Produlab Pharma

Le Vet BV
Wilgenweg 7
3421 TV Oudewater
Nederland

Manufacturer's batch certificate

Sample-code(s), 2013080344 Raamsdonksveer, 20-08-2013

Description of the product	Benakor F 20 mg tablets		
Pack size	Blister of 14 tablets (7 pcs)		
Product number	P3120	Registration number	Zul.Nr.:401022.01.00
Recipe/filling number	R0959 U0665	Order number	PO 3521
Batch number	13 H 151	Batch size	997 pcs
Batch customer	13 H 151		
Manufacturing/output date	08-2013 / 08-2013	Expiry date	01-2015

Method	Description / *Parameter*	Result	Unit	Target	Lower limit	Higher limit	Lower warning	Higher warning
LAF005A	Average weight	396	mg	406.0	376.0	436.0	385.7	426.3
LAF005B	Uniformity of mass							
	Measured units	20		informative value				
	≥ 18 units	conform		conform				
	≤ 2 units	conform		conform				
	Variation	2.7	%	informative value				
LAF009A	Dimensions							
	Diameter	7	mm		6.8	7.8	6.9	7.3
	Height	5	mm		4.8	5.2		
	length	14	mm	14	13.8	14.2	13.9	
LAF010A	Shape							
	Appearance	tablet		tablet				
	Mark of division	1, double sided		1, double sided				
	Shape	oblong		oblong				
LAF011A	Colour	orange		orange				
LAF022A	Disintegration time	4.08	min.			15		
LAF033A	Hardness	83	N		60	120		
LAF024A	Friability	0.1	%			1		
LAV179A	Benazepril							
	Benazepril HCl	19.7	mg/unit	20.0	19.0	21.4	19.4	21.0
	Identification Benazepril HCl	positive		positive				
LAV179B	Benazepril impurities							
	Impurity C	0.1	%			3.0		1.0
	Impurity individual	0.2	%			1.0		0.5
	Impurities total	0.6	%			2.0		1.0
LAV800A	Water according to Karl-Fischer	1.5	%			3.0		
LAF004D	Content (pcs)	14	pcs	14				

All mentioned limits are equal to or stricter than the limits mentioned in the available documentation. *Additional items may be specified without actual impact on the product specifications.* LAV901A = component(s) not tested; result declared on the basis of the production amounts. LAV903A = component(s) not tested; result is declared amount according the composition.
Produlab Pharma retains samples till 1 year after the expiry date. Records of the analysis are retained for 7 years and are available on request.
We hereby certify that the above information is authentic and accurate. This batch of product has been manufactured and analysed at a qualified third party site, packaging and further quality control being performed at the below mentioned site in full compliance with the EU GMP requirements and with the specifications as agreed with the marketing authorization holder of the importing country. The batch processing, packaging, and analysis records were reviewed and found to be in compliance with GMP.

No deviations with a direct impact on the product quality are applicable for this product batch.
The batch is released into the market.

Initials qualified persons: _____

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Produlab Pharma

Certificate Q

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Produlab Pharma bv, Forellenweg 16, NL-4941 SJ Raamsdonksveer Manufacturing licence 1401-BVEAK

P.P.A. Rompa
Laboratory manager

H.J. Nooteboom
QA manager, QP

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