HANNS G. WERNER GMBH + CO. KG			
Werner's Teine Dragées	Qualitätsmanagementsystem Formblätter	freigegeben und gültig ab: 20.03.2013	Seite:1 von: 1
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Version 01	Product specification DMF	Codierung: QMS-FBL-7_2-03-00-116	

DMF

As manufacturer of the pharm-a-spheres[™] neutral pellets we submitted a type IV drug master file (DMF) to the FDA in the United States. It has been assigned the following number:

17994.

Through annual updates it presents always the current situation.

If the FDA needs access to this DMF in the course of one of your applications we can issue a letter of authorization for you to reference to it. In this case please send us the necessary details as address and name of contact person.