

Institute of Pharmaceutical Technology and Biopharmacy Technological laboratory educational practice		Manufacturing process and production control sheet	
Granulatum simplex 2 PHT01B		Batch number:	Production weight: 1000 g
			Pages: 1/2

Standard specification:	Beginning of production:	Finishing of production:	Expiry: 1 year
By: Dr. Pál	Approved by: Dr. Dévay	QC:	
Signature:			
Date: 20.09.2003	20.09.2003		
VALID:	from 20.09.2003		

A detailed description of the production
Participants in the production are bound to do registration of all the procedure of production according to the worksheet!

1./ Preparation: Check the purity of tools before using.

Tools	Qualification		Controller's signature
	Appropriate	Inappropriate	
Balance (scale)			
Patendule			
Beaker glass			
Z-shaped kneader			
Granulating sieve			
Sieve V. (800µm), IV. (1200 µm)			
Erweka oscillating granulator			

2./ Qualification of base materials: Detection of base materials by labels.

Quality of useable materials: Ph.Hg.VII., Ph.Hg.VIII., Ph. Eur.				
Material	Test number	Identity	Identified	Date
Solani amyllum				
Aqua purificata				
Lactosum monohydricum				
Controller's signature:		Date:		

3./ Measuring:

Material		Specified weight (g)	Tare (g)	Measured weight (g)	Gross(g)	Measured:	Controlled:
I.	Solani amyllum	238.0					
	Lactosum monohydricum	710.0					
II. Mucilago ad granulationem II.	<i>Aqua purificata</i>	<i>17.0</i>					
	<i>Solani amyllum</i>	<i>30.0</i>					

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4./ Production:

Sieve the lactose and starch through the V. sieve. Prepare the granulating solution (Mucilago ad granulationem II.) as follows: make a suspension with a cold water from the starch. *Heat the solution with water-bath while the starch becomes gelatinous (10-15 minutes). Cool down the granulating solution to 40 °C and refill the evaporated water. Homogenise the sieved powders, and knead it with small details of granulating solution in Z-shaped kneader. Break the wet stuff through the granulating sieve IV (1.2 mm).*

5./ Procedures:

Procedure	Time of procedure	Procedure
Sieving of lactose through the V. sieve		
Sieving of potato starch through the V. sieve		
Mixing of powders with Z-shaped kneader		
<i>Making of starch suspension</i>		
<i>Gelatinization of starch suspension on a water-bath</i>		
<i>Cooling of mixture to 40 °C</i>		
<i>Refilling the water until the defined weight</i>		
Kneading of powders with a small details of granulating liquid in Z-armed mixer		
Break of wet stuff through the IV. granulating sieve		

6./ Summarizing product:

Output	Amount		Lost mass (g)	Output %	Measured:	Date:
	Theoretic (g)	Effective (g)				

Justification of loss :

Signature:

Granulatum simplex 2 PHT01B
Batch number:
Expiry date:

	Date	Signature	Controller
Approval:			