TRANSFER OF TECHNOLOGY FOR PRODUCTION OF VITAMIN C tbl 500 mg

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INTRODUCTION

Vitamin C is a vitamin that is soluble in water that is found in fruits and vegetables. If not enough is introduced through the fruits and vegetables it can be entered through the tablets, because vitamin C is first synthesized vitamin. AD Jaka 80 Radovis produces Vitamin C 500 mg tablets in which active substance is ascorbic acid. These tablets are manufactured for many years at Marshal Tito 42 in Radovis, with proven quality and standard. Due to the commercial reasons these tablets will be no longer produced in the old location, but on the new location in a production plant at Prvomajska bb Skopje. Transfer of technology is made according to the requirements prescribed in this regulation.
For that purpose were made two pilot series of Vitamin C tbl 500 mg a new location. He was made a comparison of all parameters of the manufacturing protocol (apperance, weight, size, streinght friability, decomposition and content). Also according validation protocols were collected and analyzed samples from several critical points production process. I needed to prove the identity of the tablets of the two locations.

APPARATUS

The production of Vitamin C tbl 500 mg using the following equipment:
- Vibrating sieve,
- Rotating sieve,
- Powder-blender, V - blender,
- Ronchi tableting machine enclosure 23 with 7 mm matrices for tableting with broken line on one side
- Machine for packaging in blister-packing contact AL / PVC foil.

Quality control of tablets was made with the following equipment:
- VAN KEL VK 200 tablet hardness tester - apparatus for determining the strength of tablets.
- VAN KEL friability tester - apparatus for determining friability the tablets.
- VAN KEL HAAKE DC - apparatus for the decomposition of tablets.

PROCEDURE

To transfer technology, has been made validation protocol validation scheme. Were identified critical points in the technological process by which samples are taken for analysis (Fig 1).

