient
3	Dispersible Cellulose	BP	Kg	0.070	Excipient
4	Polyethylene Glycol 6000	USP	Kg	0.400	Excipient
5	Disodium Edetate	BP	Kg	0.050	Excipient
6	Sodium Benzoate	BP	Kg	0.140	Excipient
7	Tribasic Sodium Phosphate (Anhydrous)	USP	Kg	0.090	Excipient
8	Aspartame (Powder)	USP	Kg	1.400	Excipient
9	SD Banana Flavor (Powder)	Ph.Gr.	Kg	0.700	Excipient
10	Titanium Dioxide	BP	Kg	0.140	Excipient
11	Colloidal Anhydrous Silica (Aerosil 200)	USP	Kg	0.630	Excipient
12	Sucrose	BP	Kg	**33.280	Sweetening agent and weight adjuster

Note: (**) these should be calculated

Calculation 1: Azithromycin should be calculated as per potency.

Calculation 2: Sugar should be adjusting with Azithromycin raw material which calculated as per potency.

Manufacturing Process

A. Mixing & Drying of Excipients:

1. Sieve the following materials one after another through # 40 mesh screen and place them into a poly bag. Finally mix for 5 minutes manually.

Name of the item	Quantity (Kg)	Note
Xanthan Gum	0.160	
Dispersible Cellulose	0.070	
Disodium Edetate	0.050	
Sodium Benzoate	0.140	
Tribasic Sodium Phosphate (Anhydrous)	0.090	
Titanium Dioxide	0.140	
Colloidal Anhydrous Silica (Aerosil 200)	0.630	

2. Dry the blend of step 1 in a tray dryer at (70-75) °C for three 1 hour & 30 minutes to achieve %LOD below 1.0%.

Observed Temperature: _____ °C and %LOD: _____ %.

B. Crushing of Sucrose:

3. Crush Sucrose using Multi-mill by passing through 1.0 mm screen at medium speed in Sugar Crushing area.

RM	Quantity (Kg)	Note
Sucrose		Calculation No. 2

C. Premixing & Blending:

4. Pass the following items through # 40 mesh screen & transfer into the Double Cone Blender.

RM	Quantity (Kg)	Note
Azithromycin Dihydrate (Micronized)		Calculation No. 1
Aspartame (Powder)	1.400	
SD Banana Flavor (Powder)	0.700	
Polyethylene Glycol - 6000	0.400	
Sucrose		Calculation No. 2

5. Add 15 Kg of the crushed Sucrose into the Double Cone Blender (at step 4) by passing through # 20 mesh screen and blend for 5 minutes.

6. Add the dried materials of step 2 at step 5 (into the Double Cone Blender) and mix for 10 minutes.

7. Add remaining portion of the Crushed Sucrose at step 6 (into the Double Cone Blender) by passing through # 20 mesh screen. Then blend for 15 minutes.

8. Finally collect the mixed granules into the container and fix a product label outside the Drum, then store them for filling.