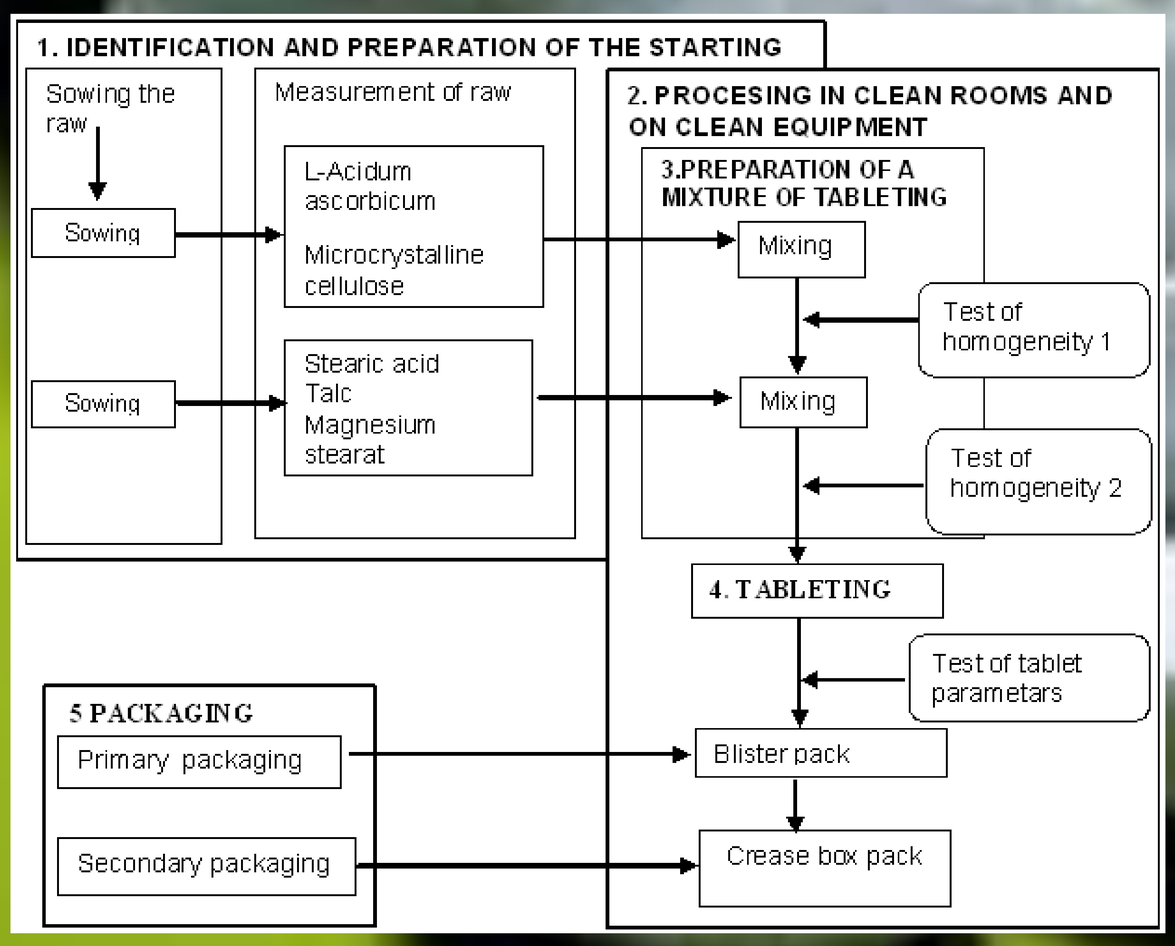

Fig.1. Validation pattern of critical parameters in the technological process

RESULTS AND DISCUSSION

To make a comparison of all analyzed parameters are made two pilot series on the new location in the production plant of "Jaka 80 AD Radovis" ul.Prvomajska bb Skopje
According to protocol validation samples taken from three critical points. Taking a sample is performed by quality control. Samples from the first and second critical point are taken after the specified period of mixing, 30 minutes for the first critical point (Table 1) and after 5 minutes for the second critical point (Table2). A sample is taken from three places on container production: surface, middle and bottom.

The third critical point is after tableting, so here are taken tablets from the two pilot series immediately after the tableting. There is a determination of all parameters of the tablet. The results in Table 3 show matching values for all parameters analyzed in the two pilot series.

Table 1 Homogeneity of the first critical point

		Given parameter	Place of sampling	pilot series / date 01-039 05.2007	02-039 05.2007
Critical parameter	Mixing duration	30 min.	Department of solid forms	30 min.	30 min.
Point of validation testing	Homogeinity of the mixture	469.315 - 573.607mg	surface	502.14 mg	522.21 mg
			middle	512.47 mg	518.87 mg
			bottom	514.35 mg	505.69 mg

Table 2 Homogeneity of the second critical point

		Given parameter	Place of sampling	pilot series / date 01-039 05.2007	02-039 05.2007
Critical parameter	Mixing duration	5 min.	Department of solid forms	5 min.	5 min.
Point of validation testing	Homogeinity of the mixture	469.315 - 573.607mg	surface	505.67 mg	513.64 mg
			middle	504.21 mg	519.41 mg
			bottom	506.97 mg	515.74 mg

Table 3. Test of tablet parameters of the third critical point

			Given parameter	Borders	pilot series / data 01-039 05.2007	02-039 05.2007
Critical parameter	Speed machine(tbl/h)		-	-	30 000	30 000
	Initial pressure (kP)		(are controlled by strength)	-	2	2
	Pressure (kP)		(are controlled by strength)	-	10	10
Point of validation test	Appearance		white tablets with a flat surface, with embended line on the one side	white tablets with a flat surface, with embended line on the one side	match	match
	Average mass of tablets (mg)		680	Allowed variation ± 5.0%	680.3	680.4
	Diameter (mm)		13	13	13	13
	Strength (kp)		7.5 - 13	7.5 - 13	8.45	9.02
	Friability (%)		max 1	max 1	< 0,1	< 0,1
	Decomposition (min)		max 30	max 30	9	9
	Identification		Ascorbic acid	Ascorbic acid	match	match
	Content	mg	450-550	450-550	490.77	491.67
		%	90 - 110	90 - 110	98,15	98,33
	Total time of tableting (h)		-	-	3	3

CONCLUSION

It is made a technology transfer of Vitamin C tbl 500 mg from one location to another location and change of the lot size from 100 kg to 50 kg. To this end was made validation protocol under which samples are taken from the three critical points of the technological process. There have been two pilot batches of the new location. There is a determination of the content and homogeneity of the samples from the first and second critical point and determination of all parameters for the tablet samples from the third critical point. In all samples of the three critical points is observed deviation from the prescribed values. The results confirm the transfer of technology.